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Excerpts from “Research Handbook on EU Health Law and Policy”

Tamara K Hervey, Calum Alasdair Young and Louise E Bishop (eds)

Alberto Alemanno, Oliver Bartlett, Estelle Brosset, Gilles Dussault, André den Exter, Mark L Flear, Markus Frischhut, Amandine Garde, Scott L Greer, Johan W van de Gronden, Mary Guy, Holly Jarman, Meri Koivusalo, Ellen Kuhlmann, Iris Goldner Lang, Christa Larsen, Jean V McHale, Aurélie Mahalatchimy, Claudia B Maier, Dorte S Martinsen, Nikola Mijatović, Emmanuele Pavolini, Marcus Pilgerstorfer, Tomislav Sokol, Clemens Rieder, Anniek de Ruijter, Catalin S Rusu and Wolf Sauter

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Introduction

Tamara Hervey, Calum Young, Louise Bishop

As we complete and submit this manuscript, in early July 2016, it seems almost wrong for a book on EU Health Law and Policy to be co-edited by three scholars in the United Kingdom. The referendum on the UK's membership of the EU reverberates across the EU, with some even interpreting it as a portent for the end of the European project as we know it.

Questions of health were among the key issues for the referendum debates in the UK. The now infamous claim on the 'Leave battlebus' that leaving the EU would release £350 million a week to be spent on the UK's NHS was one of the first 'promises' of Leave to be revealed as a total fabrication. Claims that EU membership meant privatisation of the NHS via the backdoor of TTIP were not far behind in being exposed as inaccurate scaremongering by Leave. Among the concerns of the subsequently regretful Leave voters is access to free health care while on holiday in other EU countries. Much more seriously, the position of the many UK nationals living and working in other EU countries quickly became a significant anxiety. As did the position of non-UK EU nationals in the UK – especially those working in the health system. Provision of nursing care, in particular, would be quite simply impossible without the many EU nationals who provide the backbone of such care in the UK. A debate in the House of Commons on protecting the 'acquired rights' of EU citizens in the UK attracted significant media attention. Noticeable were the abstentions from a very large number of Conservative MPs, along with the inevitable statement from the Government that no promises could be made.

Whatever the future relationship between the UK and the EU, and whichever way the EU itself develops, the EU's involvement with health law and policy will continue. Indeed, in some possible futures, much if not all of what we have written in this Research Handbook on EU Health Law and Policy will continue to apply in the UK. Even if it does not, there are 27 other Member States for which it will continue to be important. Health is one of the issues that concerns Europeans the most.

And so we are delighted to be able to offer this collection of analyses on EU Health Law and Policy. Each chapter in the Research Handbook reflects on the 'state of the art' in a particular aspect of the broad topic. Each chapter brings together an account of the legal position, including questions that remain unresolved, and reflects on the broader policy contexts. We asked each author also to consider the 'direction of travel': what are the current issues, and how might these unfold in the short and medium term? The result is more than a timely snapshot of where we are now – it is also an agenda for the future.

EU Health Law and Policy is not a subject that can be readily understood from the perspective of any one discipline. Consequently, we count ourselves very fortunate as editors in having attracted a group of contributors whose interests and expertise across several disciplines: in particular, law, political science, policy studies and sociology. We also sought

to include contributors from a range of stages in their careers. This allows the views of the ‘old hands’ or ‘established names’ to be balanced by fresh voices in the field: a blend of expertise significantly strengthening the Handbook. We are particularly grateful to our contributors for the open-minded and respectful way in which they approached the collaborative task we set for them.

Our contributors also come from many different countries: both within the EU and beyond. Bringing some degree of coherence into such a project is made easier when contributors are able to meet and discuss their work in progress face-to-face. With the support of the Observatoire Social Européen, the Society of Legal Scholars, the University Association for Contemporary European Studies, and the Health Law and Policy Research Group at the University of Sheffield, we were able to organise a round-table workshop. In January 2016 in Brussels, the majority of the papers were discussed and we are grateful to all our sponsors for facilitating this. This workshop followed directly after an open event, with a large audience, at which some of the contributors spoke. Hearing the views of a range of stakeholders enriched our own small workshop immeasurably. We would like to thank all the workshop participants, particularly our hosts Bart Vanhercke and Rita Baeten, as well as the excellent administrative support provided by Françoise Verri in Brussels and Sarah Beedham in Sheffield. We would also like to express our thanks to those who gave their time and expertise as discussants, especially Martin McKee, Bart and Rita, Katherine Fierlbeck and Eleanor Brooks.

THE ‘STATE OF THE ART’

The Handbook is organised into five main parts, reflecting the broad divisions within EU health law and policy as we see them. We begin by considering the historical and institutional contexts. Mary Guy and Wolf Sauter draw out the broad historical trends in EU health law and policy. Their analysis reveals three broad periods of its development: up to 1992; 1992–2007; and 2007 onwards. In so doing, they also define the scope of EU health law and policy, noting that it has moved beyond a ‘patchwork’ or ‘interface’ approach. It has emerged as both a legal and policy domain, and a subject for academic study in its own right. Dorte Sjindberg Martinsen uses the example of the Patients’ Rights Directive to show how institutional structures and political preferences enable and constrain EU policy-making in health fields. The impact of the Directive on actual patient mobility is negligible. However, the ways in which different stakeholders were able to access and condition the law-making process nonetheless gives important insights into the past and future of EU health law and policy-making.

As EU Health Law and Policy is often seen as a creation of courts, rather than legislatures or executives, two chapters follow in which the roles of national courts and the CJEU (under the powerful narratives of human rights) have played out in the unfolding of EU Health Law and Policy. Clemens Rieder considers both the implications of actual litigation, and the ‘shadow of litigation’, which may indeed be more important. The relationships of the CJEU with national courts, the governments of the Member States, and the European Court of Human Rights in Strasbourg are all crucial institutional contexts for the development and future trajectory of EU Health Law and Policy. The emergent and powerful narrative of human rights is taken up by Calum Young, who characterises this as an area of ‘frustrated potential’ for the future development of EU health law and policy.

The second part of the Handbook concerns people and products. Readers may be a little surprised to discover that there is no stand-alone chapter on free movement of patients, either on the law or on its practical impact. In a book of this nature, coverage cannot be exhaustive, and as editors we made some difficult choices of exclusion. The actual numbers of mobile patients within the EU are so small as to have led to Martin McKee describing EU patient mobility as a ‘solution without a problem’. That is the principal reason for our decision: other areas of EU Health Law and Policy have much more significant effects than patient mobility. Moreover, we have provided for readers who want to learn more about that particular topic through the information in Chapters 2, 3, 4 and 19.¹ Ellen Kuhlmann and others explain the effects of EU Health Law and Policy on health professionals. Drawing on new empirical data, they show how the EU’s free movement law, combined with its fiscal disciplines (considered further in Chapter 12), have challenging effects on sustainability of healthcare systems, reinforcing negative implications for equality and solidarity. Both people and products – as ‘citizens’ and ‘science’ – appear in Mark Flear’s chapter on EU biomedical research law and policy. Flear shows how the spaces created for biomedical research by EU law and policy embody a particular type of citizen, and play on narratives of hope and promise. The result is an obfuscation of the dominant drivers of market-oriented norms and values.

The ways in which EU Health Law and Policy protects consumers – through regulation and litigation – are the subject of Marcus Pilgerstorfer’s chapter on pharmaceuticals. Interactions between those two regimes leave uncertainties in the legal position, with implications for policy. The development and regulation of, as well as potential liabilities for, new health technologies are also the subject of Estelle Brosset and Aurélie Mahalatchimy’s chapter. They consider both EU pharmaceuticals and medical devices law, as new health technologies may occupy either space, even though a separate body of EU law and policy, with its own logics, has developed for each. The theme of novelty in health products is continued in the chapters by Jean McHale and Aurélie Mahalatchimy, and Andre den Exter. McHale and Mahalatchimy note insufficient attention to the ethical dimensions of EU human materials law. den Exter’s chapter shows how EU law and policy on innovative health technologies raise similar legal and ethical concerns. The complexities of legal liabilities alone, in the context of a market for e-health technologies spanning over 28 legal systems, provide ongoing challenges for health lawyers.

A short part 3 of the Handbook focuses on the implications of EU Health Law and Policy for health systems. Johan van de Gronden and Catalin Rusu investigate the extent to which EU competition law and policy may improve, or worsen, the efficiency of national health systems. The application of EU competition law to the behaviour of powerful market actors, such as the pharmaceutical industry, (social) health insurance providers or hospital chains, certainly has the potential to do so. But this may be at the cost of health-specific values – a point which is taken up in Chapter 19. For Eurozone Member States, the

¹ For further information, see N Azzopardi-Muscat and others, ‘The impact of the EU Directive on patients’ rights and cross border health care in Malta’; (2015) 119 Health Policy 1285; H Nys, ‘The Transposition of the Directive on Patients’ Rights in Cross-Care Healthcare in National Law by the Member States: Still a Lot of Effort to Be Made and Questions to Be Answered’ (2014) 21(1) European Journal of Health Law 1; S Olsena, ‘Implementation of the Patients’ Rights in Cross-border Healthcare Directive in Latvia’ (2014) 21(1) European Journal of Health Law 46; H Vollaard and DS Martinsen, ‘Bounded Rationality in Transposition Processes: The Case of the European Patients’ Rights Directive’ (2014) 37(4) West European Politics 711; W Palm and R Baeten, ‘The quality and safety paradox in the patients’ rights Directive’ (2011) 21(3) European Journal of Public Health 272; D Delnoij and W Sauter, ‘Patient information under the EU patients’ rights Directive’ (2011) 21(3) European Journal of Public Health 271.

requirements of economic and fiscal governance are even more challenging than competition law for health systems and the values they embody. Tomislav Sokol and Nikola Mijatović show how the consequences of these rules, enforcing austerity economics, are felt unevenly across EU Member States. The resulting negative effects on access to medical care raise important questions of equality.

Public health is (arguably) the longest-standing area of EU Health Law and Policy. It is covered in part 4 of the Handbook. Markus Frischhut and Scott Greer explain how EU communicable disease policy is intertwined with EU law on communicable diseases, particularly as embodied in the ‘precautionary principle’. There follow a trio of chapters on products which pose threats to public health: tobacco, alcohol and food. Alberto Alemanno’s review of the constitutional debates surrounding the EU’s tobacco law shows how a direction of travel (to significantly constrain the freedom of operation of the tobacco industry) may have reached its limits in recent developments. These align more with soft regulatory approaches (‘nudging’) than with hard EU-level restrictive laws. From a different direction, Oliver Bartlett and Amandine Garde reach a similar conclusion. The limits of EU law create significant constitutional imbalances, which impede national evidence-based policies seeking to constrain alcohol consumption. At the same time, EU-level alcohol control measures are hortative only. Iris Goldner Lang tracks the development of EU food law and policy from an original focus on food safety (where public health concerns were encapsulated in EU-level regulatory measures, and significant institutional structures) towards a focus on the key public health challenge of obesity. Here again, the consequences of the EU’s free movement rules and limited Member State discretion to protect public health, combined with the lack of political will to adopt EU-level binding measures, leave public health protections embodied in ‘soft’ rather than ‘hard’ norms.

The final substantive part of the Handbook turns from the internal aspects of EU Health Law and Policy to the external context. Holly Jarman and Meri Koivusalo consider the health implications of the EU’s external trade policies and law. From the narrow focus (essentially on food) of the past, the EU’s trade agreements now concern a very wide range of matters concerning health. Included are pharmaceuticals, insurance and even the provision of healthcare services themselves. If health ministers are not ‘at the table’ of these negotiations, Jarman and Koivusalo warn that the values associated with European health systems will be ‘on the menu’. Similar conclusions are arrived at concerning the fragility of health in EU external relations law and policy. Here Tamara Hervey broadens the focus to include the EU’s development law and policy, as well as its external human rights work. Echoing Young’s chapter, the overall analysis reaches a conclusion of unfulfilled potential and missed opportunities.

Anniek de Ruijter’s concluding chapter is a powerful discussion of the values of solidarity, universal access, equality and human dignity, in the context of EU Health Law and Policy. de Ruijter assesses the extent to which such values are – and could ever be – promulgated through EU Health Law and Policy, given the EU’s constitutional arrangements. She shows how the EU’s infamous ‘constitutional asymmetry’ leaves solidarity, universal access, equality and human dignity – more often than not – in a non-equal relationship with free trade, free competition, competitiveness, the knowledge economy, and above all, fiscal austerity. Fundamental (human) rights represent a possible future site for constitutional realignment, allowing ‘the constitutional order of the EU to be changed or set up in a manner in which EU health laws values will not have to compete so hard with EU economic values’. This is – at present – the ‘road not taken’ by the EU and its health law and policy.

THE ‘STATE OF THE ART’: THREE THEMES

Overall, from the detailed analyses in the Handbook, we discern three broad themes.

1. Fractured Decision-Making, Leading to Policy Ineffectiveness or Incoherence

We are not the first to observe that the pursuit of health agendas within the EU’s institutional structures is complicated by the actors and the decision-making processes involved. The need to secure agreement from multiple parties or bodies, often with conflicting interests, sometimes with no expertise in health, damages the pursuit of policies with a central focus on health and its protection and improvement. This fracturing is evident in Martinsen’s chapter (legislative institutions); Rieder and Young’s chapters (courts and litigation); and de Ruijter’s chapter (the ‘constitutional asymmetry’ of EU Health Law and Policy) and what this means for health values. It is also either evident or implicit in the detailed accounts of specific health policy areas in the other chapters of the book. For instance, McHale and Mahalatchimy are critical of the lack of a coherent EU policy for human materials, leading to an inconsistent approach to its regulation. The ways in which the EU’s laws and policies on novel health technologies are similarly dispersed among different institutional settings is reflected in Pilgerstorfer’s, Brosset’s and Mahalatchimy’s, and den Exter’s chapters.

Health law and policy does not ‘belong’ and has never fitted within a single law or policy-making space in the EU’s institutions. As Martinsen’s chapter shows, the governance of health for the sake of health, and especially law and policy affecting health systems, are areas of law and policy that the EU has found difficult to enter. Where the EU does adopt law and policy affecting health systems, the effects may be undesirable, as van de Gronden and Rusu, and Kuhlmann et al. demonstrate. The difficulties are present even in the area of public health, where the EU has significant formal competences. Alemanno’s, Bartlett’s and Garde’s, and Goldner Lang’s chapters show how the EU is still searching for the right set of tools to solve a series of public health problems through different institutional settings, none of which is squarely concerned with public health protection or promotion per se.

Further, law and policy-making competences are shared between the EU and its Member States in virtually every health policy area discussed in this Handbook. Even in areas where the movement over time is for policy to be increasingly made at EU level, as, for instance Frischhut and Greer argue is the case for communicable diseases, significant powers remain with national bodies. Those policy areas where the EU has ‘exclusive competence’ (for instance, trade deals concerning goods, marketing authorisation for novel pharmaceuticals) are very much the exception. Distribution of policy competences between different institutional actors, within the EU and at national level, makes for fractured decision-making with discernable consequences for responsibilities and effectiveness. The EU’s Eurozone governance arrangements have unplanned effects on health systems, as shown by Sokol and Mijatović. Moreover, the dispersion of powers between the EU, its Member States and the IMF means it is impossible to use traditional accountability mechanisms, such as judicial review of executive decisions. Regulatory vacuums can emerge, as Kuhlmann et al. demonstrate, where neither EU nor national institutions are sufficiently able to control unwelcome developments. Yet shared decisions between EU and national institutions are impossible to reach. None of this institutional context is good for hammering out legal and policy settlements that are good for health.

2. The Place of ‘Science’ and ‘Innovation’ in EU Health Law and Policy

Innovation is a significant challenge for EU Health Law and Policy. The balance between enabling novel technological developments and securing protection for patients, health systems and others, is a theme that emerges in several chapters of the book. It is most evident in the chapters by Flear, Pilgerstorfer, Brosset and Mahalatchimy, McHale and Mahalatchimy, and den Exter. All of these chapters, along with those in the part of the Handbook on public health, consider the extent to which the EU institutions have secured a fair and effective compromise between competing interests. The EU’s ‘scorecard’ in this regard is mixed, at best. In particular, McHale and Mahalatchimy consider that the ethical dimensions of innovation have been insufficiently accommodated in the EU’s regulation of human materials.

The ways in which litigation (or the mere threat of litigation) interacts with legislation and other regulatory measures, including executive decision making, are an important institutional context here. This theme is taken up by Rieder, Pilgerstorfer and, in particular, by Frischhut and Greer, who explore how the legal concept of ‘the precautionary principle’, based on the idea of ‘scientific evidence’, is articulated in various policy contexts. The notion of ‘science-based’ policy making thus imbues EU legislation and litigation alike.

de Ruijter argues that ‘good science’ should be a value that plays an important role in health policy. Where the EU’s policies incorporate ‘good science’, these are often said to encapsulate nuanced and balanced settlements between competing interests. They are also considered to be effective, in that they express the state of the art in terms of technological innovation, and seek to regulate it. Elements of the EU’s food, tobacco, clinical trials, pharmaceuticals, medical devices and e-health technology laws and policies may be said to meet this description. But the EU does not always meet the health policy community’s standards of such ‘science-based’ decision making, as, for instance, Bartlett’s and Garde’s chapter demonstrates, in their argument that the EU has failed to engage with the scientific evidence on alcohol. Likewise, Frischhut and Greer argue that the EU’s communicable disease policy is not simply a product of ‘science-based’ decision making.

Nonetheless, as Flear reminds us, ‘good science’ is not a ‘scientifically’ determined concept. The social construction of ‘science’, and indeed also of ‘innovation’ forms a crucial vector in understanding the EU’s Health Law and Policy. ‘Innovation’ can be an opportunity for the EU institutions to become involved in health law and policy making in unexpected ways. For instance, by supporting health technology industries through Horizon 2020, itself part of the EU’s economic governance mechanisms. The notion of the ‘knowledge economy’ as the future for the EU includes the health knowledge economy. Here, the imbalances between different parts of the EU (as Sokol and Mijatović show) cannot themselves be corrected by ‘science-based’ decision-making alone. The benefits of health innovation will not be evenly enjoyed across the EU without some kind of redistributive policies. And – of course – the EU lacks redistributive competences. This brings us to our final theme.

3. The Fragility and Frustrated Potential of EU Health Law and Policy, and Yet its Remarkable Durability

The EU institutions have been involved in health policy for a considerable period of time – arguably from the inception of the EEC. We see the temporal aspect of EU Health Law and

Policy in Sauter's and Guy's historical chapter, but also in the timelines de facto considered in all the substantive chapters of this Handbook. There is hardly a chapter which does not reach back to at least the 1980s, if not earlier, in its substantive scope. In that sense, therefore, EU Health Law and Policy has proven remarkably durable through time.

However, although EU Health Law and Policy may be seen as long-standing, it is also seen as precarious. Many commentators on EU Health Law and Policy frame their analysis in terms of a 'clash' between the values of the market and the values of health – with health in a suboptimal position in that conflict of values. The majority of the contributors to our Handbook follow this approach. This 'standard narrative' sees the EU's market orientation (free movement of factors of production, free competition) in conflict with a wide range of public interests. Health is such a public interest. What is good for businesses (or more accurately for private capital) can be damaging to individual human beings or wider society.

The classic articulation of this dynamic in EU law is known as 'constitutional asymmetry'.² Where EU law applies, the logic of the market stands in a hierarchical relationship above other logics. It follows that where health goals can be successfully aligned with economic goals, health can be improved through EU law and policy. But the converse is also true: EU market law and policy can be detrimental to human health.

In this Handbook, these ideas are expressed in their purest form in van de Gronden's and Rusu's chapter. Their analysis shows that, where Member States choose to shelter their healthcare systems from competition, the effects of EU law are significantly different from the effects of EU law on those Member States which seek to bring competition within their healthcare systems. In the latter case, the EU approach in general does not protect healthcare-specific values. In this instance, bringing EU law into healthcare – with all that entails – is a choice for governments of Member States.

But in many instances, once a country is a Member State of the EU, and even more so if it is a Eurozone Member State, any such choice is removed. Health stands in a non-equal relationship to market-based, or fiscal-austerity based, values, with negative consequences for health systems (Sokol and Rusu); public health protection (Frischhut and Greer, Alemanno, Bartlett and Garde, Goldner Lang); securing professional care for patients (Kulmann); and global health (Jarman and Koivusalo, Hervey). EU law's entitlements for healthcare professionals to move throughout the EU undermine an approach to healthcare capacity-building based on accountability to national populations. This approach leads to growing inequalities between patients in different EU countries. In the Eurozone, the pursuit of macroeconomic stability through a narrow approach to austerity affects the de facto provision of healthcare in crisis-hit economies. EU law on free movement of products prevents Member States from enacting legislation to tackle (childhood) obesity or alcoholism. In the EU's global trade and development policies, economic liberalism is pursued over and above increasing health protection in the global South.

The idea that health is in a non-equal relationship to market-based values such as free trade also features strongly in Young's and de Ruijter's chapters. Those chapters, along with Sjindberg Martinsen's, and several other chapters, also explore the ways that litigation based on the logics of EU market law is fundamentally disruptive of health policy. The ability of

² F Scharpf, 'The European social model: coping with the challenges of diversity' (2002) 40 *Journal of Common Market Studies* 645; F Scharpf, 'The Asymmetry of European Integration or Why the EU Cannot be a "Social Market Economy"' (2010) 8(2) *Socio-Economic Review* 211.

individual market actors (usually powerful companies) to rely on their rights to trade in EU law is a crucial feature of the highly fragile position of health within the EU's law and policy.

And yet, there is nothing inherent about the place of health (or other non-market) values within EU law. It is a matter of law and policy-making choice. For courts, and administrative authorities, it is a matter of interpretation. Specific considerations and concrete choices can be made to ensure the promotion and protection of health. The place of 'services of special economic interest' in EU competition law is a case in point. The EU's approach to tobacco regulation is another. These examples show how in many ways what is remarkable about EU health law and policy is its very durability in the face of such fragility. The very fact that EU health law and policy is under discussion at all is itself significant.

Here, our Handbook offers a potential direction of travel – an increased focus on human rights – which would see the protection and promotion of health as a central value of EU law and policy. Human rights – as an embodiment of EU law and policy value in itself, as part of the EU's 'constitutional settlement' – offer a value system for the EU's general law and policy-making orientation (de Ruijter). They also offer a strategy of judicial interpretation (as Young's discussion of AG Opinions shows), or a policy goal (eg Frischhut and Greer). We do not have space here to explore the problems with such a human rights-based approach. As this was not our agenda for the Handbook, we simply note here that we are not in agreement (as contributors or as editors) as to the desirability of this potential future for EU health law and policy.

What we do agree on is that rather than the frustrated potential, or missed opportunities (Hervey), inherent in the standard narrative, a health-values based future for the EU may be within reach. A systemic approach to values would fundamentally change EU health law and policy. For instance in the regulation of human material (McHale and Mahalatchimy, Flear); the sharing of the benefits of novel medical technologies (Pilgerstorfer, Brosset and Mahalatchimy, den Exter); the deployment of human (Kulmann et al.) and other (van de Gronden and Rusu, Sokol and Mijatović) resources; and the protection of human health in the spaces occupied by powerful global industries (Pilgerstorfer, McHale and Mahalatchimy, Brosset and Mahalatchimy, den Exter, Frischhut and Greer, Alemanno, Bartlett and Garde, Goldner Lang). If the reasons for the EU institutions not having pursued health agendas in the past, despite formal legal competence and sufficient resources, lie in the political preferences of governments of powerful Member States, an EU without the UK may offer altered possibilities.

THE 'DIRECTION OF TRAVEL'

These themes are, in our view, likely to influence the overall direction of travel for the EU's health law and policy. It seems presumptuous to say that EU Health Law and Policy as a whole has a single direction of travel. Of course, we recognise that each area of EU health law and policy progresses at its own pace and following its own logics. We respect the different conclusions on the trajectory of a particular area reached by each of our contributors. Nonetheless, as editors, we offer some final thoughts, drawing together the threads of analysis which we hope our readers will explore through the rest of the Handbook.

As editors located in the UK, we expect that the EU without the UK will be a different forum for health law and policy making, and to the extent to which we are able, we reflect on that future EU in the remaining paragraphs.

The British referendum of June 2016 represented an opportunity for various calls to reshape the EU as a whole. If such reshaping takes place, it could include a dramatic change for EU Health Law and Policy. We note that, looking across European integration as a whole, periods of centralisation involve many areas of EU law and policy-making developing at the same time, at a significantly faster pace than at periods of stagnation or sclerosis. Key to these periods of centralisation are questions of legitimacy: in whose name is the European project being carried out, and how are the voices of European populations heard in the integration process? The movement over time from an EEC which was a governance space for technical elites, to an idea of a EU in which citizens feel allegiance, may be continued more readily without a Member State 51.9% of whose population does not share that allegiance. We note that calls for similar referenda in other supposedly ‘Eurosceptic’ countries, such as Denmark, have been significantly muted as the effects of the UK’s referendum are beginning to be felt. To the extent that the UK government represents a barrier to the transfer of competences to the EU, the EU’s powers in the future might be significantly enhanced in many areas that are important to European populations, including health.

In the alternative, of course, the UK leaving the EU could be taken as a signal that the EU has become too centralised. We might see the ‘repatriation’ of legal and policy-making competences to national or regional levels, returning the EU to a more inter-governmental era. With the exception of areas where a clear inter-governmental mandate is present (for instance, regulation of pharmaceuticals or communicable disease control), in that scenario we would expect much less in the way of EU health law or policy. Even those areas might revert to non-EU international fora, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use or the World Health Organisation. A possible future sees the end of the EU as we know it, including as a site for health law and policy.

In either future, we see the possibility for the articulation of the core values of the EU (or whatever it becomes) to include health – and not just health as a factor of production or a contribution to economic growth and prosperity. Human health will remain a significant consideration for the legitimacy of any government. This is also true for any inter-governmental or supranational arrangements, through which national governments and other institutions cooperate to create law and policy. There is scope for the European project to be given greater legitimacy to include a re-articulation of health values – whether through a human rights frame, or in another way such as within equality policies concerned with redistribution. The ‘health in all policies’ approach of the current position, along with the idea of the EU as a ‘social market economy’,³ and the EU’s constrained competences over national welfare settlements, are good places to start. This moment represents an opportunity to revisit the tensions in the current constitutional arrangements of the EU, and to articulate more clearly which are inherent and which are the product of choices of the EU’s institutions and those of its Member States.

³ Article 3(3) TEU.

The effects of economic integration, even when they translate into increased overall prosperity, are not equally felt in all parts of an economy or society. Equality and dignity – including in health contexts – requires redistribution, not growth alone. Legitimated constitutional arrangements respect that insight. When the balance between the powers and capabilities of international, EU, national and local institutions reflects this position, whatever the EU becomes, it can contribute to the health of Europe, and of the world.

PART 2

PEOPLE AND PRODUCTS

5. EU law, policy and health professional mobility

Ellen Kuhlmann, Claudia B Maier, Gilles Dussault, Christa Larsen, Emmanuele Pavolini and Marius-Ionuț Ungureanu

I. INTRODUCTION

Free movement in the European Union (EU) single market has created a novel situation for health professionals and workforce governance. Healthcare organisations can recruit from a larger pool of human resources, providers and policymakers can mitigate shortages and maldistribution of skills, and EU health sciences and research benefit from knowledge exchange. For individual health professionals, an open EU labour market improves employment and career opportunities. A ‘rosy picture’ of an EU single market and its mobile professionals is however challenged, when looking at it from a public health and health system perspective.

The EU free movement law came at a time of turbulent health labour markets with adverse dynamics caused by high demand for healthcare workers in most EU countries and cuts in public sector and healthcare services as part of austerity measures.¹ Economic push-pull factors create uneven and unpredictable mobility flows, which may negatively affect the health labour markets of

¹ J Buchan, IA Glinos and M Wismar, ‘Introduction to health professional mobility in a changing Europe’ in J Buchan and others (eds), *Health Professional Mobility in a Changing Europe: New dynamics, mobile individuals and diverse responses* (World Health Organisation 2014) 3–16; J Buchan, ‘Health worker migration in context’ in E Kuhlmann, and others (eds), *The Palgrave International Handbook of Healthcare Policy and Governance* (Palgrave 2015) 241–258; J Campbell and others, ‘A Universal Truth: No Health without a Workforce’ (Forum Report, Global Health Workforce Alliance and WHO 2013); G Dussault, ‘Bringing the health workforce challenge to the policy agenda’ in Kuhlmann and others (2015); G Dussault and J Buchan, ‘The economic crisis in the EU: impact on health workforce mobility’ in Buchan and others (2014); IA Glinos and others, ‘How can countries address the efficiency and equity implications of health professional mobility in Europe? Adapting Policies in the Context of the WHO Code and EU Freedom of Movement’ (Policy Report, WHO 2015); SL Greer and others, ‘Health law and policy in the European Union’ (2013) 381 *The Lancet* 9872, 1135–1144; SL Greer and others, *Everything you Always Wanted to Know About European Union Health Policies But Were Afraid to Ask* (WHO 2014); TK Hervey and JV McHale, *European Union Health Law – Themes and Implications* (CUP 2015) Chapter 6; E Kuhlmann, R Batenburg and G Dussault, ‘Editorial. Health workforce governance in Europe: where are we going?’ (2015) 119(12) *Health Policy* 1515; T Ono, G Lafortune and M Schoenstein, ‘Geographic imbalances in the distribution of doctors and health care services in OECD countries’ in *Health Workforce Policies in OECD Countries: Right Jobs, Right Skills, Right Places* (OECD Publishing 2013).

Eastern Member States, and of Southern Europe hit by austerity programmes.² Health professional mobility creates and reinforces inequality within the EU and may threaten universal healthcare coverage in resource-poorer EU countries. Until recently, only few EU countries heavily relied on foreign-trained health professions.³ Yet a self-sufficient health workforce is increasingly difficult to achieve and more countries recruit from a European and international pool to respond to a growing demand for health workers.⁴

Health workforce mobility and cross-border movements have created new demand for complex transnational EU regulation and an integrated, multi-level governance approach, while EU law is primarily concerned with labour markets, leaving healthcare regulation a domain of Member States.⁵ These conditions of poor sectoral coordination between labour market and healthcare policies as well as between transnational EU and national/regional regulations cause a continuing

² Dussault and Buchan (2014) (n 1); T Correia, G Dussault and C Pontes, 'The impact of the financial crisis on human resources for health policies in three Southern-European countries' (2015) 119(12) *Health Policy* 1600; IA Glinos, 'Health professional mobility in the European Union: exploring the ethics and efficiency of free movement' (2015) 119(12) *Health Policy* 1529; I Kolčić and others, 'Emigration-related attitudes of the final year medical students in Croatia: a cross-sectional study at the dawn of the EU accession' (2014) 55(5) *Croatian Medical Journal* 452; C Leone and others, 'Work environment issues and intention-to-leave in Portuguese nurses: A cross-sectional study' (2015) 119(12) *Health Policy* 1584; C Leone, C Conceição and G Dussault, 'Trends of Cross-border Mobility of Physicians and Nurses between Portugal and Spain' (2013) 11 *Human Resources for Health* 36; C Leone and others, 'Nurse migration in the EU: a moving target?' (2016) 22(1) *EuroHealth* 7; L Paina, M Ungureanu and V Olsavszky, 'Implementing the Code of Practice on International Recruitment in Romania – Exploring the current state of implementation and what Romania is doing to retain its domestic health workforce' (EHMA Conference, Tilburg, May 2015); J Ribeiro and others, 'Health professionals moving to and from Portugal' (2014) 114 *Health Policy* 97; P Saar and J Habicht, 'Migration and attrition: Estonia's health sector and cross-border mobility to its northern neighbour' in M Wismar and others (eds) *Health Professional Mobility and Health Systems: evidence from 17 European countries* (WHO 2011).

³ R Young, 'A major destination country: The United Kingdom and its changing recruitment policies' in M Wismar and others (n 2).

⁴ IA Glinos and J Buchan, 'Health professionals crossing the EU's internal and external borders: a typology of health professional mobility and migration' in Buchan and others (2014) (n 1); Glinos (n 2); J Buchan, IA Glinos and M Wismar, 'Introduction to health professional mobility in a changing Europe' in Buchan and others (2014) (n 1); M Kroezen, and others, 'Recruitment and retention of health professionals across Europe: a literature review and multiple case study research' (2015) 119(2) *Health Policy* 1517; CB Maier and others, 'Monitoring health professional mobility in Europe' in Buchan and others (2014) (n 1); CB Maier and others, 'Cross-country analysis of health professional mobility in Europe: the results' in Wismar and others (n 2); Ono, Lafortune and Schoenstein (n 1); Wismar and others (n 2).

⁵ R Baeten and B Vanhercke, 'Inside the black box: the EU's economic surveillance of national healthcare systems' (2016) *Comparative European Politics* DOI: 10.1057/cep.2016.10 <<http://link.springer.com/article/10.1057%2Fcep.2016.10>> accessed 2 June 2016; Greer and others (2013) (n 1); Greer and others (2014) (n 1); SL Greer and M Mätzke, 'Health policy in the European Union' in Kuhlmann and others (2015) (n 1); SL Greer and B Vanhercke, 'The 'hard politics' of 'soft law': the case of health' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of EU Law and Policy* (CUP 2010); Hervey and McHale (n 1); TK Hervey and B Vanhercke, 'Health care and the EU: the law and policy patchwork', in Mossialos and others (2010); E Kuhlmann and others, 'Bringing a European approach to the health human resources debate: A scoping study' (2013) 110 *Health Policy* 6; E Kuhlmann and C Larsen, 'Why we need multi-level health workforce governance: case studies from nursing and medicine in Germany' (2015) 119 *Health Policy* 1636; Mossialos and others (2010).

‘regulatory gap’ between free labour markets and the needs of healthcare systems for qualified professionals. Although a sector-based regulatory approach is gaining momentum, as illustrated by the EU Professional Qualifications Directive,⁶ there are currently no signs of a systematic policy change and coherent governance approach to close the gap.

The chapter is framed as a clash between the core EU values of free movement on the one hand, and the healthcare system needs for qualified professionals on the other. More specifically, the problems are exemplified by health workforce mobility, using empirical data to highlight the problematic effects on health systems. Three case studies provide deeper insights into the regulatory dilemma. Case study (i) reveals tensions between the EU’s objective to promote financial discipline and Member States’ health workforce recruitment and retention policies. The other two cases illustrate how open labour markets counteract sustainable and responsible policy solutions in the healthcare sector. Case (ii) looks at nurses and how EU mobility is used to mitigate system deficits in the skill mix of the workforce. Case (iii) sets the focus on doctors and illustrates the unequal effects of (missing) EU regulation that hit the healthcare systems of Eastern EU Member States the most.

The chapter begins with an overview of EU regulation and policy as relevant for our topic and comparative empirical data on health workforce mobility in the EU, followed by three case studies. Finally, conclusions are drawn on the direction of travel in EU law and the need for more visionary approaches to reduce inequality in healthcare in the EU.

II. EU HEALTH WORKFORCE MOBILITY: REGULATION, POLICY AND EMPIRICAL FACTS

Health workforce issues have moved up the EU policy agenda, and data sources and monitoring systems have improved.⁷ The following sections provide an overview based on document analysis, statistical data and secondary sources, including new research carried out by the authors.

⁶ Various contributors, ‘Perspectives on the Professional Qualifications Directive’ (2011) 17(4) EuroHealth <www.euro.who.int/_data/assets/pdf_file/0004/154516/Eurohealth_Vol-17_No-4_web.pdf?ua=1> accessed 2 June 2016; Commission, ‘New European Professional Card helps professionals work throughout the EU’ (European Commission, 18 January 2016) <http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8627> accessed 2 June 2016; Commission, ‘Working Group on the European Workforce for Health: Ticking the Boxes or Improving Healthcare and Patient Safety? Optimising Continuous Professional Development of Health Professionals in the EU’ (European Commission, 11 February 2016) <http://ec.europa.eu/health/workforce/events/ev_20160211_en.htm> accessed 2 June 2016; Commission, ‘European Professional Card: Electronic procedure for the recognition of professional qualifications’ <http://ec.europa.eu/internal_market/publications/docs/european-professional-card_en.pdf> accessed 2 June 2016; C Hager, ‘Continuous professional development: European context’ (Presentation to the Working Group on the European Workforce for Health, Brussels, 11 February 2016) <http://ec.europa.eu/health/workforce/docs/ev_20160211_co01_en.pdf> accessed 2 June 2016.

⁷ Commission, ‘Green Paper on the European Workforce for Health’ COM (2008) 725 final; Commission, ‘An Action Plan for the EU Health Workforce’ (Staff Working Paper) SWD (2012) 93 final; Commission, ‘New European Professional Card helps professionals work throughout the EU’ (n 6); Commission, ‘Working Group on the European

II.i EU Health Labour Market and the Health Professions: Regulation and Policy

EU law is still ‘patchy’⁸ and fragmented into sector-specific policy domains, promoting EU regulation on labour markets and protecting the rights of Member States in healthcare including finance, provision of care and regulation of the health workforce. This fragmentation and distribution of responsibilities is key to understanding the EU politics of health workforce regulation and the governance challenges embedded in growing health workforce mobility. ‘EU health law treats health professionals as first and foremost as market actors, as ‘service providers’, subject to consumer law; not as professionals subject to legal and ethical frameworks of professional regulation.’⁹ This approach preserves the ‘regulatory trade-off’ between the EU and its Member States, whereas ‘[S]ervice providers are understood as operating in a market; professionals are operating in the context of national health (insurance) systems’.¹⁰

In what follows from this approach, EU law sees a health professional ‘as equivalent to any other professional who provides services, takes up employment, or establishes herself in a Member State other than the state she became professionally qualified’.¹¹ Regulation of education/training and recognition of qualifications across the EU as well as working conditions of employees in the healthcare sector are therefore the major concern of EU health workforce regulation.¹² An individualised approach and labour market focus of EU law cause major problems for health systems and services accountable to the ‘public’, in terms of serving the health needs of citizens. At present, EU law creates strong incentives for mobility but does not provide appropriate governance tools to better target the free movement of healthcare workers and counteract asymmetric mobility flows.

With the enlargements since 2004, the EU has become more diverse in terms of salary levels, career opportunities and working conditions. This has provided strong pull factors drawing health professionals from less affluent EU Member States to move to wealthier countries. A precondition for a well-functioning labour market for health professionals is to have the right numbers and the right skills. But this is being jeopardized because as the EU population ages and shrinks, so does the health workforce.¹³

Workforce for Health’ (n 6); Hager (n 6); Hervey and McHale (n 1); A Malgieri, P Michelutti and M Van Hoegaerden (eds), *Handbook on Health Workforce Planning across EU Countries* (Slovak Ministry of Health 2015); Maier and others (2014) (n 4); WHO, ‘Global Strategy on Human Resources for Health: Workforce 2030’ (Draft for the 69th World Health Assembly, 2015); WHO, ‘Core Health Indicators in the WHO European Region. 2015 Special Focus: Health Human Resources’ (2015).

⁸ Baeten and Vanhercke (n 5); Hervey and Vanhercke (n 5); Hervey and McHale (n 1).

⁹ Hervey and McHale (n 1), (n 2).

¹⁰ Ibid.

¹¹ Hervey and McHale (n 1), (n 5).

¹² eg, Commission (2012) (n 7).

¹³ Greer and others (2014) (n 1) 94.

Greer and colleagues have highlighted that the ‘European Commission has, therefore, tried to forecast future workforce supply and demand and has projected a shortage of two million health and social workers by 2020. The supply of nurses is a particular concern.’¹⁴

Improved ‘forecasting’ efforts can be viewed as a policy shift in the wider context of EU policy development and increasingly more complex challenges of workforce mobility flows.¹⁵ EU law responds to the challenges by expanding a ‘sectoral approach’, while keeping the labour market and employment focus.

At EU level, Directive 2003/88/EC (the Working Time Directive) aims at providing minimum standards common to all EU countries to protect workers from health and safety risks associated with excessive or inappropriate working hours, and with inadequate time for rest and recovery from work.¹⁶

The Directive appears in the shape of employment policy, while the effects may stretch far beyond. For instance, ‘Nursing Times’ described a direct impact in professional development and the composition of the health workforce in the English National Health Service (NHS):

The impact of cutting junior doctors’ hours started a sea change in nursing in terms of how it is planned, coordinated and led. The result of this was a shift of responsibility from doctors to nurses and a raft of new opportunities for nurses. Different working patterns, skill mixing, and new and extended nursing roles have resulted from these changes...¹⁷

Similarly, bringing workforce planning higher up the policy agenda¹⁸ not only improves data and planning but also promotes coordination and governance of the health workforce across the Member States. Most recent regulatory attempts furthermore expand a labour market approach by focusing on professional qualification and quality standards. The revised Professional Qualifications Directive¹⁹ significantly facilitates the recognition of qualifications of the main State-regulated health professions, including doctors, dentists, pharmacists, midwives and general care nurses.²⁰ A broader approach to all healthcare workers and workforce governance is lacking, however.

The Professional Qualifications Directive as well as the Working Time Directive provide examples of the dynamics released in the health workforce by EU law. The Professional

¹⁴ *ibid*; see Commission SWD (2012) 93 final (n 7).

¹⁵ Hervey and McHale (n 1).

¹⁶ Commission, ‘Public Consultation on the Review of the Working Time Directive Background’ <<http://ec.europa.eu/social/BlobServlet?docId=13085&langId=en>> accessed 2 June 2016.

¹⁷ ‘European Working Time Directive’ Nursing Times (London, 13 December 2007) <www.nursingtimes.net/european-working-time-directive/360887.fullarticle> accessed 2 June 2016.

¹⁸ Malgieri, Michelutti and Van Hoegaerden (n 7); Ono, Lafortune and Schoenstein (n 1).

¹⁹ Commission, ‘New European Professional Card helps professionals work throughout the EU’ (n 6); Commission, ‘Working Group on the European Workforce for Health’ (n 6).

²⁰ Hervey and McHale (n 1) 9.

Qualifications Directive includes in its current version only the regulated healthcare professionals, which fall in the category of high- or middle-level qualifications, while ignoring the occupational groups at the basis of the care sector, namely the predominantly female carers with lower-level or no formal qualifications and lack of power in policymaking. The new regulation may therefore reinforce a negative trend of employment conditions of less qualified, female-dominated groups.²¹ In contrast, the Working Time Directive has been shown to favour the interests of nurses in relation to doctors by shifting tasks and responsibilities (at least in more centralised healthcare systems, like the English NHS), thus promoting a professional group with weaker power resources and higher proportions of women.

Overall, the recent Directives (both the Working Time and the Professional Qualifications Directive) mark a further step towards sectoral regulation of an EU single market and the blurring of boundaries between the labour market and healthcare sectors. For instance, the Briefing Note on the amended EU Qualifications Directive mentioned health professional mobility in the context of changing demand of healthcare services systems²² and highlighted the benefits of common training frameworks.²³ As Baeten and Vanhercke argue, the ‘Eurozone crisis created a policy ‘window of opportunity’ to push through fiscal surveillance of health systems as part of the solution to the crisis. The cognitive frameworks put forward by certain elites added up to the primacy of an economic perspective over health objectives.’²⁴

In relation to international migration and recruitment,²⁵ there are more general problems, which limit direct EU interventions. Most importantly, EU health law follows a partnership model (state, private and ‘third sector’ institutions). While there are some successful efforts of the EU to act globally by collaborating on initiatives such as the Global Fund to fight HIV/AIDS, Tuberculosis and Malaria, and the ‘Global Alliance for Vaccines and Immunisation’, it has not taken a global leadership role.²⁶

II.ii EU Health Professional Workforce and Mobility Flows: Facts and Figures

Health professional mobility is highly variable across Europe’s single market, the largest free movement zone worldwide. Countries have virtually zero governance options to restrict flows within Europe’s free movement zone (which includes all 28 EU Member States plus Economic Free Trade Area countries and Switzerland). Instead, governments and health planners must react to the

²¹ E Pavolini and E Kuhlmann, ‘Health workforce development in Europe: a matrix for comparing trajectories of change in the professions’ (2016) 120 *Health Policy* 654 <www.ncbi.nlm.nih.gov/pubmed/27021776> accessed 2 June 2016.

²² H Davies, ‘EUA Briefing Note on Directive 2013/55/EU, containing the amendments to Directive 2005/36/EC on the Recognition of Professional Qualifications’ (2014) <www.eua.be/Libraries/higher-education/EUA_briefing_note_on_amended_Directive_January_2014.pdf?sfvrsn=0> accessed 2 June 2016, 1.

²³ *ibid* 2.

²⁴ Pavolini and Kuhlmann (n 21).

²⁵ Buchan (2015) (n 1); Glinos (n 2); OECD, *Health Workforce Policies in OECD Countries: Right Jobs, Right Skills, Right Places* (OECD Publishing 2016).

²⁶ TK Hervey, ‘Legal and institutional contexts of EU external relations law relevant to health’ (Presentation to the Panel ‘EU Health Law in Global Contexts’, Brussels, 28 January 2016); Hervey and McHale (n 1) 491–492.

consequences of mobility by adjusting workforce policies, planning and education.²⁷ Five health professions benefit from automatic recognition of diplomas: medical doctors, nurses, midwives, pharmacists and dentists. Within Europe's free movement zone, in the early 2010s, approximately 2–3% of all physicians, 1–2% of nurses and 2–3% of dentists worked in another country.²⁸ These figures are probably higher as a result of the economic crisis which has hit many Member States. There are, however, large variations across countries, leading to an asymmetrical situation in the region. Moreover, mobility has increased and diversified over the last decade, where short-term and temporary flows are increasing and co-exist with long-term migration.²⁹

Classic destination countries, such as Germany, France, Ireland, Norway, Switzerland, Sweden and the United Kingdom (UK) are benefiting from this mobility, with more than 20% of their medical doctors trained abroad³⁰ (Figure 5.1). These countries are among the top destination countries worldwide, on par with Australia, Canada, New Zealand and the US.³¹ Among nurses, mobility tends to be lower compared to medical doctors. Top destination countries within Europe are Norway, Switzerland and the UK, with more than 10% of their nursing workforces being foreign-educated³² (Figure 5.2). It should be noted, however, that 'foreign-trained' professionals also subsume national citizens having obtained their education abroad (e.g., due to domestic restrictions on student intakes, such as *numerus clausus* or other reasons) and returned to their home country for completion of their education or for work. The numbers are estimated to be low but increasing due to the increasing options globally to study abroad.³³

Mobility often happens between neighbouring countries with similar socio-cultural traditions and linguistically close ties. Examples include bi-directional movements between Germany and Austria, and France–Belgium–the Netherlands, or movements from Latin America to Spain, from Estonia to Finland, within a larger mobility context between Finland, Sweden, Estonia and the Russian Federation.³⁴ The picture and reasons for mobility are highly diverse – individual reasons to work in another country are triggered by economic factors, such as unemployment rates and perceived (higher) salary, but also professional development opportunities, perceived better work environment or work-life balance, personal reasons, as well as language and cultural factors in the destination countries.³⁵

²⁷ Glinos (n 2); Maier and others (2011) (n 4).

²⁸ D Ognyanova and others, 'Mobility of health professionals before and after the 2004 and 2007 EU enlargements: evidence from the PROMeTHEUS project' (2012) 108 *Health Policy* 122.

²⁹ Maier and others (2011) (n 4).

³⁰ OECD (n 25).

³¹ *ibid.*

³² *ibid.*

³³ *ibid.*

³⁴ Maier and others (2011) (n 4); *ibid.*

³⁵ Glinos and Buchan (n 4); Glinos (n 2).

Figure 5.1 and Figure 5.2 Countries' reliance on foreign-trained physicians and nurses, by % of foreign-trained physicians and nurses of total physician/nursing workforces, 2014 or nearest years available.

Figure 5.1

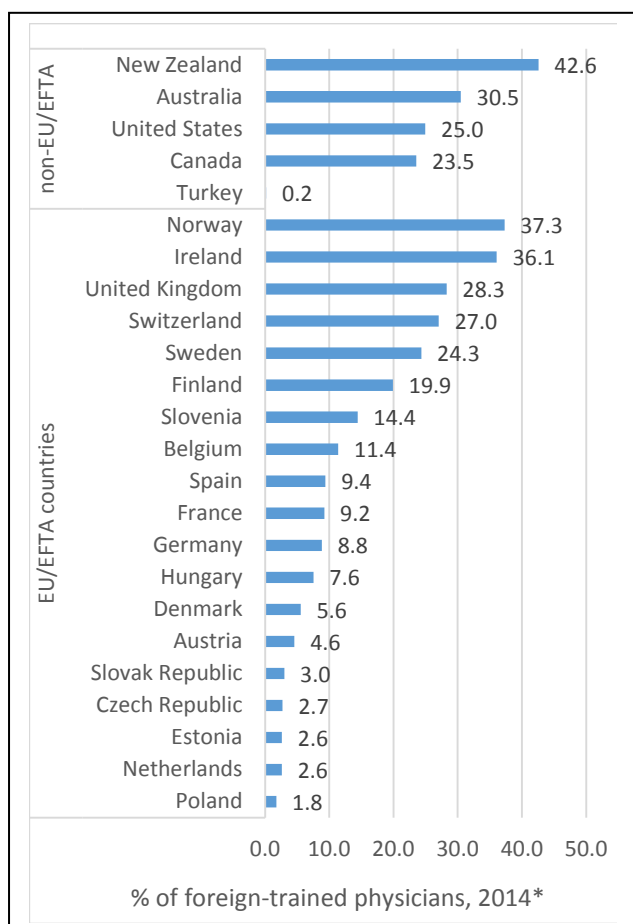
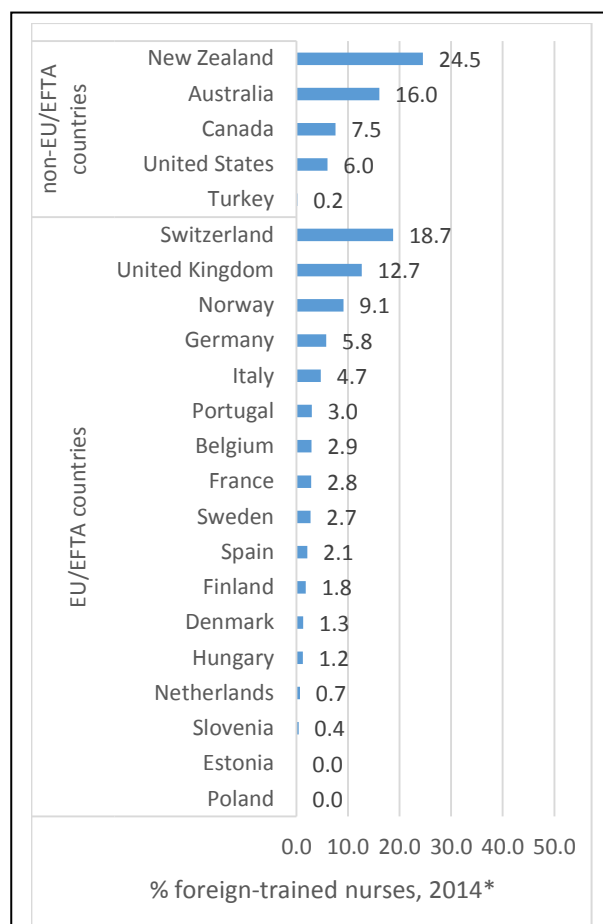


Figure 5.2



Source: OECD database 2016, OECD.stat. Data extracted on 11 January 2016 10:20 UTC (GMT) from OECD.stat <http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT#>.

Notes: *years 2014: except for (data on physicians): Canada, United States, Australia, Slovenia, France, Germany, Hungary, Turkey: 2013 covered; for Switzerland, Sweden, Finland, Denmark, Poland: 2012, and Netherlands, Slovak Republic, Spain: 2011; (data on nurses): Australia, Canada, United States, Portugal, Hungary, Slovenia, Turkey: 2013, Switzerland, Sweden, Finland, Denmark, Poland: 2012; Netherlands, Spain: 2011, Germany: 2010.

In addition to the ‘net gainers’ of mobility, there are several countries within Europe that do not receive a large influx, moreover, they lose parts of their workforce. Countries for which data were available, such as Poland, Estonia, Czech Republic, Slovakia and the Netherlands have low levels of less than 3% reliance on foreign-educated medical doctors and/or nurses.³⁶ Since joining the EU, Estonia, Hungary, Poland, Romania, Slovakia and Slovenia for instance saw increasing numbers of health professionals leaving their countries, peaking in 2004 and 2007 at the time of the EU enlargements. While rates stabilised thereafter in many countries, they remained at higher levels than before. In addition, countries hit by the economic crisis often faced increasing rates of outflows during the economic downturn.³⁷ Typical source countries are often those with lower economic status where health professionals’ income is low and unemployment high, acting as an economic push factor to emigration.³⁸

Mobility has increased and further diversified since the global economic crisis.³⁹ New and changing mobility directions have emerged. There is an increasing trend of movements from lower-income countries in Southern or Eastern Europe to higher-income countries in Northern and Western parts of the EU.⁴⁰ The 2008 economic and financial crisis impacted the entire European region, but some countries, such as Greece, Ireland, Italy, Portugal and Spain, were more heavily hit than others. They implemented large-scale cost containment strategies in healthcare, including salary freezes and cuts that acted as push factors for health professionals to leave the country.⁴¹ A new trend of short-term, fluctuating movements has emerged, in addition to long-term migration, where foreign health professionals stay in the destination country for periods of several months or less. Weekend work in another country and other short-term movements have also been observed.⁴² Movements have been triggered by economic or geopolitical developments within a variety of governance approaches.

This asymmetric situation with rapidly changing mobility directions requires countries to monitor flows and include net gains or losses of their workforce into their workforce strategies and planning. Yet, often data are not available, or are of poor quality or patchy.⁴³ Moreover, the new and emerging trend of short-term, fluctuating movements further challenges an adequate country and EU response towards countries’ workforce self-sufficiency. At the EU level, governance options face a paradox: the EU free movement principle across countries of various economic levels facilitates mobility and does not leave

³⁶ OECD, ‘Health Status’ (OECD.stat) <http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT> accessed 11 January 2016.

³⁷ Dussault and Buchan (n 1).

³⁸ Maier and others (2011) (n 4); OECD (n 36).

³⁹ Dussault and Buchan (n 1).

⁴⁰ *ibid*; Maier and others (2011) (n 4); OECD (n 36).

⁴¹ Dussault and Buchan (n 1).

⁴² IA Glinos, J Buchan and M Wismar, ‘Health professional mobility in a changing Europe: lessons and findings’ in Buchan and others (2014) (n 1).

⁴³ Maier and others (2014) (n 4).

options for restrictions, but all countries have signed the WHO Code of practice in 2010 towards ethical recruitment practices.⁴⁴ The following sections of this chapter will show in more detail how this clash between different policy areas and values plays out in the health workforce.

III. CONFRONTING EU SINGLE MARKET REGULATION WITH HEALTH WORKFORCE AND SYSTEMS EFFECTS: CASE STUDIES

III.i EU Law, Austerity Measures and Country-Specific Health Workforce Effects: The Case of Portugal

EU regulations apply equally to all Member States, but their effects are not neutral. They vary in function of economic, political and social factors, as well as in function of the specificities of the healthcare system. The case of Portugal serves to illustrate two such specific effects: the impact of austerity measures on migratory flows of nurses and physicians; and the challenge to health workforce planning posed by nationals graduating from medical schools in other EU countries.

Portugal was already a heavily indebted country when the economic and financial crisis of 2008 erupted. An austerity programme was agreed with the European Central Bank, the European Commission and the International Monetary Fund (the so-called Troika), as a condition for access to loans of 78 billion Euros. This programme included a series of measures that eventually affected the health workforce in the public sector, even though they did not target it specifically. These included salary cuts, which amounted to more than 30% over three years for those earning above 1,400 Euros monthly, a freeze on promotions and of recruitment, increase in hours worked and of workloads, and reduction in the number of statutory holidays.⁴⁵

These measures applied across public services. In health, only physicians working in primary care services succeeded in maintaining their salaries in exchange for increasing their work schedule and patient list. In nursing, unemployment, particularly of new graduates, grew. The government-stated policy was that these measures would remain in place at least for the whole duration of the agreement with the Troika. The overall result was high dissatisfaction rates among nurses and physicians, as illustrated by the numerous strikes in the National Health Services. Austerity measures also affected the private sector as it lost 'clients' who could less afford the direct costs or those of insurance and switched to public services.

These effects combined to push an increasing number of health workers to consider moving to another country, an option made easier by the EU regulations on free movement as

⁴⁴ Glinos (n 2); WHO, 'WHO Global Code of Practice on the International Recruitment of Health Personnel' Sixty-third World Health Assembly (May 2010) Resolution WHA63.16.

⁴⁵ Dussault and Buchan (n 1).

described previously.⁴⁶ The number of potential emigrants corresponds to the number of applicants for the relevant documentation, figures that professional Councils in Portugal provide. For nurses, there have been 11,144 requests for documentation confirming qualifications between 2009 and mid-2015, which on an annual basis represents between one-third and 50% of new graduates, and 4% of the total of registered nurses (in 2013, the number was 2,366 and in 2014, it was 2,278).⁴⁷

The number of those who effectively left the country can only be estimated. Figures for registration in another country exist but they have to be retrieved from registries of every other country of the EU. A recent study⁴⁸ reports that the most important emigration destinations are the UK (mainly England), France, Germany, Switzerland and Belgium in that order. In the UK, the number of new registrations of Portuguese nurses increased from 91 in 2008 to a peak of 1,286 in 2014 and a total of 4,351 between these two dates. Interviews with a sample (n=398) of Portuguese nurses working in England confirmed that the ‘push factors’ that led to their decision to emigrate were linked to the austerity context: difficulty in finding a post; reduced salary; increased workload; and lack of career opportunities. Most had been recruited through recruitment agencies or directly by hospitals who had organised recruitment campaigns in Portugal itself.⁴⁹

For physicians, numbers are not published, and estimates have to be gathered from public statements from representatives of the profession. Even though the issue of losses of physicians to emigration has received much attention from the press, the phenomenon, which is typically described as ‘augmenting’, is not properly documented.⁵⁰ The President of the Medical Council has given the figure of 1,122 requests for Certificates of professional status in 2014, adding that it was five times more than in 2010.⁵¹ No exact figures of doctors leaving the country are published, but the President of the Medical Council used the figures of 300 in 2013 and 400 in 2014. What is known is that there is active recruitment from EU countries, such as Denmark and England.

With respect to the impact of the regulation on the recognition of professional qualifications, it is potentially a problem if high numbers of foreigners want to work in a specific country, which is not the case in Portugal. On the other hand, it is a problem when nationals train in a foreign country and return. They compete with students who trained in Portugal for available specialty internships whose number is based to the output of national programmes. In 2015, more than 200 graduates could not enter an internship. Medical Council data to the end of 2015 report that 1,405 Portuguese trained in other EU countries

⁴⁶ See also, Leone and others (2013) (n 2); Leone and others (2016) (n 2); Ribeiro and others (n 2).

⁴⁷ C Pereira, *Vidas Partidas. Enfermeiros Portugueses no Estrangeiro* (Lusodidactica 2016).

⁴⁸ *ibid.*

⁴⁹ Ribeiro and others (n 2).

⁵⁰ S Amaral and AP Marques, ‘Emigração Portuguesa de Profissionais de Saúde (Di) Visões em torno de um fenómeno emergente’ in MI Carsalade Martins and others (eds), *Trabalho em Saúde, Desigualdades e Políticas Públicas* (Health Sciences Research Centre 2014) 141–158.

⁵¹ MF Reis, ‘Bastonário dos Médicos defende ser preciso travar as causas da emigração’ *Jornali* (27 May 2015) <www.ionline.pt/393732> accessed 3 June 2016.

were registered.⁵² The number of Portuguese studying medicine in countries like Hungary, the Czech Republic, Romania, Slovakia or Spain, the principal destinations, is not known.⁵³

In sum, EU law and the values of free movement can have undesirable effects in some circumstances. When push factors (economic crisis, lack of jobs, low salaries, poor career prospects) are strong, freedom to move may stimulate emigration at a cost for the sending country and healthcare system. Also, regulations on the recognition of professional qualifications, combined with the availability of training opportunities in other EU countries, create an important challenge for planners and policymakers.

III.ii EU Workforce Mobility and the Volatile Mitigation of Health System Deficits: The Case of Foreign Nurses in Italy

A major problem of the Italian healthcare system is a lack of efficient health workforce policies to change the skill mix of the workforce. Italy shows one of the highest doctors' density in the EU, but suffers from shortage of nurses and other health and social care personnel, especially for basic tasks of care provision.⁵⁴ The healthcare sector lacks investigation in the education of nurses as well as attention to the consequences of an ageing labour force.⁵⁵ These challenges need to be met in the context of a relatively devolved healthcare system, with significant powers vested in regional and local institutions.

Against this backdrop, the EU single market and free movement of workers opened up new opportunities for the Italian NHS to tackle some of the workforce imbalances. The strategies and recruitment patterns vary, however. Two different phases emerged over the past 15 years: phase I from the 2000s until around 2010; and phase II starting with the economic crisis and, more specifically, with the austerity measures. Until 2000 or so, Italy's healthcare workforce was 'home made', staffed by nationals. The situation changed markedly within only one decade for nurses and other health professions, while the medical profession remained largely untouched by growing EU mobility; approximately 1%–3% of the medical workforce were foreigners, often trained in Italy.⁵⁶

In 2002, nurses with foreign citizenship represented around 0.7% of the total nursing workforce.⁵⁷ Within just a few years, until 2010, numbers have increased to around 38,000

⁵² Ordem dos Medicos, 'Estatísticas Nacionais' (Ordem dos Medicos) <www.ordemdosmedicos.pt/?lop=conteudo&op=da4fb5c6e93e74d3df8527599fa62642&id=3ce3bd7d63a2c9c81983cc8e9bd02ae5> accessed 3 June 2016.

⁵³ A Campos, 'Já há muitos estudantes de Medicina no estrangeiro que pensam não regressar' *Publico* (29 December 2013) <www.publico.pt/portugal/jornal/ja-ha-muitos-estudantes-de-medicina--no-estrangeiro-que-pensam-nao-regressar-23694085> accessed 3 June 2016.

⁵⁴ OECD (n 36); Pavolini and Kuhlmann (n 21).

⁵⁵ G Vicarelli and E Pavolini, 'Health workforce governance in Italy' (2015) 119 *Health Policy* 1606.

⁵⁶ L Bertinato and others, 'Oversupplying doctors but seeking carers: Italy's demographic challenges and health professional mobility' in Wismar and others (n 2).

⁵⁷ European Migration Network (EMN) 'Politiche migratorie, lavoratori qualificati, settore sanitario' (Primo Rapporto EMN Italia, European Migration Network 2009).

nurses, equal to 10.2% of the total nursing workforce.⁵⁸ By the end of the last decade, absolute numbers as well as trends showed a strong increase: around 25% of newly enrolled nurses between 2007 and 2010 were foreign.⁵⁹ This increase was mainly the result of three different phenomena:

- The shortage of nurses in the Italian healthcare system increased demand for nurses with foreign citizenship;
- Italy changed its migration law in 2002, and introduced permanent exemptions for nurses with foreign citizenship from the annual quotas for entry to the Italian labour market;⁶⁰
- The EU internal market regulation has facilitated the recruitment of nurses in the new Member States of Eastern Europe.

Until the end of the last decade there were still problems for the recognition of professional degrees obtained in the countries of origin, also for nurses coming from Eastern EU countries. The situation has improved in recent years.⁶¹ As a result of these three phenomena, in the second part of the last decade between 55% and 65% of foreign nurses came from within the EU, mostly from Eastern European countries. In 2010, for instance, 43.9% of the foreign nurses were Romanian. However, since 2010 a new annual inflow of registered nurses trained in Romania has decreased sharply, from more than 1,000 in 2010 to less than 500 or even less in 2013.⁶²

The recruitment of Eastern EU nurses has been strongly supported by local and regional institutions in Italy.⁶³ Demand for EU nurses was particularly high in the private hospital sector, in nursing homes and nursing home care activities as well as in the NHS services of the central-northern Italian regions.⁶⁴ Several bilateral agreements have been signed by Italian regional and local governments and foreign nursing institutions in order to recruit

⁵⁸ E Fortunato, 'Gli infermieri stranieri in Italia: quanti sono, da dove vengono e come sono distribuiti' (2012) 1 *L'infermiere*, <www.ipasvi.it/ecm/rivista-linfermiere/rivista-linfermiere-page-7.htm> accessed 3 June 2016.

⁵⁹ *ibid.*

⁶⁰ Bertinato and others (n 56).

⁶¹ E Pavolini and G Costa, 'Lavoratori immigrati nel welfare regionale: politiche e nodi regolativi' (2007) 3 *Mondi Migranti* 131; G Rocco and A Stievano, 'La presenza degli infermieri stranieri in Italia: verso un reclutamento etico del personale sanitario' (2013) 14(3) *Salute e Società* 19.

⁶² Merçay, Dumont and Lafortune, 'Trends and policies affecting the international migration of doctors and nurses to OECD countries' in OECD (n 25).

⁶³ Bertinato and others (n 56); Rocco and Stievano (n 61).

⁶⁴ Bertinato and others (n 56); EMN (n 57); C Mellina, F Pittau and A Ricci, 'Le migrazioni di infermieri in Italia' (Atti IX Consensus Conference Sulla Immigrazione – VII Congresso Nazionale SIMM, Palermo, 27–29 April 2006).

qualified personnel.⁶⁵ Added to this, private companies increasingly act as brokers between the demand-side and the supply-side of professionals.⁶⁶

Since the onset of the economic crisis and the austerity measures (phase II) the situation, once again, changed radically. If growing mobility of foreign nurses seemed an unstoppable phenomenon until 2010, signs of a slowdown of EU nursing mobility were already observed. The crisis itself and austerity measures can only partly explain the changing trend. Moreover, more general problems of inefficient health workforce governance also came into play.⁶⁷ Migrant nurses, although qualified, represent one of the weakest segments of the health workforce, and show higher turnover rates compared to Italian nurses.⁶⁸ They have more often unstable (fixed-term) employment contracts with lower salaries due to widespread subcontracting practices: nurses work for temporary work agencies or cooperatives, which offer their services to private and public healthcare institutions.⁶⁹ As a consequence of overall poor employment and career conditions, an increasing number of EU nurses try to move to other EU countries, where contracts seem to be more attractive.⁷⁰

In summary, EU single market law and growing mobility have had positive effects on the Italian healthcare system and mitigated system deficits in the skill mix through extensive recruitment from resource-poorer Eastern EU countries. The opportunity to use EU health workforce mobility to solve country-specific system deficits is markedly constrained since austerity measures were introduced. In this situation, adverse effects of EU mobility law are gaining momentum in the Italian healthcare system, as nurses increasingly search for better work conditions elsewhere in the EU. This development is facilitated by the EU's Professional Qualifications Directive,⁷¹ which makes 'country hopping' easier for professionals. Ironically, the Italian NHS may itself face in future the symptoms of 'draining' (although not at the same level) that its foreign recruitment policy caused in Eastern EU Member States.

⁶⁵ J Chaloff, 'Mismatches in the Formal Sector, Expansion of the Informal Sector: immigration of health professionals to Italy' (2008) OECD Health Working Paper No 34
<www.who.int/hrh/migration/Case_study_Italy_2008.pdf> accessed 3 June 2016.

⁶⁶ Rocco and Stievano (n 61).

⁶⁷ Vicarelli and Pavolini (n 55).

⁶⁸ Fortunato (n 58).

⁶⁹ IRES, *Il lavoro di cura degli stranieri nella sanità* (IRES 2008).

⁷⁰ Rocco and Stievano (n 61).

⁷¹ European Parliament and Council Directive 2013/55/EU of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation') [2012] OJ L354/132.

III.iii EU Mobility and the ‘Draining’ of Resource-Poorer Healthcare Systems: The Case of Romanian Doctors

Since joining the EU in 2007, Romania has become one of the major source countries of health professionals for Western European countries, although migration was also relevant prior to EU membership. Health professionals trained in Romania (mainly doctors) represent one of the largest shares of foreign-trained health professionals in Germany, Belgium and France.⁷² However, the figures of foreign-trained doctors may include nationals who were not admitted to medical studies in their country and who went to Romania to qualify as medical doctors. Growing shortages of doctors in Germany and other resource-rich EU countries will reinforce a trend of ‘fishing’ from the pool of other healthcare systems,⁷³ such as in Romania, which are heavily struggling to establish universal healthcare coverage and improve healthcare for the population.

The present situation has emerged as the result of a combination of factors, originating both in Romania, as source country, and in the destination countries. In Romania, although the health professionals’ emigration was expected to increase after Romania joined the EU, little was done to prevent this development.⁷⁴ Moreover, since the phenomenon became more pressing in the years after 2007, there were no significant efforts and policy changes towards managing health professionals’ migration more efficiently.⁷⁵ Low wages, poor working conditions and widespread corruption, among other things, acted as strong push factors.⁷⁶ On the other hand, pull factors such as better payment, greater access to modern technology to support clinical care, and more transparent and systematic opportunities for professional development, further influenced the decision to emigrate and accelerated the mobility flows.⁷⁷

The number of doctors trained in Romania increased significantly over the past years.⁷⁸ Apart from the push and pull factors, aggressive recruitment campaigns from, or

⁷² Ognyanova and others (n 28).

⁷³ Glinos (n 2).

⁷⁴ A Galan, ‘Health worker migration in selected CEE countries in Romania, Czech Republic, Serbia and Croatia’ in C Wiskow (ed), ‘Health Worker Migration Flows in Europe: overview and case studies in selected CEE countries – Romania, Czech Republic, Serbia and Croatia’ (2006) International Labour Office Working paper 245 <www.ilo.org/sector/Resources/publications/WCMS_161162/lang--en/index.htm> accessed 3 June 2016; A Galan, V Olsavszky and C Vladesc, ‘Emergent challenge of health professional emigration: Romania’s accession to the EU’ in Wismar and others (2011) (n 2).

⁷⁵ Kroezen and others (n 4).

⁷⁶ Ungureanu and others, ‘It’s not all about money: Exploring health workers’ motivation when choosing a workplace’ (Paper presented at the American Association of Public Health Annual Meeting and Expo, Chicago, November 2015) <<https://apha.confex.com/apha/143am/webprogram/Paper328671.html>> accessed 3 June 2016.

⁷⁷ Galan and others (2011) (n 74); D Ognyanova and R Busse, ‘A destination and a source: Germany manages regional health workforce disparities with foreign medical doctors’ in Wismar and others (n 2); Ognyanova and others (n 28).

⁷⁸ Glinos and others (n 1); G Lafortune, ‘Monitoring health workforce migration through international data collection: progress with the OECD/Eurostat/WHO-Europe Joint Questionnaire’ (Paper presented at ‘The Joint

incentivised by, institutions from Germany and other destination countries largely contributed to the high figures of emigrating Romanian doctors. Germany has proven to be especially welcoming to young Romanian doctors by offering attractive packages, including accommodation and language training. A statement from the German government highlighted the Professional Qualifications Directive as a success story: between 2012 and 2014 about 5,000 foreign doctors applied for a work permit in Germany, thus helping to fill the gaps: Romania was among the major sending countries.⁷⁹ At the same time, many of the doctors are hired by private hospital chains, which have more flexibility than public sector hospitals in salary negotiations. Also, foreign-trained doctors may not be fully aware of their rights as employees; they are often less well integrated in professional networks and in doctors' trades unions or professional organisations.

Data provided by Germany through the Joint Questionnaire⁸⁰ shows a close to ten-fold increase of doctors trained in Romania currently working in Germany, from 342 doctors in 2000, to 3,042 doctors in 2013.⁸¹ Most recent data from the German Physicians' Chamber show an ongoing increase. The overall proportion of foreign EU doctors working in Germany increased to 11.1% (10.3% in 2013) with Romanian doctors leading the table of EU doctors: in 2014, the total number of Romanian doctors increased to 3,857.⁸² However, most recent data suggest a decline in the annual inflow since 2014.⁸³

The situation of Romanian doctors moving to Germany shows a lack of concerted workforce governance at all levels (micro, meso, macro and transnational). This lack of coordination calls for a European policy approach based on solidarity, which may be promoted by bilateral agreements. The WHO Global Code of Practice on the International Recruitment of Health Personnel⁸⁴ could represent a starting point for designing improvements in a joint effort between Romania and Germany.⁸⁵ Three areas could be explored in more detail, including bilateral agreements, circular migration and health workforce recruitment practices.

- Bilateral agreements could serve as overarching frameworks that set out the direction of Romania–Germany collaboration on health workforce issues;

Action Conference on Planning & Educating Health Workforce without Borders', Varna, February 2016)
<http://healthworkforce.eu/wp-content/uploads/2016/02/Lafortune_Gaetan.pdf> accessed 3 June 2016.

⁷⁹ 'Anerkennungsgesetz ist ein Erfolg' Die Bundesregierung (2 April 2014)
<www.bundesregierung.de/Content/DE/Artikel/2014/04/2014-04-02-bericht-erkennungsgesetz.html>
accessed 3 June 2016.

⁸⁰ The OECD/Eurostat/WHO-Europe questionnaire.

⁸¹ Lafortune (n 78).

⁸² Bundesärztekammer, 'Ärztstatistik 2014' (Bundesärztekammer)
<www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/Statistik2014/Stat14AbbTab.pdf> accessed 3 June 2016; see Glinos and others (n 1) Figure 5.2.

⁸³ Bundesärztekammer (n 82); see also Merçay and others (n 62) 111, who reported a similar trend for France.

⁸⁴ WHO (n 44).

⁸⁵ Paina, Ungureanu and Olsavszky (n 2).

- Circular migration could be an option to replace or at least supplement the current non-structured movement of doctors from Romania to Germany, by following the principle of triple win – for the source country, the destination country and the health professionals themselves;
- Health workforce recruitment practices by German recruiters in Romania should be better regulated by the Romanian Government, to ensure that health professionals are fully aware of the benefits and risks of any position advertised.

Mobility and migration of health professionals are part of any individual's fundamental human rights, but the manner in which mobility is managed at a systemic level is a health policy and systems issue. As such, mobility can either be useful or damaging for a healthcare system.⁸⁶ The example of Romanian doctors emigrating to Germany shows the lack of coherence and 'joined up-ness' of the EU law and policy. It highlights the need for more systematic and elaborated policy efforts to sustain the health workforces in both the sending and receiving countries. If benefits of a mobile health professional workforce are to be enjoyed equally, and values of healthcare systems to be respected, EU regulation should provide a policy framework and governance incentives to prevent aggressive recruitment and to support health workforce retention strategies of small countries in Eastern Europe.

IV. CONCLUSION: CLASHING POLICY GOALS AND THE DIRECTION OF TRAVEL IN EU HEALTH PROFESSIONAL MOBILITY

This chapter has set out to explore a regulatory gap in EU law and policy of health professional mobility. Using a public health and health systems lens and empirical data, we have illuminated how this gap affects the healthcare workforce in Member States in different ways. Our analysis reveals unequal effects of growing mobility (Figure 5.1 and Figure 5.2) caused by the clashing logics of labour markets and free movement on the one hand, and healthcare goals and principles, such as universal health coverage and solidarity, on the other. More generally, the politics of EU health professional mobility embody the contrasting logics of individual human rights and opportunities for health professions and service providers, and the population-based logics of (public) healthcare systems accountable to the citizens' health and in need of a qualified health workforce.⁸⁷

Our analysis also reveals more specific problems of current EU law. One important problem is the distribution of policy responsibilities between the EU and Member States, which is manifest in the austerity measures aiming to improve fiscal stability while being blind to the needs of healthcare systems.⁸⁸ Another issue is the EU policy focus on the regulated professions, which reinforces an existing trend of more negative occupational development at the basic levels of the health workforce compared to the higher qualified

⁸⁶ Merçay and others (n 62).

⁸⁷ Campbell and others (n 1).

⁸⁸ Baeten and Vanhercke (n 5); Mossialos and others (n 5), Greer and others (2014) (n 1); Hervey and McHale (n 1).

groups.⁸⁹ Finally, within a regulatory vacuum of EU law, market powers are gaining momentum and create a spiral of inequality, which may boost health workforce policy and service provision in the more powerful countries, and threaten weaker Member States.⁹⁰ This pattern was observed for nurses and for doctors, and hits Eastern healthcare systems the most.

The direction of travel of EU law and policy has changed, since free movement was first introduced. The EU Working Time Directive⁹¹ marks an important policy shift that is becoming even more visible with the Professional Qualifications Directive⁹² and its most recent updates. Although the developments bring about only ‘creeping change’, there is a uniform direction of travel, which expands EU law towards the Member States’ domain of healthcare and workforce issues. However, entering the regulatory territory of Member States via the health workforce is still framed in terms of labour market policy; so EU law acts sideways to enter ‘foreign’ terrain of Member States regulation. This strategy has brought about some remarkable improvements in EU health workforce governance, such as improved data and monitoring,⁹³ but it does not provide an opportunity to overcome market logics,⁹⁴ where these are ill-suited to serve values such as equality and solidarity.

Our empirical data have shown that inequality between Member States is reinforced, since regulatory mechanisms to control such market forces are lacking. This situation should be alarming for EU law and for health policymakers. It highlights a need for systematic policy changes and more visionary approaches to EU law and policy. A promising future direction of travel would be the development of an EU approach to healthcare policy, which is based on solidarity to promote a needs-based distribution⁹⁵ of health professionals across Member States.

⁸⁹ Pavolini and Kuhlmann (n 21).

⁹⁰ OECD (n 26).

⁹¹ European Parliament and Council Directive 2003/88/EC of 4 November 2003 concerning certain aspects of the organisation of working time [2003] OJ L299/9.

⁹² European Parliament and Council Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22.

⁹³ Malgieri, Michelutti and Van Hoegaerden (n 7); Matrix Insights, ‘Feasibility Study on EU Level collaboration on forecasting health workforce needs, workforce planning and health workforce trends’ (2012) <http://ec.europa.eu/health/workforce/key_documents/study_2012/index_en.htm> accessed 3 June 2016; WHO, ‘Core Health Indicators in the WHO European Region’ (n 7); OECD (n 25).

⁹⁴ Baeten and Vanhercke (n 5).

⁹⁵ G Dussault and others, ‘Assessing Future Health Workforce Needs’ (Policy Summary prepared for the Belgian EU Presidency Conference, La Hulpe, 9–10 September 2010).

PART 3

SYSTEMS

12. EU Health Law and Policy and the Eurozone crisis

Tomislav Sokol and *Nikola Mijatović**

I. INTRODUCTION

Healthcare represents one of the most important areas of public policy in the world. The economic, social and political choices this area of human activity entails are regularly in the limelight, with many different stakeholders involved in the public debate. The European Union is no exception in this regard. Issues of prolonged lifespan influencing healthcare costs, public versus private governance of healthcare institutions, costs of medicines and access to publicly covered healthcare, just to name a few, are of crucial importance for the future of Europe and its inhabitants.¹

The economic crisis of the Eurozone, which has spilled over to other EU Member States as well, although not caused by the health sector, has affected healthcare systems in many respects. The most important of these is the decrease in healthcare spending in many Member States which have the primary competence to organise and regulate provision of healthcare in the EU.² Of course, such a situation reflects heavily on those aspects of healthcare law and policy where the EU has a role to play, like free movement of healthcare professionals, marketing of medicines and similar.³

This chapter presents the developments in EU health law and policy since the start of the economic crisis, the impact of the latter on the said developments and indicates the future trends concerning that field in the years to come.

First, the chapter provides a brief overview of the instruments of economic governance the EU has at its disposal and their development since the start of the Eurozone crisis. Crucial areas of EU health law, like access to healthcare, free movement of healthcare professionals and regulation of medicines are covered next, along with an analysis of the impact of the crisis in those areas. Finally, possible trends in the years to come will be discussed.

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¹ See, for example, Council, ‘Council conclusions on the economic crisis and healthcare’ [2014] OJ C217/2.

² See Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C326/1 (TFEU), Article 168 and Council Conclusions (n 1).

³ See, on some of these issues, European Parliament and Council Directive 2011/24/EU of 9 March 2011 on the application of patients’ rights in cross-border healthcare [2011] OJ L88/45 (Patients’ Rights Directive).

II. EUROZONE ECONOMIC GOVERNANCE INSTRUMENTS

Limitation of healthcare public expenditure is not a novelty in the framework on coordination of EU Member States' macroeconomic policies. The Stability and Growth Pact facilitating and maintaining the stability of the Economic and Monetary Union is the key instrument in understanding these limitations on public expenditure. The Pact has set thresholds of 3% of GDP concerning government deficit and 60% of GDP concerning public debt. If these thresholds are breached, the Council may initiate an Excessive Deficit Procedure (EDP) which can result in financial sanctions for the Member State in question.⁴

The Eurozone crisis that started in 2008 has put pressure on EU Member States to hand over strong powers to the EU's institutions, concerning the control of national fiscal and economic policies, including national healthcare spending. The strongest control mechanism, involving the European Commission, European Central Bank and International Monetary Fund (Troika) has focused on the countries belonging to the Eurozone. The Eurozone countries, in need of financial assistance from the EU's institutions and the IMF, need to fulfil conditions consisting of reforms in economic and social policies determined by Memorandums of Understanding (MoUs) concluded with those institutions. The Memorandums are not legal instruments of internal EU law, but are based on the intergovernmental European Stability Mechanism established by the Eurozone countries. The European Stability Mechanism has generally assumed the tasks of providing future assistance previously fulfilled by the European Financial Stability Facility and the European Financial Stabilisation Mechanism (which nonetheless still exist). These MoUs represent a strong tool for ensuring compliance of the countries concerned. The European Commission is primarily responsible for monitoring whether the Member States fulfil the conditions set by the MoUs and non-compliance may result in sanctions and strict conditions for future financial assistance.⁵

For all other EU Member States, crucial instruments are set in the framework of the European Semester for economic policy coordination, presented in Figure 12.1 below. Within the European Semester, a 'soft' governance framework concerning Member States' employment and social policies has complemented the coordination of national macroeconomic and fiscal policies based on the Stability and Growth Pact. The Semester starts in November each year with the European Commission's Annual Growth Survey, determining EU priorities for growth and job creation in the year to come. On the basis of Guidelines made by the Council, Member States prepare National Reform Programmes for the coming

⁴ See TFEU, Article 126 and TFEU Protocol 12 on the excessive deficit procedure, along with Council Regulation (EC) 1466/97 of 7 July 1997 on the strengthening of the surveillance of budgetary positions and the surveillance and coordination of economic policies [1997] OJ L209/1 and Council Regulation (EC) 1467/97 of 7 July 1997 on speeding up and clarifying the implementation of the excessive deficit procedure [1997] OJ L209/6.

⁵ See TFEU, Article 136 and Treaty Establishing the European Stability Mechanism between the Kingdom of Belgium, the Federal Republic of Germany, the Republic of Estonia, Ireland, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Italian Republic, the Republic of Cyprus, the Grand Duchy of Luxembourg, Malta, the Kingdom of the Netherlands, the Republic of Austria, the Portuguese Republic, the Republic of Slovenia, the Slovak Republic and the Republic of Finland. See also TFEU, Article 122, European Financial Stability Facility Consolidated Articles of Association and Council Regulation (EU) 407/2010 of 11 May 2010 establishing a European financial stabilisation mechanism [2010] OJ L118/1. According to these rules, the European Financial Stabilisation Mechanism may provide EU financial assistance to all Member States.

year. The latter are reviewed by the Commission which publishes Country Reports for each Member State, analysing national economic and social policies which are then followed by the Council's Country-Specific Recommendations (CSR). Strict procedures for the detection, prevention and correction of macroeconomic imbalances have also been put in place by the EU legislation, ensuring national implementation. All in all, monitoring of Member States' fiscal policies has been strengthened, forcing the countries in question to respect concrete deadlines for sustainably correcting their deficits. Member States which do not implement the recommendations in time may be issued policy warnings that are endorsed by the Council and can finally result in financial sanctions.⁶

⁶ See, for example, Council Regulation (EC) 479/2009 of 25 May 2009 on the application of the Protocol on the excessive deficit procedure annexed to the Treaty establishing the European Community (Codified version) [2009] OJ L145/1; Council Directive 2011/85/EU of 8 November 2011 on requirements for budgetary frameworks of the Member States [2011] OJ L 306/41; European Parliament and Council Regulation (EU) 1173/2011 of 16 November 2011 on the effective enforcement of budgetary surveillance in the euro area [2011] OJ L 306/1; European Parliament and Council Regulation (EU) 1174/2011 of 16 November 2011 on enforcement measures to correct excessive macroeconomic imbalances in the euro area [2011] OJ L306/8; European Parliament and Council Regulation (EU) 1176/2011 of 16 November 2011 on the prevention and correction of macroeconomic imbalances [2011] OJ L306/25; European Parliament and Council Regulation (EU) 472/2013 of 21 May 2013 on the strengthening of economic and budgetary surveillance of Member States in the euro area experiencing or threatened with serious difficulties with respect to their financial stability [2013] OJ L 140/1; and European Parliament and Council Regulation (EU) 473/2013 of 21 May 2013 on common provisions for monitoring and assessing draft budgetary plans and ensuring the correction of excessive deficit of the Member States in the euro area [2013] OJ L 140/11. Additionally, European Structural and Investment Funds (ESIF) rules provide for macroeconomic conditionality, meaning that the European Commission may request review of Member States' programmes if they are not acting sufficiently in accordance with Country-Specific Recommendations. See to this effect European Parliament and Council Regulation (EU) 1303/2013 of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) 1083/2006 [2013] OJ L 347/320. See also R Baeten and B Vanhercke, 'Inside the black box: the EU's economic surveillance of national healthcare systems' (2016) *Comparative European Politics* DOI: 10.1057/cep.2016.10 <<http://link.springer.com/article/10.1057%2Fcep.2016.10>> accessed 2 June 2016.

Only three Member States received Country-Specific Recommendations for reform of their healthcare and/or long-term care systems in 2011, within the European Semester. But by 2014, the number had increased to 20. The recommendations are somewhat more multi-dimensional, mostly focusing on sustainability and cost-effectiveness of national health systems (but sometimes also mentioning access to healthcare), requesting reforms in the most important sectors of these systems.⁸

Such EU policies and instruments have influenced access to healthcare, as one of the most important aspects of health law and policy in Europe. The crucial question here is not so much physical access to medical facilities, which is generally not a huge problem within most of the EU Member States, but rather the bearing of treatment costs. Of course, within this context, a very important role belongs to the national social security healthcare systems. These can be described as statutory systems based on the principle of solidarity, providing protection against (the threat of) a lack of earnings, or against particular costs in case of an occurrence of a recognised social risk. The systems can be further divided according to different criteria.⁹ One of these divisions is between the social health insurance systems and national health services. The former originally covered only economically active persons, and they are financed primarily from earmarked contributions, with the insurer and the provider being separate entities. Today the vast majority of the population is covered also in the European countries using that type of system.¹⁰ The latter generally cover the entire population, are financed via taxation, with healthcare funding and provision being carried out through a single entity.¹¹ An example of the former can be found in various countries, for example some central European ones, while the example of the latter can be found (at least historically) in the UK National Health Service (NHS).

The diversity of national (social) healthcare systems is not limited to the personal scope of application and the formal source of funding. One of the most important aspects which came to the fore through the economic crisis involves the range of healthcare covered. This can be analysed via three dimensions: depth, height and breadth. Depth means the

⁸ See Commission, 'European Semester 2016' (European Commission) <http://ec.europa.eu/europe2020/making-it-happen/country-specific-recommendations/index_en.htm> accessed 16 September 2015 and Council, 'Economic and fiscal policies: Council approves country-specific recommendations' (European Council, 19 June 2015) <<http://www.consilium.europa.eu/hr/press/press-releases/2015/06/19-country-specific-recommendations/>> accessed 16 September 2015. See also F Stamati and R Baeten, 'Varieties of healthcare reform: understanding EU leverage' in D Natali and B Vanhercke (eds), *Social policy in the European Union: state of play 2015* (ETUI 2015) 187.

⁹ For a discussion, see TK Hervey and JV McHale, *European Union Health Law: Themes and Implications* (CUP 2015).

¹⁰ See National Health Service Act 2006 (NHS Act 2006). See also, for example, Croatian Compulsory Health Insurance Act (Official Gazette 80/13 to 137/13) (Zakon o obveznom zdravstvenom osiguranju NN 80/13 do 137/13) and Slovenian Health Care and Health Insurance Act (Official Gazette 9/92 to 47/15) (Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju Ur.I. RS, št. 9/92 do 47/15). See also Croatian Contributions Act (Official Gazette 84/08 to 143/14) (Zakon o doprinosima NN 84/08 do 143/14) and Slovenian Social Security Contributions Act (Official Gazette 5/96 to 26/14) (Zakon o prispevkih za socialno varnost Ur.I. RS, št. 5/96 do 26/14). See also, in the UK for example, Department of Health (UK – England), 'Departmental Report' (2006) 40.

¹¹ See D Pieters, *Social Security: An Introduction to the Basic Principles* (2nd edn, Kluwer Law International 2006) 2–3, 21–22, 89.

number and character of covered health services; height means the extent of the coverage of healthcare costs and breadth means the extent of the covered population.¹²

The economic crisis has generally affected financial aspects of public health systems in the EU¹³ and this has also influenced the above mentioned aspects of social healthcare coverage, mainly the height of the coverage. The development can be illustrated by an example of a Member State particularly hard hit by the crisis, Ireland. In Ireland, the budget of the public health provider the Health Service Executive (HSE) was reduced by €4bn (27%) between 2008 and 2014.¹⁴ This is an enormous amount, both in absolute (the amount of money) and in relative (percentage of the entire public health budget) terms. Of course, reductions in health spending were not limited to Ireland. It can be mentioned for example that, besides Ireland, Bulgaria, Croatia, Estonia, Hungary, Italy, Greece, Latvia, Romania, Portugal and Spain reduced their health budgets between 2007 and 2011. Reductions in terms of per capita healthcare spending between 2007 and 2012 occurred in Ireland (the largest), Portugal, Latvia, Greece and Croatia.¹⁵

Generally, changes in the national healthcare policies which have taken place between 2008 and 2013, influencing, inter alia, the range of healthcare covered, have not been along the lines of differing types of national healthcare systems mentioned at the beginning of this section. They depended on the level of EU influence instead. Where national and supranational decision-making have been entwined the strongest (Greece, Ireland and Portugal), through Memorandums of Understanding, the emphasis was placed on cost-containment and privatisation. In Ireland, for instance, several co-payments have been increased or newly introduced, including an amount of €2.50 which persons who are entitled to the highest range of coverage (having ‘full eligibility’) have to pay for a prescribed medicine. In Greece, a €25 admission fee and an extra €1 payment (in addition to the existing 25% co-payment) for prescriptions were imposed in 2014. Also, the number of publicly provided beds has been reduced by more than 10%, and for-profit financing of hospital infrastructure has been expanded. In countries where this ‘EU leverage’ was moderate, reforms were focused on a ‘changing healthcare mix’. Reforms either shifted control powers from insurance funds towards the State (France, Germany), or the market (Italy and the Netherlands) with some degree of privatisation of service provision. Finally, the countries in which the influence of the EU was weakest, like Lithuania, Sweden and the UK (significantly not belonging to the Eurozone, at least at the time), reforms were more focused on systemic reorganisation, driven by domestic policy considerations.¹⁶ Therefore, where the influence of

¹² See, for example, S Smith, ‘The Irish ‘health basket’: a basket case?’ (2010) 11 *European Journal of Health Economics* 343, 344.

¹³ See, for example, Council Conclusions (n 1).

¹⁴ See Health Service Executive, ‘November 2014 National Performance Assurance Report’ (2014) 51.

¹⁵ See P Mladovsky and others, ‘Health policy responses to the financial crisis in Europe’ (Policy Summary, WHO 2012) 15 and Commission, ‘Investing in Health’ (Staff Working Document) SWD (2013) 43 final, 3. See also M Jowett, S Thomson and T Evetovits, ‘Changes to public funding for the health system’ in S Thomson and others (eds), *Economic Crisis, Health Systems and Health in Europe Impact and Implications for Policy* (Open University Press 2015) 52.

¹⁶ See Stamati and Baeten (n 8) 201–210. On Ireland, see Health Act 1970, s 59 (1A–C). Another factor which needs to be taken into account is that the number of persons having full eligibility has increased from 30% to around 43% of the Irish population between 2007 and 2013. If one delves further into the past, he/she can see a 70% increase since 2005. This is important because one’s eligibility is based on a means test, meaning that there has been a significant increase in the number of persons who (in the eyes of the State) are unable to pay for their own healthcare without undue hardship. See Health Act 1970 s 45. See also, on this issue, F Paolucci, *Health*

the EU on national healthcare policies was significant, the focus was placed on fiscal consolidation, instead of ensuring access to healthcare.

How has the EU addressed these developments through its health law and policy instruments, as opposed to those of economic governance? Obviously, the overall context and primary focus on fiscal consolidation do not sit well with ensuring access to healthcare within the EU. Related to this, the Commission has identified the three biggest problems in terms of access to healthcare within the EU: waiting time, travelling distance and cost sharing, two of which are directly related to the ongoing crisis and the fiscal pressure on Member States' healthcare systems. The Commission has also acknowledged that there is no common EU methodology of measuring and monitoring access to healthcare.¹⁷ Still, it has emphasised three areas which can contribute to increasing the accessibility of healthcare. Apart from cost-effective use of medicines and the EU health workforce, which will be analysed in the following sections discussing free movement of healthcare professionals and regulation of medicines, the optimal implementation of the Patients' Rights Directive has been emphasised:

Directive 2011/24 broadens patient choice in healthcare and helps them avoid undue delay in receiving the treatments they need. The Directive will improve transparency by requiring the Member States to set up national contact points to provide information to citizens, including on their rights and entitlements, patient safety and quality of care standards. It also calls for a better understanding of baskets of healthcare. Member States should ensure that all the provisions of the Directive are properly implemented. The Commission will closely monitor how the concept of undue delay is applied in Member States.

Reference networks will promote cooperation among highly specialised providers across Member States, allowing patients with low prevalence, complex or rare diseases to access high quality care.

The Commission intends to launch calls for expressions of interest in becoming European reference network members, who could also provide training for health professionals and support in defining common quality assurance requirements.¹⁸

The above extract shows the limitations of EU health law and policy mechanisms. On one side, there are relatively strong regulatory tools described in the previous section to force the Member States to reduce their budgetary deficits according to (inter alia) TFEU Articles 121, 126 and 136, as well as EU secondary legislation. As has also been observed in the literature, the EU has exerted influence on national healthcare system reforms either directly – through the Memorandums of Understanding and Country-Specific Recommendations – or indirectly, via hardening public budget constraints within the Eurozone. On the other side, the consequences of these cuts are addressed via 'developing recommendations, common tools, indicators and guidelines' to support Member States in their actions.¹⁹ All this means that the

Care Financing and Insurance (Springer 2011) 35 and A Nolan and B Nolan, 'Eligibility for free GP care, "need" and GP visiting in Ireland' (2008) 9(2) *European Journal of Health Economics* 157. In Greece, the overall government deficit has reduced 3.6% in 2014, from double-digit figures in the previous years. See EUROSTAT, 'General government deficit (-) and surplus (+) – annual data' (EUROSTAT) <<http://ec.europa.eu/eurostat/tgm/table.do?tab=table&plugin=1&language=en&pcode=teina200>> accessed 19 March 2016.

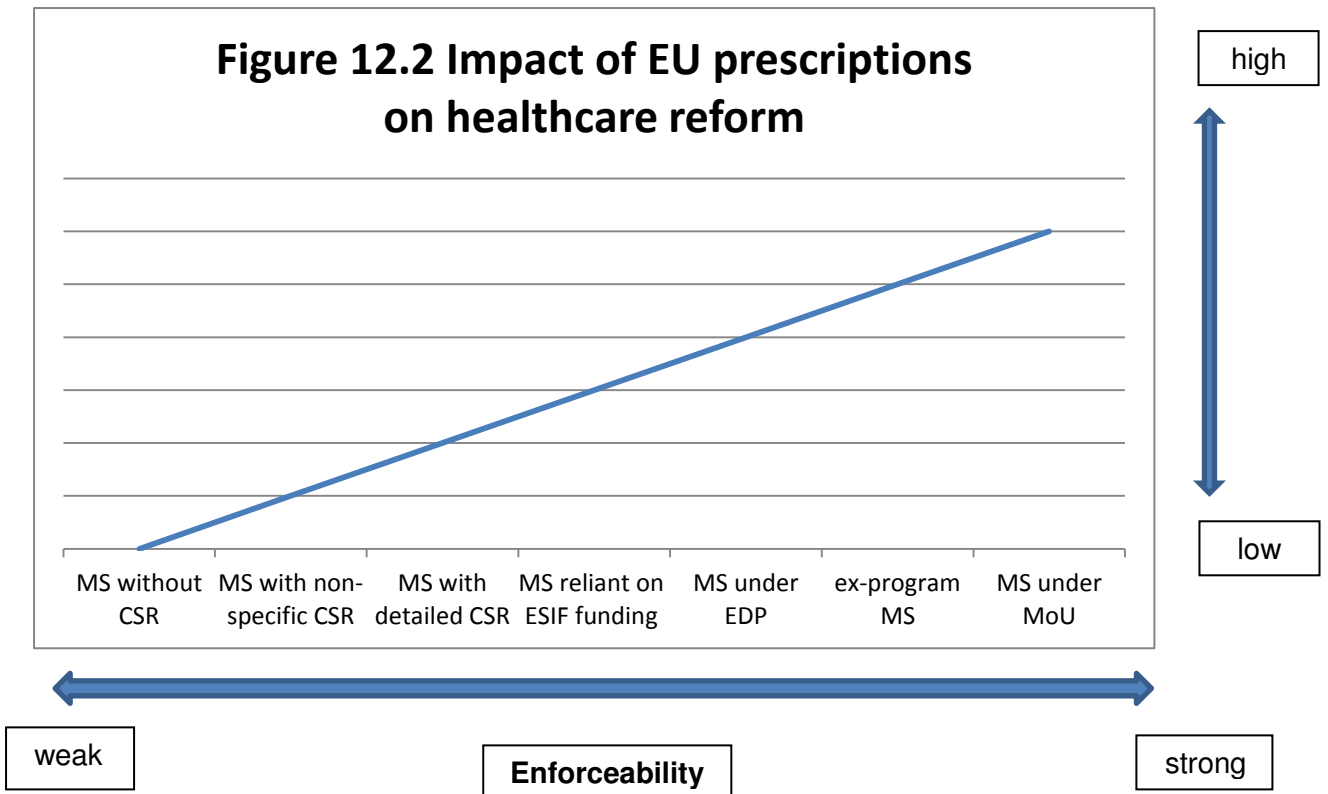
¹⁷ See Commission, 'On effective, accessible and resilient health systems' (Communication) COM (2014) 215 final, 8.

¹⁸ *ibid* 14.

¹⁹ See also TFEU, Protocol 12 on the excessive deficit procedure. For the mentioned literature, see Stamati and Baeten (n 7).

instruments of EU economic governance (especially those concerning the Eurozone) have had the biggest practical impact on Member States' healthcare systems. The situation can be understood through Figure 12.2 below.

Figure 12.2 The relationship between EU economic governance and health reform



Source: Baeten and Vanhercke (n 6) 26.

Additionally, despite the best intentions, it remains questionable how the greater efficiency of health systems that the Commission promotes, and which Member States may achieve (for example, through better procurement, generic substitution of medicines, development of e-health and better planning) can offset budgetary cuts in the long run. This is especially questionable in the countries hardest hit by the crisis. Even the Commission itself recognises that a number of factors (including population ageing) will result in public expenditure on healthcare and long-term care generally increasing by one-third by 2060. Still, the relationship between healthcare expenditure and health outcomes is not linear, with the same amount of per capita expenditure being associated with very different health outcomes even after taking into account the specificities of different countries. Future developments are thus hard to predict.²⁰

All in all, the issue of ensuring access to medical care is very complex, and may be seen as exacerbated by the crisis, at least in some Member States. Unfortunately, the current legal framework of the EU does not seem to be best equipped to answer the challenges.

²⁰ See Commission, 'The 2012 Ageing Report: Economic and budgetary projections for the EU27 Member States (2010–2060)' (Joint Report 2012) 157–194 and Commission SWD (n 15). See also Jowett, Thomson and Evetovits (n 155) 169.

IV. FREE MOVEMENT OF HEALTHCARE PROFESSIONALS

As noted in the preceding sections, EU economic governance instruments have emphasised fiscal consolidation of the Member States. A question emerges of whether this emphasis has influenced the mobility of healthcare professionals between different Member States.

Before describing migration patterns in more detail, another significant aspect of the EU legal framework facilitating them needs to be investigated. These are free movement rules which influence possibilities of healthcare providers to establish themselves in a Member State other than that of which they are a national, or in which they are medically qualified. A significant case-law on this issue concerns TFEU Article 49, according to which restrictions on the freedom of establishment of nationals of a Member State in the territory of another Member State are prohibited, which is relevant for self-employed healthcare professionals. The notion of ‘restrictions on the freedom of establishment’ may include both national measures the wording of which discriminates between providers on the basis of nationality, and those which do not. For example, a national rule which allows only pharmacists to operate pharmacies, and denies other economic operators access to this self-employed activity in the Member State concerned, is a restriction upon the freedom of establishment.²¹ Of course, the national measures which restrict the freedom of establishment may be justified by reasons of general interest, as is the case with the other freedoms like the freedom to receive healthcare services.²²

Apart from EU primary law, freedom of movement of healthcare professionals is protected by EU secondary legislation on the recognition of professional qualifications, enacted to facilitate free movement of persons, services and establishment within the EU. This Professional Qualifications Directive has been generally well implemented by the Member States.²³

²¹ See Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and others* (Doc Morris) ECLI:EU:C:2009:316, [2009] ECR I-4171; On national criteria for opening new pharmacies, see Joined Cases C-570/07 and 571/07 *Blanco Pérez and Chao Gómez* ECLI:EU:C:2010:300, [2010] ECR I-04629. As regards the freedom of establishment, it is important to note that the CJEU took a different approach within the context of applicability of internal market rules to national social security systems, than was the case with respect to free movement services. See to that effect Case C-70/95 *Sodemare SA and others v Regione Lombardia* ECLI:EU:C:1997:301, [1997] ECR I-3395 paras 26-35.

²² For another example see Case C-169/07 *Hartlauer* ECLI:EU:C:2009:141, [2009] ECR I-1721 paras 37–40. Apart from the restrictions provided by the Treaty, the CJEU recognises other reasons of general interest the Member States can invoke in order to justify national rules that hinder freedom of establishment (in cases where there is no discrimination on grounds of nationality). See to that effect Doc Morris (n 211) paras 26–61, *Hartlauer* (n 22) paras 45–72 and *Blanco Pérez* (n 211) paras 61–114. See on these issues, for example, L Hancher and W Sauter, ‘One Step Beyond? From *Sodemare* to *Docmorris*: The EU’s Freedom of Establishment Case Law Concerning Healthcare’ (2010) 47 *Common Market Law Review* 117.

²³ For further discussion, see Chapter 5 in this book. See European Parliament and Council Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22 (Professional Qualifications Directive). This Directive has also been extensively analysed in the literature. See, for example, V Costigliola, ‘Mobility of medical doctors in cross-border healthcare’ (2011) 2 *EPMA Journal* 333; M Peeters, ‘Free Movement of Medical Doctors: The new Directive 2005/36/EC on the Recognition of Professional Qualifications’ (2005) 11 *European Journal of Health Law* 373 and M Peeters, M McKee and S Merkur, ‘EU law and health professionals’ in E Mossialos, G Permanand, R Baeten and TK Hervey (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010).

EU policies of cost containment, combined with the right to free movement protected by EU law, have had an impact on the mobility of healthcare professionals in the EU. As the European Commission already stated in 2012, reduction in public expenditure is strongly affecting the recruitment and retention of professionals, like nurses, within national healthcare systems. A significant pattern of healthcare professional outflows from certain Member States has been observed. These are countries hardest hit by the spending cuts, along with corresponding worsening of working conditions, lower wages and difficulties in finding employment, resulting partly from the EU law and policy instruments described in the previous two sections.²⁴

If we look for some particular examples and patterns concerning countries subjected to the fiscal consolidation imposed by the EU, one of them may include Greece. The number of Greek doctors in Germany grew by 50% during the period 2010–2014. Also, analyses covering Ireland, Italy, Portugal and Spain which have been conducted across three time points, covering the period before and during the impact of the crisis, have shown a variable change in the different Member States but real reductions in the number of physicians in Portugal, as well as nurses in Italy and Ireland. This is not surprising due to healthcare being labour-intensive whereby the workforce is a major cost and staffing reductions can reduce these costs within the periods of reduced health spending (like the one witnessed in Ireland subjected to fiscal consolidation via Memorandum of Understanding). As noted in the literature, this can be achieved *inter alia* by direct reductions of personnel, by changing skill-mix to a less costly one, by reducing pay and conditions of employment and by reducing pension entitlements, as has been observed in different EU Member States.²⁵

Increased outflows of healthcare professionals can have negative consequences in terms of efficiency, since funds for training in source countries are redistributed to destination countries and planning the workforce becomes more problematic. In the destination Member States, arrivals from the other Member States may require time and resources to fully integrate into the system, while source Member States may lose their best personnel, resulting in a greater workload for those who remain and imbalances in areas already lacking relevant expertise. In terms of equity, the differences between the Member States may be strengthened when health professionals exit the resource-strained systems to work in more advantageous Member States. Mobility also favours those professionals who are more able to radically change their lives, such as young physicians without families.²⁶

How has the European Commission responded to these migration patterns and their influence on health workforce imbalances? Concerning the EU health workforce, the Commission has stated:

Health workforce planning efforts should develop sustainable solutions at EU level to ensure sufficient numbers of adequately trained health professionals with the right skills to provide care to all who need it. To avoid future shortages and skills mismatches, the Commission intends to work

²⁴ See Commission, ‘An Action Plan for the EU Health Workforce’ (Staff Working Paper) SWD (2012) 93 final, 5. See also IA Glinos and others, ‘How can countries address the efficiency and equity implications of health professional mobility in Europe? Adapting Policies in the Context of the WHO Code and EU Freedom of Movement’ (Policy Brief, WHO 2015) 9.

²⁵ See G Dussault and J Buchan, ‘The economic crisis in the EU: impact on health workforce mobility’ in J Buchan and others (eds), *Health Professional Mobility in a Changing Europe: New dynamics, mobile individuals and diverse responses* (WHO 2014) 41–42. See also Glinos and others (n 244) 9.

²⁶ See Glinos and others (n 244) 5.

further with Member States on developing recommendations, common tools, indicators and guidelines, strengthening EU support for Member States' planning.²⁷

This extract shows that the issue of imbalances concerning healthcare professionals in certain parts of the EU has been recognised by the European Commission. Unfortunately, the instruments it has at its disposal to tackle the problem are significantly limited, as has also been observed in the case of access to healthcare.

All in all, it can be seen that the free movement of health professionals, protected by EU primary and secondary law, may result in certain imbalances within the healthcare systems of the EU. These fears have been exacerbated with the onset of the economic crisis, which has resulted in adverse effects for those healthcare systems hit hardest by the economic crisis and the subsequent spending cuts triggered to a large extent by the EU itself.

V. REGULATION OF MEDICINES

European Union instruments of economic conditionality imposed upon certain Member States have had an important impact on regulation of medicines as well. Control of the pricing of medicines is an important tool for achieving sustainability of national public (healthcare) spending. Lowering of prices, for example through the increase of generic medicine usage and reference pricing, has been especially important in that regard and as such explicitly mentioned in the Memorandums of Understanding addressed to individual Member States.²⁸

It is impossible to explain the Member States' responses to this context without briefly analysing the EU legal framework concerning medicines. As noted in the previous chapters, regulation of medicines in the EU is divided between the EU and the Member States. The legal framework on the placing of medicinal products on the market of the EU is set by the EU. This includes also supervision of products after putting them on the market, the manufacturing, wholesaling, advertising of medicinal products for human use, clinical trials and similar. The European Medicines Agency evaluates medicines according to safety standards with the final approval granted by the European Commission.²⁹ On the other hand,

²⁷ See Commission, COM (2014) 215 final (n 177) 14.

²⁸ See, for example, Department of Finance (Ireland), 'Memorandum of Understanding On Specific Economic Policy Conditionality (Eighth Update)' (2013) 4, 9, concerning European Financial Stabilisation Mechanism. There are interesting interactions between the efficiencies pursued by economic governance rules, and those pursued by EU competition law and policy. See to this effect the chapter on EU competition law and health systems.

²⁹ See, on these issues, European Parliament and Council Regulation (EC) 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1. See also European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67, European Parliament and Council Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [2001] OJ L121/34 and European Parliament and Council Regulation (EU) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC [2014] OJ L158/1. See also, for example, J-J Borg, G Aislaitner, M Pirozynski and S Mifsud, 'Strengthening and Rationalizing Pharmacovigilance in the EU: Where is Europe Heading to?' (2011) 34 Drug Safety 187; G Permanand, E

putting healthcare products within the ambit of social security coverage still primarily belongs to the Member States' autonomy, in line with TFEU Article 168, and national social security spending covers the bulk of cost of medicines in the EU.³⁰ The only EU-level limitations on this national competence are that decisions on (not) including certain medicinal products in the national coverage must contain reasoning based on verifiable objective criteria, avoiding discrimination against products from other Member States. Also, these decisions must be subject to judicial control.³¹

A related issue concerns pricing and, within the context of the crisis, external reference pricing mechanisms used by several Member States are especially relevant. This means that official prices of medicines in certain Member States are used by other Member States in determining their own official price. The economic crisis has affected this issue in a way that some countries have taken measures that have resulted in significant drops in the pricing of medicines. As stated by the Commission, these developments have been a cause of concern, since reference prices affected by these national measures may influence the price level in other Member States or in third countries.³² The consequences resulted in significant discussions between public authorities and the relevant stakeholders. According to the European Commission:

Cost-effective use of medicines

The EU needs a competitive pharmaceutical industry. With this background, Member States and the Commission should reflect further on how to reconcile the policy objectives of ensuring accessible healthcare for all EU citizens with the need for cost containment. Consideration should be given to improved cooperation on building mechanisms for increased transparency and better coordination to minimise any unintended effects that current national pricing systems may have in terms of accessibility throughout the EU.³³

This extract from a Commission Communication shows the good intentions of the Commission to address important but also conflicting issues of ensuring accessible healthcare for EU citizens with the need for cost containment (and also a competitive pharmaceutical industry). The EU pharmaceutical industry remains the world leader in the trade of medicines, traditionally being the biggest exporter of medicinal products in the world, accounting for more than a quarter of Europe's high technology exports. On the other hand, the worldwide competition from emerging countries is growing³⁴ and it is questionable whether the EU has

Mossialos and M McKee, 'Regulating medicines in Europe: the European Medicines Agency, marketing authorisation, transparency and pharmacovigilance' (2006) 6 *Clinical Medicine* 87 and J Regnstrom and others, 'Factors associated with success of market authorisation applications for pharmaceutical drugs submitted to the European Medicines Agency' (2010) 66 *European Journal of Clinical Pharmacology* 39.

³⁰ See, for example, S Vogler, N Zimmermann, C Leopold, K de Joncheere, 'Pharmaceutical policies in European countries in response to the global financial crisis' (2011) 4 *Southern Med Review* 69, 70.

³¹ See Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L40/8. See also, for example, Case C-424/99 *Commission v Austria* ECLI:EU:C:2001:642, [2001] ECR I-9285; Case C-229/00 *Commission v Finland* ECLI:EU:C:2003:334, [2003] ECR I-5727; Case C-691/13 *Les Laboratoires Servier* ECLI:EU:C:2015:121 and Joined Cases C-271/14 and C-273/14 *LFB and others* ECLI:EU:C:2015:237.

³² See Commission, 'Pharmaceutical Industry: A Strategic Sector for the European Economy' (Staff Working Document) SWD (2014) 216 final/2, 10.

³³ See Commission, COM (2014) 215 final (n 177) 14.

³⁴ See Commission, SWD (2014) 216 final/2 (n 322) 12.

enough tools to answer these challenges. Deficiency of these tools is visible from the extract itself, which mentions mechanisms like improved cooperation and better coordination, which belong primarily to ‘soft law’ with all its limitations. Hard law mechanisms of binding common EU rules are still mostly present in the area of (facilitating) free movement, like the recognition of medical prescriptions issued in another Member State, or determining their minimum contents. Thus, in terms of policy responses to the crisis, Member States have had the crucial role to play, albeit some of them having been pressured by the EU’s economic governance in doing so. Important steps undertaken by several Member States have included lower prices and a focus on generic substitution of branded medicines, enhancing the efficiency of their health systems.³⁵

Generally, the weaknesses of the EU legal mechanisms are becoming especially clear within the context of an extremely diverse EU, where different socioeconomic contexts of individual Member States make common policies hard (or impossible) to develop. It has to be stated, however, that the problem may not be as acute concerning the pricing itself, since most Member States use the external reference pricing,³⁶ but is more visible in other areas. The latter will be elaborated below, within the context of a discussion of future prospects and scenarios concerning the development of EU health law and policy.

VI. DIRECTION OF TRAVEL

Previous analysis has shown that the economic crisis has had an impact upon different aspects of EU health law and policy. The impact is impossible to understand without investigating different effects of the crisis on different Member States, particularly in the area of access to (socially covered) medical care. Reductions in health budgets in the countries hit hardest by the crisis, like Ireland, have adversely affected patients’ possibilities to access publicly covered healthcare, inter alia through increases in cost sharing. Significant outflows of health professionals from certain Member States may also result in adverse effects for patients’ access to quality healthcare.

Apart from adopting different budgetary possibilities to provide the best possible healthcare, Member States also diverge in terms of legal ways of defining the depth of their public health coverage. These vary from broad duties of promoting a comprehensive health service,³⁷ to defining broad categories of public coverage³⁸ and even explicitly excluding certain types of treatment from that coverage.³⁹ Within such a diverse range of Member States’ healthcare systems, the challenges the EU is facing seem hardly surmountable.

³⁵ See Patients’ Rights Directive (n 3) Article 11 and Commission Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another Member State [2012] OJ L356/68. See also S Thomson and others, ‘The impact of the crisis on health systems and health: lessons for policy’ in Thomson and others (n 15) 169.

³⁶ See S Vogler and others, ‘Comparing pharmaceutical pricing and reimbursement policies in Croatia to the European Union Member States’ (2011) 52 *Croatian Medical Journal* 183.

³⁷ See NHS Act 2006 (n **Error! Bookmark not defined.**), s 1.

³⁸ See Croatian Compulsory Health Insurance Act (n **Error! Bookmark not defined.**) Article 19.

³⁹ See Slovenian Compulsory Health Insurance Rules (Official Gazette 79/94 to 85/14) (*Pravila obveznega zdravstvenega zavarovanja* Ur.I. RS, št. 79/94 do 85/14) Article 25.

The first step in determining the potential for future EU action in the field of health consists of setting the objectives it should try to accomplish. A good starting point is found in the Council Conclusions on Common values and principles the health systems of the EU share. According to this document, overarching values of universality, access to good quality care, equity and solidarity are shared by all the Member States, and, logically, also the EU itself. Universality means that no person is forbidden access to healthcare: solidarity is linked to the financial context of national health systems and the need to ensure accessibility to all and equity means equal access according to need, regardless of ethnicity, gender, age, social status or ability to pay.⁴⁰ On the other hand, the EU focus on the free market, visible, for example, through the above-mentioned reliance on free movement rules influencing healthcare, as well as on fiscal consolidation, poses deep questions on the real priorities of the EU in the field. If one tries to predict and evaluate possible scenarios for future development within this context, focusing on the economic aspects influencing European healthcare systems, three potential developments may come to mind.

First, it could be that the EU initiates strong policies to overcome the diversity of national health systems described above, and to achieve as much as possible equal access to healthcare for all EU citizens, irrespective of the country they live in, by way of harmonisation of healthcare provision (in the three dimension mentioned above) across the EU. This would constitute a strong articulation of one of the Council's 'values and principles' in EU health systems, that of equity. Legally, though, this would probably have to be achieved through an amendment to the TFEU, since unanimity still applies to social security (including healthcare) and obviously, it is very hard to come to unanimous decisions in a EU consisting of 28 Member States (this can be observed through the example of the time it took for the adoption of social security coordination Regulation 883/2004 and its final entry into force).⁴¹ Still, even if the Treaty were amended accordingly (and there are no signs of such a course of events), a purely regulatory role is simply not enough in a EU in which the Netherlands and Austria, for example, spend five times more per capita on healthcare than Romania, and different countries have faced the economic crisis in different ways, as shown in the previous sections. In other words, it is very hard to imagine some level of regulatory harmonisation of healthcare systems without first harmonising their financial capabilities.⁴²

So the first scenario necessarily entails strong financial input from the EU in order to tackle diversity of national health systems in Europe. Significant EU-level redistributive actions would be necessary. Does this seem realistic? It is not really realistic in a EU in which the Health Programme 2014–2020 has around €450 million at its disposal. This is a feeble amount compared even to health spending of smaller Member States such as Croatia and Slovenia, without analysing larger countries like Poland, Romania and similar.⁴³ The first scenario, therefore, remains extremely unlikely.

⁴⁰ See Council, 'Council Conclusions on Common values and principles in European Union health systems' [2006] OJ C146/1.

⁴¹ See TFEU, Article 21, 48, 153. See also R Cornelissen, 'How Difficult is it to Change EU Social Security Coordination Legislation?' (2012) 67 *Pravnik* 57, 60–61.

⁴² See OECD, 'Health at a Glance: EUROPE 2014, How does Norway compare?' (2014).

⁴³ See European Parliament and Council Regulation (EU) 282/2014 of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014–2020) and repealing Decision 1350/2007/EC [2014] OJ L86/1. See also Health Insurance Institute of Croatia, 'Izvešće o poslovanju

Since the EU budget itself does not leave much room for significant increase, a second scenario, according to which the situation stays the same, with concrete EU action mainly limited to ensuring fiscal consolidation, facilitating free movement and using ‘soft law’ mechanisms of promoting Member States’ cooperation in health matters, seems probable. Significant new mechanisms for soft law cooperation have been set up by the Patients’ Rights Directive. One area (which could be mentioned as an example) concerns cooperation and exchange of information between different national institutions on health technology assessment. Here, a health technology assessment network has been set up, with participating institutions from all Member States.⁴⁴ This kind of cooperation could result in a stronger convergence of the methods for defining the depth of coverage of different Member States. Such convergence may, for example, help Member States compare levels of health coverage in other Member States with their own and thus assist in planning their costs accordingly. A similar statement could be made regarding methods for calculating costs of medical treatments. Also, cross-border cooperation between healthcare providers through European reference networks may contribute to maximising the cost-effective use of resources by concentrating them where it is appropriate.⁴⁵

Finally, there is the third scenario which could be imagined. According to this, the EU redistributive mechanisms become even weaker than they are now, and the EU reverts to being not much more than a free trade zone with an insignificant role in other areas of human activity. This scenario is already advocated by governments of some Member States.⁴⁶ Under this scenario, some adverse impact of free movement on certain countries (like the outflow of healthcare professionals) might be maintained without the redistributive mechanisms offsetting such development. On the other hand, some level of common policy may be maintained through intergovernmental cooperation. Some of the existing mechanisms already depend on Member States’ voluntary participation, and there is no rational reason why these would not be maintained outside of the current EU legal and institutional framework. An important question is whether the current role of the Commission (which would probably diminish in this scenario) in facilitating this cooperation is indispensable. Also, the overall political climate in a (partly) disintegrating EU, as presumed in this situation, may prove to be an obstacle to strong cooperation between the national healthcare systems. Therefore, it is hard to predict how the individual EU health systems could develop in the last scenario, but in that case it would be hard to speak of a real EU health law and policy anyway.

Hrvatskog zavoda za zdravstveno osiguranje za 2014’ (2015) and Health Insurance Institute of Slovenia, ‘Poslovno poročilo za leto 2014’ (2015).

⁴⁴ See Patients’ Rights Directive, Article 15; EU Health Technology Assessment Network (HTA), ‘Strategy for EU Cooperation on Health Technology Assessment’ (2014); and Commission ‘One trillion euro to invest in Europe’s future – the EU’s budget framework 2014–2020’ (European Commission, 19 November 2013) <http://europa.eu/rapid/press-release_IP-13-1096_en.htm> accessed 16 June 2016. See also, for example, TK Hervey, ‘Cooperation Between Health Care Authorities in the Proposed Directive on Patients’ Rights in Cross-Border Healthcare’ in JW van de Gronden and others (eds), *Health Care and EU Law* (TMC Asser Press 2011).

⁴⁵ See Patients’ Rights Directive, Article 12.

⁴⁶ See, as a possible version of this scenario, Conservative Party, ‘The Conservative Party Manifesto 2015’ (2015) 72–73.

VII. CONCLUSION

The economic crisis has had an impact on health law and policy in the EU. This can be observed through areas of primary EU interest in the healthcare sector, namely free movement of healthcare professionals and regulation of medicines, but also access to healthcare. This impact has been visible through the increase in cost sharing and privatisation of parts of healthcare provision in Member States subjected to the EU instruments of economic governance, outflow of healthcare professionals from the States hit hardest by the crisis and efforts to reduce prices of medicines in various Member States.

It is impossible to understand EU health law and policy within the context of the crisis without analysing the problems national (public) healthcare systems are facing in trying to ensure access to medical treatments for their population. The economic crisis has generally affected their capabilities of providing social healthcare coverage to patients, especially in Member States under EU fiscal control. The EU has addressed these issues, but that reaction has only stressed the limited mechanisms the EU has at its disposal to influence the level of health protection within different Member States, when compared to mechanisms of imposing fiscal consolidation upon the countries concerned.

Out of the three scenarios of future development, the first one, consisting of stronger integration, seems the least likely. A prognosis on which of the second two (status quo or disintegration) will prevail is hard to make, meaning that the future remains uncertain, to say the least.

PART 4

PUBLIC HEALTH

15. EU public health law and policy – on the rocks? A few sobering thoughts on the growing EU alcohol problem

Oliver Bartlett and Amandine Garde

I. INTRODUCTION

The consumption of alcoholic beverages has been an important part of European culture for centuries.¹ Alcoholic beverages are important commodities that are widely traded across frontiers.² Alcohol is, however, a toxic substance whose excessive consumption is one of the four leading risk factors for the development of non-communicable diseases (NCDs),³ which account for around 86% of deaths and 77% of the disease burden in Europe.⁴

The prevention of alcohol-related harm and NCDs is complex, not least because multiple factors influence alcohol consumption and various policy tools of differing effectiveness are available to address them.⁵ This chapter analyses the issues that this complexity poses for both Member States and the EU. For Member States this comprises balancing the global commitments they have made to reduce alcohol-related harm as members of the World Health Assembly, while respecting their obligations under the EU Treaties to protect the free movement of goods. For the EU this comprises fulfilling their own Treaty obligations – supporting the Member States in developing their public health policies and alleviating cross-border health problems, while respecting the principles of conferred powers, subsidiarity and proportionality.

We will begin by analysing the effect of EU law on the adoption of alcohol control measures by Member States, first placing the adoption of these measures in their international public health context, then discussing the way in which the Court of Justice of the European Union (CJEU) has assessed the compatibility of these measures with Articles 34 and 36 TFEU on the free movement of goods. We will argue that the CJEU's analysis has not fully captured the complexity of alcohol control, nor the fact that Member States must balance trade and public health interests in light of the international commitments they have made, and that this potentially threatens the multisectoral, evidence-based approach that all Member

¹ P Anderson and B Baumberg, 'Alcohol in Europe: A public health perspective' (Report for the European Commission, 2006); R Room and K Makela, 'Typologies of the cultural position of drinking' (2000) 61(3) *Journal of Studies on Alcohol* 475; T Babor and others, *Alcohol: No Ordinary Commodity* (2nd edn, OUP 2010).

² Anderson and Baumberg (n 1). See the figures on the quantity of beer, wine and spirits exported each year at Market Analysis and Research, International Trade Centre, 'Home & Search' (Trade Map) <<http://www.trademap.org/Index.aspx>> accessed 7 July 2016.

³ WHO Europe, *Status Report on Alcohol and Health in 35 European Countries 2013* (WHO 2013); P Anderson, L Møller and G Galea (eds), *Alcohol in the European Union: consumption, harm and policy approaches* (WHO 2012).

⁴ WHO Europe, *Action Plan for Implementation of the European Strategy for the Prevention and Control of Noncommunicable Diseases 2012–2016* (WHO 2012) 1.

⁵ See A Alemanno and A Garde, 'The Emergence of an EU Lifestyle Policy: The case of Alcohol, Tobacco and Unhealthy Diets' (2013) 50(6) *Common Market Law Review* 1745.

States have committed to. We will then analyse the direct contribution of EU law to preventing alcohol-related harm, examining key EU legislative and policy measures. We will conclude that the EU has failed to use evidence effectively to discharge its duty to ensure a high level of public health protection in all EU policies. Ultimately, we argue that if the EU does not seize the opportunities that the EU Treaties offer, Member States will continue to face problems in negotiating the dual nature of alcoholic beverages as they seek to find effective solutions to an inherently complex issue.

II. EU JUDICIAL SCRUTINY OF NATIONAL ALCOHOL CONTROL MEASURES

The Court's case law assessing the compatibility of national laws with EU free movement Treaty provisions (II.i) must first be contextualised (II.ii).

II.i The International Public Health Context for Member State Alcohol Control

All EU Member States are parties to the UN Political Declaration of September 2011 on the prevention and control of non-communicable diseases.⁶ They have all also committed to the WHO Global strategy to reduce the harmful use of alcohol⁷ and the WHO Global Action Plan on the Prevention and Control of NCDs for 2013–2020.⁸ Furthermore, within the WHO European Region, the Member States have committed to a European Action Plan to reduce the harmful use of alcohol.⁹

All these strategic documents recognise the severity of alcohol-related harm. The Political Declaration states plainly that NCDs are 'one of the major challenges for development in the twenty-first century'.¹⁰ According to the WHO Global strategy, harmful use of alcohol alone accounts for 3.8% of global deaths and 4.5% of the global disease burden.¹¹ The burden of alcohol-related harm is especially pressing in Europe, which has the highest levels of alcohol consumption and thus the highest levels of alcohol-related harm in the world.¹² In response to the critical need to address alcohol-related harm, WHO members have committed to evidence-based action on alcohol control, recognising that 'countries that are most active in implementing evidence-based and cost effective alcohol policies and programmes will profit from substantial gains in health and well-being'.¹³

There is international recognition however that, despite the available evidence, responses to alcohol-related harm are currently insufficient at both global and European level. According to the Global strategy, 'policy responses are often fragmented and do not always

⁶ UNGA, 'Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases', UNGA 66th Session (16 September 2011) UN Doc A/66/L.1.

⁷ WHO, 'Global strategy to reduce the harmful use of alcohol' Sixty-third World Health Assembly (May 2010) Resolution WHA63.13.

⁸ WHO, 'Global Action Plan on the Prevention and Control of NCDs for 2013–2020' Sixty-sixth World Health Assembly (May 2013) Resolution WHA66.10.

⁹ WHO Europe, European Action Plan to Reduce the Harmful Use of Alcohol 2012–2020 (WHO 2012).

¹⁰ UNGA (n 6) para 1.

¹¹ WHO, Global strategy to reduce the harmful use of alcohol (WHO 2010) 5.

¹² WHO Europe (n 9) v.

¹³ *ibid* 4.

correspond to the magnitude of the impact on health'.¹⁴ The European action plan more explicitly recognises that 'alcohol policies still do not reflect the gravity of the health, social and economic harm resulting from the harmful use of alcohol'.¹⁵ In particular, the Global strategy emphasises that addressing the 'multifaceted determinants of alcohol-related harm'¹⁶ requires 'comprehensive action across numerous sectors'.¹⁷ The European action plan similarly encourages 'coherence and "joined-up" action'.¹⁸

Accordingly, the Global alcohol strategy provides 'a portfolio of policy options and interventions that should be considered ... as integral parts of national policy'.¹⁹ These options are organised into 10 action areas, which broadly cover leadership, research, treatment and prevention. The action areas relating to prevention focus on a range of legal interventions, which are also recommended by the European action plan. First, 'the implementation of even small reductions in the availability of alcohol can bring health gain[s]',²⁰ so Member States are encouraged to strengthen laws on alcohol outlet density and maintain government retail monopolies where they exist.²¹ They are furthermore encouraged to set minimum purchase ages at 18 years and develop strong systems for licensing the sale of alcohol. Second, Member States should 'have systems in place to prevent inappropriate and irresponsible alcohol advertising and marketing that targets children and young people',²² and are urged to consider the following options: regulating the content of advertising; regulating sponsorship by alcohol brands; regulating alcohol marketing in new media; and restricting or banning promotions that target children. The European action plan specifically notes that supranational action is needed with respect to commercial communications that cross borders.²³ Member States are reminded that 'action in drinking environments is also fundamentally important',²⁴ and that 'labelling should be introduced like that used for other foodstuffs ... on the content and composition of the product for the protection of [consumer] health and interests'.²⁵ Finally, 'of all alcohol policy measures, the evidence is strongest for the impact of alcohol prices as an incentive to reduce heavy drinking occasions and regular harmful drinking'.²⁶ States are encouraged to both increase alcohol taxation and consider imposing minimum prices for alcohol.

States are urged to take primary responsibility for adopting as broad a range of the above measures as possible, but they are not expected to do so unaided. The European Action Plan therefore declares that 'international frameworks should enable, rather than hinder, individual countries to be bold and innovative in taking evidence-based approaches to reducing the harmful use of alcohol'.²⁷ Although such bold pursuit of public health interests must be balanced against other competing policy interests, such as free trade, the Global Strategy notes that free trade agreements recognise the right of countries to adopt justifiable,

¹⁴ WHO (n 11) 6.

¹⁵ WHO Europe (n 9) 4.

¹⁶ WHO (n 11) 9.

¹⁷ *ibid.* 6.

¹⁸ WHO Europe (n 9) 5.

¹⁹ WHO (n 11) 3.

²⁰ WHO Europe (n 9) 20.

²¹ *ibid.*

²² *ibid.* 22.

²³ *ibid.* 23.

²⁴ *ibid.* 26.

²⁵ *ibid.*

²⁶ *ibid.* 25.

²⁷ *ibid.* 5.

non-discriminatory public health measures. Therefore it is noted that, ‘national, regional and international efforts should take into account the impact of harmful use of alcohol’²⁸ in the balancing process.

Member States must also be mindful of the economic and political power of the global alcohol industry. Multinational alcohol corporations recorded profits in 2005 totalling \$26 billion, and the top 10 alcoholic beverage manufacturers accounted for 48% of branded sales.²⁹ For particular alcoholic beverages, the concentration of economic power is even greater, with 50% of the global beer market belonging to only five corporations.³⁰ The largest multinational alcohol corporations therefore have considerable market leverage, especially in Europe from which 70% of the world’s alcohol is exported.³¹ As a result, these corporations are also powerful political players and attempt to influence policymaking through a number of overt and covert tactics, including: the manipulation of evidence;³² the direct lobbying of policymakers and politicians;³³ the promotion of personal responsibility through social marketing campaigns;³⁴ and the co-opting of policymaking processes,³⁵ often through front groups.³⁶ Member States must therefore be aware of the tactics of the alcohol industry, and take steps to avoid conflicts of interest which would limit the effectiveness of their alcohol control policies.

II.ii The Compatibility of Member State Alcohol Control Policies with EU Internal Market Law

Since the Member States have committed at WHO level to implementing a range of legislative alcohol control measures, and since free trade and public health interests are often likely to collide,³⁷ it is unsurprising that the CJEU’s alcohol control case law under Article 34 TFEU is extensive. Restricting alcohol advertising makes it ‘more difficult for new foreign products to break onto the market’,³⁸ which is ‘liable to impede access to the market’³⁹ more

²⁸ WHO (n 11) 9.

²⁹ DH Jernigan ‘The global alcohol industry: an overview’ (2009) 104(suppl.1) *Addiction* 6; D Miller and C Harkins, ‘Corporate strategy, corporate capture: food and alcohol industry lobbying and public health’ (2010) 30(4) *Critical Social Policy* 564.

³⁰ A Ulstein, ‘Alcohol trends – markets and innovations: Analyses and Forecasts, compiled from Business Insights 2008/9 reports’ (Eurocare 2009) 4.

³¹ Anderson and Baumberg (n 1) 51.

³² J McCambridge, B Hawkins and C Holden, ‘Industry use of Evidence to Influence Alcohol Policy: A Case Study of Submissions to the 2008 Scottish Government Consultation’ (2013) 10(4) *PLoS Med* e1001431 DOI: 10.1371/journal.pmed.1001431

<<http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001431>> accessed 7 July 2016.

³³ Miller and Harkins (n 29).

³⁴ R Moodie and others ‘Profits and pandemics: prevention of harmful effects of tobacco, alcohol, and ultra-processed food and drink industries’ (2013) 381 *Lancet* 670, 674.

³⁵ O Bartlett and A Garde, ‘The EU Platform and the EU Forum: new modes of governance or a smokescreen for the promotion of conflicts of interest?’ in A Alemanno and A Garde (eds), *Regulating Lifestyle Risks: The EU, Alcohol, Tobacco and Unhealthy Diets* (CUP 2015) 283.

³⁶ P Anderson, ‘The beverage alcohol industry’s social aspects organizations: a public health warning’ (2004) 99(11) *Addiction* 1376.

³⁷ For an interesting analysis of the relationship between the law of the World Trade Organization and NCD prevention, see B McGrady, *Trade and Public Health: The WTO, Tobacco, Alcohol and Diet* (CUP 2011).

³⁸ B Baumberg and P Anderson, ‘Health, alcohol and EU law: understanding the impact of European single market law on alcohol policies’ (2008) 18(4) *European Journal of Public Health* 392, 393.

³⁹ Case C-405/98 *Gourmet International Products* ECLI:EU:C:2001:135, [2001] ECR I-1795, para 21, annotated by A Biondi, ‘Advertising alcohol and the free movement principle: the Gourmet decision’ (2001) 26(6) *European Law Review* 616, 619.

for imported products than for domestic products. Minimum unit pricing prevents ‘the lower cost price of imported products being reflected in the selling price to the consumer’⁴⁰ which in itself is capable of hindering market access. Information disclosure measures that require physical changes in labelling or production impose dual regulatory burdens on alcoholic beverages, and there is ‘no valid reason why, provided that they have been lawfully produced and marketed in one of the Member States, alcoholic beverages should not be introduced into any other Member State’.⁴¹ Finally, the Court has consistently held that conditioning the importation of alcoholic beverages can create barriers to trade (though retail monopolies are permissible).⁴²

Measures caught by Article 34 can be justified under Article 36 TFEU or the mandatory requirement doctrine.⁴³ They must pursue a legitimate objective of public interest and satisfy the principle of proportionality, which means that they must be appropriate for securing the achievement of the objective pursued and not go beyond what is necessary in order to attain it.⁴⁴ Early cases explicitly acknowledged the ‘undeniable’ link between alcohol advertising and consumption, and the Court has recognised that preventing alcohol-related harm is ‘indisputably one of the grounds which may justify derogation from [Article 34] of the Treaty’.⁴⁵ However, if establishing a legitimate objective for alcohol control is not contentious, establishing the proportionality of alcohol control measures that fall within the scope of Article 34 TFEU raises a range of complex questions.

II.ii.a Establishing appropriateness

To establish a measure’s appropriateness, the Court will enquire as to whether there is sufficient evidence to demonstrate that the means chosen will be suitable for achieving the objectives pursued. In earlier case law such as *Franzen*, the Court hardly engaged with evidence, insisting that it was for the Swedish government to demonstrate the proportionality of their licensing system, and that they had not done so in this instance.⁴⁶ Similarly, in *Bacardi France* (on the closely related area of free movement of services) the Court was willing to accept that rules restricting direct and indirect advertising for alcoholic beverages⁴⁷ were ‘appropriate to ensure their aim of protecting public health’⁴⁸ without any further discussion of the supporting evidence.

Recent case law however demonstrates a shift in the Court’s approach to evidence. In *Ahokainen*, the Court still insisted that Finland had not demonstrated the proportionality of its

⁴⁰ Case C-333/14 *Scotch Whisky Association* ECLI:EU:C:2015:845, para 32.

⁴¹ Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* (*Cassis de Dijon*) ECLI:EU:C:1979:42, [1979] ECR 649, para 14.

⁴² Case C-189/95 *Franzen* ECLI:EU:C:1997:504, [1997] ECR I-5909, para 73, and Case C-170/04 *Rosengren* ECLI:EU:C:2007:313, [2007] ECR I-4071, para 36;. See also Case E-01/94 *Restamark* (EFTA Court, 16 December 1994), para 50.

⁴³ *Cassis* (n 41) para 8.

⁴⁴ *Scotch Whisky* (n 40) para 38.

⁴⁵ *Franzen* (n 42) para 76.

⁴⁶ *ibid.*

⁴⁷ Case C-429/02 *Bacardi France* ECLI:EU:C:2004:432, [2004] ECR I-6613; Case C-262/02 *Commission v France* (*loi évin*) ECLI:EU:C:2004:431, [2004] ECR I-6569. For an analysis of the services dimension of the *Bacardi France* and *Commission v France* (*loi évin*) cases, see: J Stuyck, ‘Case C-262/02, *Commission v France* and Case C-429/02, *Bacardi France SAS and Télévision française 1 SA (TF1) et al.*, judgments of the Grand Chamber of the Court of Justice of 13 July 2004’ (2005) 42 *Common Market Law Review* 783.

⁴⁸ *Bacardi France* (n 47) para 38.

licensing system,⁴⁹ however then proceeded to refer to the judgments in *Heinonen*⁵⁰ and *Gourmet*, acknowledging that those cases presented a variety of plausible arguments on the relative desirability of alcohol control measures. In doing so the Court showed a more nuanced appreciation of the way in which alcohol control policy is shaped by evidence and context.

In *Rosengren*, the Court went further, weighing the ban on personal importation of alcohol against the fact that the alcohol monopoly could theoretically refuse to import any beverage that it did not stock. It concluded that ‘in the light of the alleged objective ... limiting generally the consumption of alcohol in the interest of protecting the health and life of humans, that prohibition, because of the rather marginal nature of its effects in that regard, must be considered unsuitable for achievement of that objective’.⁵¹ Thus, in *Rosengren* the Court directly engages with the supporting evidence, albeit that this led to a conclusion of inappropriateness in the circumstances.

Scotch Whisky confirms that the Court is now prepared to directly engage with public health evidence. The Court explicitly acknowledged that a minimum unit pricing measure ‘is part of a more general political strategy designed to combat the devastating effects of alcohol’ and that the measures ‘constitutes one of 40 measures whose objective is to reduce, in a consistent and systematic manner, the consumption alcohol’.⁵² This awareness of the fact that single interventions may play a particular role within a more complex strategy led the Court to conclude that it was not unreasonable to consider that minimum unit pricing was suitable for reducing alcohol consumption.⁵³

II.ii.b Establishing necessity

In establishing the necessity of alcohol control measures the Court must ask whether the public health objective(s) pursued could have been equally attained with less trade-restrictive alternative measures.

In early alcohol control cases, the Court’s necessity review was ‘light touch’.⁵⁴ In *Aragonesa*, restrictions on advertising in public places did ‘not appear to be manifestly unreasonable as part of a campaign against alcoholism’.⁵⁵ In *Commission v France (loi Evin)* the Court found that ‘although there are less restrictive measures ... there is not currently any measure which is less restrictive which can exclude or conceal indirectly television advertising for alcoholic beverages’.⁵⁶ The review of necessity tended to pay greater attention to the viability of alternative alcohol control options, and to whether the Member State had exceeded its margin of discretion in electing to implement the measure it did.

However, the CJEU’s review of necessity has become increasingly focussed on the substance of the measures under review. In *Rosengren*, the Court examined the merits of

⁴⁹ Case C-434/04 *Ahokainen* ECLI:EU:C:2006:609, [2006] ECR I-9171, para 35.

⁵⁰ Case C-394/97 *Heinonen* ECLI:EU:C:1999:308, [1999] ECR I-3599.

⁵¹ *Rosengren* (n 42) para 47.

⁵² *Scotch Whisky* (n 40) para 38.

⁵³ *ibid* para 36.

⁵⁴ A Alemanno and A Garde, ‘The emergence of EU lifestyle risk regulation: new trends in evidence, proportionality and judicial review’ in HW Micklitz and T Tridimas, *Risk and EU Law* (Edward Elgar 2015) 164.

⁵⁵ *Joined Cases C-1/90 and C-176/90 Aragonesa* ECLI:EU:C:1991:327, [1991] ECR I-4151, para 17.

⁵⁶ *Commission v France (loi evin)* (n 47) para 34.

monopoly rules on personal importing, distribution and age checks in depth, and concluded that the ban went ‘manifestly beyond what is necessary for the objective sought’,⁵⁷ and that ‘it does not appear that there is, in all circumstances, an irreproachable level of effectiveness’.⁵⁸ Establishing ‘an irreproachable level of effectiveness’ of the chosen measure was not previously the objective of the necessity review. Member States have a margin of discretion in determining which measures are ‘likely to achieve concrete results’⁵⁹ in pursuit of legitimate objectives, and may therefore give ‘regard to the particular social circumstances and to the importance attached ... to [those] objectives’.⁶⁰ Thus, the purpose of the necessity review should arguably be to ensure that Member States have demonstrated that they have not been unreasonable in deciding how to strike the balance between cross-border trade and public health interests. However, the necessity review conducted in *Rosengren* purports to increase the intensity of the burden placed upon Member States to demonstrate the effectiveness and thus proportionality of their chosen measures. This arguably restricts the previous flexibility they enjoyed by requiring even greater diligence in adducing evidence to demonstrate the precise necessity of the measures chosen, where plausible and less trade restrictive alternatives may exist..

The consequences of *Rosengren* can be observed in *Scotch Whisky*. The Court appeared to start from a presumption that alternative measures were more proportionate due to their being less restrictive of trade, and conducted an analysis of whether minimum unit pricing offered anything more towards the achievement of the legitimate objective than the alternatives.⁶¹ The Court states at one point that they were examining the ‘question as to whether it is possible to prefer the adoption of [a minimum unit price] to fiscal measures’.⁶² The increased scrutiny of the substance of the measures chosen in light of potential alternatives eventually led the Court to conclude that the perceived additional benefits of increased taxation over minimum unit pricing ‘not only cannot constitute a reason to reject such a measure, but is in fact a factor to support that measure being preferred to the measure imposing [a minimum unit price]’.⁶³ The Court nonetheless left it to national courts to assess this factor alongside any other relevant factors.

Ultimately, one can observe a distinct intensification in the standard of the Court’s necessity review in alcohol control cases.– Instead of being largely content to enquire whether Member States overstepped their margin of discretion in deciding that certain measures were necessary to achieve certain objectives of alcohol control, it now appears willing to examine the whether a measure is effective enough to warrant a particular level of trade restriction. This higher standard arguably makes it far more difficult to justify alcohol control measures that make greater restrictions on trade but offer greater public health benefits. This is because ‘as many factors may contribute to some health conditions, the causal link between a risk factor and the harm may be impossible to estimate with any degree of accuracy’.⁶⁴ Such a standard arguably sidelines Member States’ traditionally broad margin of discretion to ‘decide what degree of protection they wish to ensure, and the manner in which that degree can be achieved’⁶⁵ – an argument which is reinforced by the fact that in

⁵⁷ *Rosengren* (n 42) para 51.

⁵⁸ *ibid*, para 54.

⁵⁹ *Ahokainen* (n 49) para 32.

⁶⁰ *ibid*.

⁶¹ *Scotch Whisky* (n 40) paras 42–48.

⁶² *ibid* para 47.

⁶³ *ibid* para 48.

⁶⁴ *Alemanno and Garde* (n 54) 154.

⁶⁵ *Ahokainen* (n 49) para 32.

Scotch Whisky the issue of discretion was mentioned only in order to support the assertion that Member States might adopt taxation measures over minimum unit pricing.⁶⁶

II.ii.c Issues arising from the Court's review of the compatibility of alcohol control measures with the free movement of goods

We can highlight two issues from the above analysis. First, it seems that the burden of proof has been placed far more stringently upon Member States to show that the bold, evidence-based measures they have committed to pursue to comply with their WHO commitments are more effective than other measures that they could adopt. This is despite the fact that Member States have collectively agreed as WHO State Parties that pursuit of such measures as part of a multisectoral approach are likely to be effective, and should be pursued in order to reduce the burden of alcohol-related harm. Demonstrating the explicit need for strong alcohol control measures in isolation will be difficult, since Member States are urged to adopt them as part of a complex network of interdependent legal and non-legal measures,⁶⁷ some of which perform very specific roles, meaning that their specific effects on other interests such as free trade may be balanced by other policies within the overall strategy.⁶⁸ This makes it hard to explicitly demonstrate the projected public health effects of a particular alcohol control measure, and thus difficult to show in isolation that it is necessary as compared to other interventions that appear to achieve the same result.⁶⁹ Thus, Member States face the problem of being committed to adopting a plethora of interlinked, evidence-based alcohol control measures, but unable to prove that every measure they adopt will make a contribution to reducing alcohol-related harm commensurate to the distortion of trade it may create by its very nature. The consequence is that pursuit of the full range of measures pursued at WHO level may potentially be compromised by the preclusion of certain measures at EU level.

Second, in defence of the CJEU, European judges are not expert public health practitioners, nor do they have full knowledge of the circumstances driving alcohol policy in each Member State. They must therefore base their judgments on the facts they are presented with, and are reliant upon Member States framing the objectives of measures and the evidence supporting their adoption in a clear and accurate manner. It is understandable, though regrettable, that when this does not happen the Court will not be able to reflect the full complexity of the evidence base or the national public health context in their legal assessments. For example, in *Scotch Whisky* the Court, when told that the MUP measure pursued a dual objective, were arguably misled into inappropriately comparing MUP and taxation, leading to an inaccurate application of the evidence base. The Court concluded that increased taxation of alcoholic beverages may be an effective alcohol control tool after analogously applying evidence presented to it on tobacco taxation. However it did not factor into its analysis that tobacco is a homogenous consumer product that is always harmful to health, and for which price increases are always desirable – whereas alcoholic beverages are an extremely heterogeneous set of products, consumption of which is not always harmful, and for which increasing prices in a blanket fashion through taxation is not always

⁶⁶ *Scotch Whisky* (n 40) para 43.

⁶⁷ *Alemanno and Garde* (n 5) 1752.

⁶⁸ *ibid.*

⁶⁹ A Garde, 'Freedom of Commercial Expression and Public Health Protection: The Principle of Proportionality as a Tool to Strike the Balance' in L Gormley and N Shuibhne (eds), *From Single Market to Economic Union—Essays in Honour of John A Usher* (OUP 2012) 126.

appropriate.⁷⁰ The Court's task is indeed a difficult one -it may be asked to review individual measures out of the international public health context in which they were adopted, against a legal standard that is designed to protect economic interests, and which frames the issues to be analysed in terms of a simple dichotomy between trade restriction and public health protection. It should not therefore be surprising that it is difficult for the Court to fully factor the incredibly complex evidence base and the WHO-level commitments that the Member States have made into its legal analysis of complex matters of public health practice. Inevitably, when the Court's capacity to achieve this is over-stretched, the outcomes can be disappointing from a public health perspective.

The Member States' internal market obligations should be approached within the context of the commitments that Member States have now made at WHO level to pursue a multisectoral and evidence-based approach to alcohol control. However the development of the CJEU's alcohol control case law has not been able to reflect the developing international public health context. Neither the Member States nor the CJEU can resolve this clash on their own – individual Member States are not in a position to determine how supranational legal frameworks make provision for the balancing of interests. EU regulatory intervention is therefore required if the EU legal framework is going to support rather than hinder Member States' pursuit of their WHO commitments. The EU has a duty to help resolve issues that are generated by the cross-border nature of the alcohol trade.

III. REGULATING THE CROSS-BORDER TRADE OF ALCOHOLIC BEVERAGES AT EU LEVEL

As public health policy within the EU began to develop, the Member States agreed that the EU should be given the legal competence to act in the field of public health, to reflect the public health activities that had been taking place at European level for some time.⁷¹ This competence, introduced in the Maastricht Treaty, was subsequently strengthened when demands were made of the EU to step up its efforts to contain BSE.⁷² The latest revision of the EU Treaties specifically refers to the prevention of alcohol- and tobacco-related harm, while continuing to exclude 'any harmonisation of the law and regulations of the Member States'. However, beyond this supportive competence in the field of health, the EU also has a mandate to adopt a high level of public health protection in the development and implementation of all its policies, including its internal market policy.⁷³ Thus, the EU can rely on Article 114 TFEU – the EU's general power to enact harmonisation measures which

⁷⁰ O Bartlett, 'Minimum Unit Pricing for Alcohol May Not be a Proportionate Public Health Intervention' (2016) 7(1) *European Journal of Risk Regulation* 218. See also A Alemanno, 'Balancing free movement and public health: The case of minimum unit pricing of alcohol in Scotch Whisky' (2016) 53 *Common Market Law Review* 1037.

⁷¹ TK Hervey, 'Mapping the contours of European Union health law and policy' (2002) 8(1) *European Public Law* 69, 72.

⁷² SL Greer, 'Uninvited Europeanization: neofunctionalism and the EU in health policy' (2006) 13(1) *Journal of European Public Policy* 134, 139.

⁷³ Consolidated version of the Treaty on the Functioning of the European Union [2012] OJ C326/01 (TFEU), Article 168(5). For an analysis of what actions might be permitted under such powers, see F Geber, 'Between a rock and a hard place: The controversial case of legislative harmonisation and national lifestyle policies' in Alemanno and Garde (n 35); O Bartlett, 'The EU's competence gap in public health and non-communicable disease policy' (2016) 5(1) *Cambridge Journal of International and Comparative Law* 50.

have as their object the establishment and functioning of the internal market – to adopt alcohol control measures with cross-border implications.

The EU legal mandate to ensure a high level of public health protection in all its policies, and therefore tackle cross-border issues arising from the consumption of alcoholic beverages, is supplemented by a firm political mandate from Member States. In 2001 the European Council asked the European Commission to develop a ‘comprehensive Community strategy aimed at reducing alcohol-related harm’,⁷⁴ and in particular pushed for the Commission to ‘make full use of all Community policies’.⁷⁵ These calls were reiterated in particular with the Council’s Conclusions on alcohol and young people in 2004⁷⁶ and those on alcohol and health in 2009.⁷⁷ More recently, the European Parliament joined the chorus with its Resolution on Alcohol Strategy in 2015,⁷⁸ which prompted yet another set of Conclusions from the Council.⁷⁹

However, it is clear that, over the years, the EU has failed to effectively mainstream the protection of public health in its internal market policy in light of existing evidence (III.i) and has ‘instrumentalised’ the principle of subsidiarity to minimise its intervention in this controversial policy area where political will has been lacking (III.ii).

III.i The EU’s Failure to Fulfil its Obligation to Mainstream Public Health Concerns into its Internal Market Policy

Article 168(1) TFEU requires that ‘A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.’ This ‘mainstreaming’ obligation can also be found in Article 114(3) TFEU, and has been further reinforced following the entry into force of the Lisbon Treaty, with new Article 9 TFEU and Article 35 EU Charter. The purpose of these provisions is to ensure that any policymaking in fields that could have either a positive or a negative impact on health are arranged in such a way as to have a positive impact upon health. Even though the threshold of what would constitute ‘a high level of public health protection’ remains undefined, these provisions nonetheless require the EU to place health concerns at the centre of the policy process and to give them sufficient consideration when balancing them against other interests, not least economic interests.

Mainstreaming is particularly important if the issue at hand is as complex as alcohol control and requires a multisectoral response to the problems excessive alcohol consumption raises. It should help ensure that a given issue is treated consistently across multiple policy fields, when input from multiple policy fields – and therefore Directorates-General of the Commission – is required.

⁷⁴ Council, ‘Council Conclusions on a Community strategy to reduce alcohol-related harm’ [2001] OJ C175/1, 2.

⁷⁵ Council, ‘Council Recommendation on the drinking of alcohol by young people’ [2001] OJ L161/38, 40.

⁷⁶ ‘Council Conclusions on alcohol and young people’ in Council, ‘Employment, Social Policy, Health and Consumer Affairs’ (2586th Council Meeting, Luxembourg, 1–2 June 2004).

⁷⁷ Council, ‘Council Conclusions on alcohol and health’ [2009] OJ C 302/15.

⁷⁸ European Parliament, ‘Motion for a Resolution on Alcohol Strategy (2015/2543(RSP))’ (European Parliament, 22 April 2015) <<http://www.europarl.europa.eu/sides/getDoc.do?type=MOTION&reference=B8-2015-0357&language=EN>> accessed 8 July 2016.

⁷⁹ Council, ‘Council Conclusions on an EU strategy on the reduction of alcohol related harm’ [2015] OJ C418/6.

Public health mainstreaming was first seriously addressed at EU level during the Finnish Council Presidency in 2006, with the introduction of Health in All Policies,⁸⁰ a strategic initiative that was intended to galvanise policymakers to consider health determinants controlled in sectors other than health. Health in All Policies was considered necessary on the grounds that:

(a) the EU's policies did not consider health appropriately, (b) the EU's policy-making system did not utilize the available structures and mechanisms in the best possible way, from a public health point of view, and (c) simply, because an implementation shortfall was seen in how health was integrated in all community policies.⁸¹

Health in All Policies therefore offered the EU an ideal opportunity to recognise that complex economic policies could have significant health impacts which it should in turn consider as part of its obligation to ensure a high level of public health protection in all its policies. Unfortunately, the EU did not seize this opportunity.

III.i.a The EU alcohol strategy and the EU Forum

The EU's Alcohol Strategy of 2006-2012, which responded to the various calls for action discussed above, did not mention Health in All Policies, or indeed the EU's mainstreaming obligations. There was very little discussion as to how the Strategy could be used as a vehicle through which to mainstream alcohol control concerns into other relevant policy areas: the Strategy was vague at best in this regard,⁸² and failed to provide any specific guidance as to how objectives related to the prevention of alcohol-related harm could be integrated into other EU policymaking areas. Even though the Commission stated that the EU would add value to Member State actions and deal with issues that they could not effectively handle on their own⁸³ through 'a coordinated strategy to reduce alcohol-related harm',⁸⁴ it did not take the opportunity to focus on ensuring coherence between the public health and internal market imperatives set out in the Treaties.

This is all the more disappointing as the EU Alcohol Strategy presented itself as a comprehensive plan to reduce alcohol-related harm in Europe.⁸⁵ The main part of the Strategy was in reality an exercise in mapping good practice – nothing novel was suggested, rather a brief selection of measures that Member States were already undertaking was presented, organised into five focus fields.⁸⁶ In terms of the Strategy's suggestions for how the EU itself could act to reduce alcohol-related harm, the options put forward were decidedly lacklustre and did not address the conflict between public health and free trade interests. The prospect

⁸⁰ On the notion of 'Health in All Policies', see: P Puska and T Stahl, 'Health in all policies – the Finnish initiative: background, principles, and current issues' (2010) 31 *Annual Review of Public Health* 315; M Koivulsalo, 'The state of Health in All Policies in the European Union: potential and pitfalls' (2010) 64 *Journal of Epidemiology and Community Health* 500.

⁸¹ Puska and Stahl (n 80) 322.

⁸² Commission, 'An EU Strategy to support Member States in reducing alcohol related harm' (Communication) COM (2006) 625 final, 16: 'Where possible, the Commission will seek to improve the coherence between policies that have an impact on alcohol-related harm. A number of mechanisms are currently in place to ensure that health is taken into consideration in other Community policy areas.'

⁸³ *ibid* 17.

⁸⁴ *ibid* 5.

⁸⁵ *ibid* 17.

⁸⁶ *ibid* 7, these focus fields cover the protection of young people, drink driving, the prevention of adult- and work-related harm, education on the risks of alcohol-related harm, and the maintenance of a common evidence base.

of EU harmonisation in response to cross-border concerns was specifically excluded. The proposals mostly advocated reliance on self-regulatory mechanisms.

The EU Alcohol and Health Forum was set up in 2007 as the ‘cornerstone’⁸⁷ of the EU Alcohol Strategy. Conceived of as a ‘Forum for action’,⁸⁸ the Forum was a gathering of a broad range of stakeholders, from industry and hospitality operators to consumer and public health organisations. The founding Charter of the Forum required its members to ‘devote an increasing level of effort’⁸⁹ to the commitments made within the Forum to reducing alcohol-related harm, and to demonstrate how their commitments were contributing to reducing alcohol-related harm in a ‘transparent, participatory and accountable way’.⁹⁰ However, the Forum did not live up to these expectations and never was the driver of action that it purported to be. Supposedly comprised of ‘experts from different stakeholder organisations and representative from Member States, other EU institutions and agencies’,⁹¹ in reality Forum membership comprised a disproportionately large number of industry operators,⁹² who have sought to use their position to shift policymaking towards weak, smokescreen interventions.⁹³ Although the Forum was set up to cover a range of policy areas – from curbing underage drinking to commercial communications, education, enforcing age limits and changing consumer behaviour – 70% of active commitments on the Forum’s database⁹⁴ related only to education and responsible consumption. When one also considers that most Forum commitments were made by industry operators, it becomes clear that the Forum was not a vehicle for ‘concrete and verifiable’⁹⁵ commitments, but rather the alcohol industry’s vehicle for the promotion of ineffective information-based interventions and personal responsibility rhetoric.⁹⁶ Any hope that the Forum would be a way to ‘step up actions relevant to reducing alcohol related harms’⁹⁷ was also misplaced. In 2012 a quarter of Forum members did not even submit a monitoring report on their commitments.⁹⁸ The reports have also consistently failed to demonstrate the effectiveness of commitments.⁹⁹

Overall, the Forum – and somewhat by extension, the Strategy, which placed considerable reliance upon the Forum – cannot be considered a success. It acted as a vehicle for the promotion of conflicts of interest rather than the promotion of action.¹⁰⁰ It therefore was no surprise that, in 2015, all the public health NGOs resigned from the Forum on the basis that it had failed to deliver the meaningful and durable contribution to addressing

⁸⁷ Commission, ‘Charter establishing the European Alcohol and Health Forum’ (2007) 7.

⁸⁸ *ibid* 2.

⁸⁹ *ibid* 3.

⁹⁰ *ibid*.

⁹¹ Commission Communication (n 83) 16.

⁹² Around 30 at the Forum’s peak.

⁹³ Bartlett and Garde (n 35) 286 and 290–295.

⁹⁴ Available at Commission, ‘European Alcohol and Health Forum’ (European Commission) <<https://webgate.ec.europa.eu/sanco/heid/eahf/>> accessed 8 July 2016.

⁹⁵ Commission Forum Charter (n 87) 4.

⁹⁶ For an analysis of Forum commitments that illustrates these points, see Bartlett and Garde (n 35) 290–295.

⁹⁷ Commission Forum Charter (n 87) 2.

⁹⁸ G Hernández and others (COWI Consortium), ‘European Alcohol and Health Forum (EAHF) Fourth Monitoring Progress Report’ (Report for DG SANCO, 2012) 8–9.

⁹⁹ Comparisons between the First and Fourth Monitoring Progress Reports show that the same monitoring problems have persisted over a number of years. See: C Celia, S Diepeveen and T Ling, ‘European Alcohol and Health Forum (EAHF) First Monitoring Progress Report’ (Report for DG SANCO, 2010) 4.

¹⁰⁰ Bartlett and Garde (n 35) 299.

alcohol-related harm that had been promised, precipitating its eventual collapse.¹⁰¹ The lack of any ambition in the EU Alcohol Strategy to implement a Health in All Policies approach to alcohol control is astonishing. The fact that the Commission has refused to develop another EU Alcohol Strategy to replace the 2006 Strategy, which expired in 2013, means that it has relinquished yet another opportunity to uphold its public health mainstreaming obligations with respect to alcohol control.

While the EU Alcohol Strategy entrusted Member States with the adoption of comprehensive multisectoral strategies, it also explicitly acknowledged that:

Studies carried out at national and EU level show that in some cases, where there is a cross border element, better coordination at, and synergies established with, the EU level might be needed. Examples include cross-border sales promotion of alcohol that could attract young drinkers, or cross-border TV advertising of alcoholic beverages that could conflict with national restrictions. However, very few EU harmonizing rules have been adopted to date to combat alcohol-related harm.¹⁰²

III.i.b The striking paucity of EU alcohol control harmonisation measures

Ten years' later, and despite growing awareness and commitments at international level, this is still the case.¹⁰³ For the purpose of this chapter, we will focus on three regulatory instruments adopted as EU internal market measures to demonstrate the EU's insufficient commitment to addressing the public health concerns resulting from the extensive cross-border trade in alcoholic beverages.¹⁰⁴

The first area of EU regulatory intervention intended to reduce the harmful consumption of alcoholic beverages is the ban imposed on the use of nutrition and health claims on alcoholic beverages of more than 1.2% by volume of alcohol.¹⁰⁵ Claims are often used by industry operators as a means to promote the characteristics of the foods they have placed on the market, and therefore constitute a potentially powerful tool to distinguish their goods from competing goods and influence consumer behaviour. More specifically, claims may 'encourage consumers to make choices which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice'.¹⁰⁶ It is therefore not surprising that the validity of Article 4(3), which significantly limits the freedom of alcohol manufacturers and distributors to promote their products using

¹⁰¹ See the Open Letter to Commissioner Andriukaitis: Eurocare, 'NGOs resign from Alcohol and Health Forum as Commission ignores Member State and European Parliament Calls for Alcohol Strategy' (Eurocare, 3 June 2015)

http://www.eurocare.org/library/updates/ngos_resign_from_alcohol_and_health_forum_as_commission_ignores_member_state_and_european_parliament_calls_for_alcohol_strategy> accessed 8 July 2016.

¹⁰² Commission (n 82) 5. Emphasis added.

¹⁰³ J Cisneros Örnberg, 'Escaping Deadlock – Alcohol Policy-making in the EU' (2009) 16(5) *Journal of European Public Policy* 755.

¹⁰⁴ This chapter focuses exclusively on EU internal market policy. One could also look at the taxation of alcoholic beverages and at the role the Common Agricultural Policy could play in this debate.

¹⁰⁵ European Parliament and Council Regulation (EC) 1924/2006 of 20 December 2006 on nutrition and health claims made on foods [2006] OJ L404/9 (Food Claims Regulation), Article 4(3). This provision exempts nutrition claims which refer to a reduction in the alcohol or energy content from the scope of the prohibition. The notion of 'food' is defined broadly in EU law and includes alcoholic beverages (Article 2 of European Parliament and Council Regulation (EC) 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1).

¹⁰⁶ Food Claims Regulation, Recital 9.

food claims, was challenged both during the legislative process that has led to the adoption of the Food Claims Regulation (i.e. *ex ante*)¹⁰⁷ and after its adoption in a judicial review action before the CJEU (i.e. *ex post*).

The question the CJEU was requested to answer was whether, by prohibiting the description of a wine as ‘easily digestible’ (‘*bekömmlich*’), Article 4(3) violated the freedom of a German winegrowers’ cooperative to choose an occupation and to conduct a business, under Articles 15 and 16 of the EU Charter.¹⁰⁸ In its judgment, the Court placed a strong emphasis on Article 35 of the EU Charter, which requires that ‘a high level of human health protection be ensured in the definition and implementation of all the European Union’s policies and activities’, to dismiss the claim and uphold the validity of Article 4(3). After referring to the EU’s mainstreaming obligation laid down in Article 9 TFEU,¹⁰⁹ the Court pointed out that ‘in view of the risks of addiction and abuse as well as the complex harmful effects known to be linked to the consumption of alcohol, in particular the development of serious diseases, alcoholic beverages represent a special category of foods that is subject to particularly strict regulation’.¹¹⁰ Thus, even if the claim is ‘substantively inherently correct in that it indicates reduced acidity levels’, it nonetheless remains ‘incomplete’ in that it is ‘silent as to the fact that, regardless of a sound digestion, the dangers inherent in the consumption of alcoholic beverages are not in any way removed, or even limited’.¹¹¹ Consequently, the EU legislature was ‘fully entitled’ to take the view that such claims on alcoholic beverages are misleading and that ‘the prohibition of such claims is warranted in the light of the requirement to ensure a high level of health protection for consumers’.¹¹² This case provides a rare example of the EU’s attempt to effectively mainstream public health concerns in its internal market policy in that it recognises that exposure to alcohol marketing, through health and nutrition claims or otherwise, does ‘increase the risks for consumers’ health inherent in the immoderate consumption of any alcoholic beverage’.¹¹³ Subsequent case law unequivocally confirms that the CJEU will grant a broad margin of discretion to the EU when determining the extent to which public health concerns should justify a restriction to purely economic interests.¹¹⁴

The second instrument of relevance which the EU has adopted on the basis of its internal market harmonisation powers stands in stark contrast with the Food Claims Regulation in that it exempts alcoholic beverages from some of the mandatory disclosure requirements it imposes on other foods. Regulation 1169/2011 on the food information provided to consumers requires the disclosure of information intended to help consumers make ‘informed’ food choices, referring specifically to the list of ingredients and the nutrition declaration.¹¹⁵ As such, it is very much in line with the information paradigm characterising

¹⁰⁷ See in particular the proposal of the European Parliament at its first reading to delete the ban on nutrition and health claims made on alcoholic beverages: European Parliament 2005–2006 Session [2006] OJ C117E.

¹⁰⁸ Case C-544/10 *Deutsches Weintor* [2012] ECLI:EU:C:2012:526.

¹⁰⁹ *ibid* para 49.

¹¹⁰ *ibid* para 48. Emphasis added. As discussed below, the Food Claims Regulation provides the only example where the EU has effectively recognised that ‘alcoholic beverages represent a special category of foods that is subject to particularly strict regulation’ (para 48 *in fine*).

¹¹¹ *ibid* para 51.

¹¹² *ibid* para 52.

¹¹³ *ibid*.

¹¹⁴ See in particular Case C-157/14 *Neptune Distribution Service* ECLI:EU:C:2015:823 and Case C-547/14 *Philip Morris (Tobacco Products II)* ECLI:EU:C:2016:325.

¹¹⁵ European Parliament and Council Regulation (EU) 1169/2011 of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) 1924/2006 and (EC) 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive

EU consumer and health policy.¹¹⁶ However, if Article 9(1)(k) does require, as its predecessor did,¹¹⁷ that alcoholic beverages containing more than 1.2% by volume of alcohol should indicate their actual alcoholic strength by volume,¹¹⁸ Article 16(4) exempts them from the obligation to disclose the list of ingredients and make a nutrition declaration. The Commission should have produced a report by 30 December 2014 on whether alcoholic beverages should in future provide information on their energy value, and the reasons justifying possible exemptions. It was also asked to consider the need for a definition of ‘alcopops’, which specifically target young people.¹¹⁹ Leaving aside the important fact that the Commission has not complied with this mandate, it would arguably have been far more preferable – and far less reckless – to presume that alcoholic beverages, whose harmful consumption poses a real public health threat, should have been covered in the first instance. Calling on industry operators to provide voluntary information¹²⁰ will not lead to the level playing field required to promote a high level of public health protection, while it may in the longer term limit the freedom of Member States to do so at national level.

The third internal market measure of relevance is the Audiovisual Media Services Directive (AVMSD) which, among others, sets down minimum standards on audiovisual commercial communications, including advertising, teleshopping, sponsorship and product placement.¹²¹ In particular, Article 9(1)(e) requires that ‘audiovisual commercial communications for alcoholic beverages shall not be aimed specifically at minors and shall not encourage immoderate consumption of such beverages’.¹²² This provision is a missed opportunity, not least because it does not sufficiently protect children from exposure to alcohol marketing, insofar as most of the television programmes which children watch are not ‘aimed specifically’ at them and do not therefore have to be free from such marketing.¹²³ If the Commission has somewhat recognised this concern, it proposes to address it by adding a new Article 9(3) in the AVMSD which would read as follows:

90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) 608/2004 [2011] OJ L304/18 (Food Information Regulation), Article 9(1)(b) and (l).

¹¹⁶ M Friant-Perrot and A Garde, ‘From BSE to Obesity – EFSA’s Growing Role in the EU’s Nutrition Policy’, in A Alemanno and S Gabbi, *Foundations of EU Food Law and Policy: Ten Years of the European Food Safety* (Ashgate 2014).

¹¹⁷ Commission Directive 87/250/EEC of 15 April 1987 on the indication of alcoholic strength by volume in the labelling of alcoholic beverages for sale to the ultimate consumer [1987] OJ L113/57.

¹¹⁸ Food Information Regulation, Article 28: specifies that the actual alcoholic strength must be indicated in accordance with Annex XII, except for products classified in CN code 2204 to which specific EU rules apply.

¹¹⁹ *ibid*, Article 16(4). See also Recital 40 of the Preamble: ‘The Commission shall accompany that report by a legislative proposal, if appropriate, determining the rules for a list of ingredients or a mandatory nutrition declaration for those products.’

¹²⁰ *ibid* Recital 42 Preamble.

¹²¹ European Parliament and Council Directive 2010/13/EU of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services [2010] OJ L95/1 (Audiovisual Media Services Directive).

¹²² On the evidence for the link between advertising and consumption of alcohol, see: Science Group of the European Alcohol and Health Forum, ‘Does marketing communication impact on the volume and patterns of consumption on alcoholic beverages, especially by young people? – a review of longitudinal studies’ (Scientific Opinion, 2009).

¹²³ This has been recently confirmed by the study on the exposure of minors to alcohol advertising on TV and in online services, published on 4 March 2016: Commission, ‘Study on the exposure of minors to alcohol advertising on TV and in online services’ (European Commission, 4 March 2016) <<https://ec.europa.eu/digital-single-market/en/news/study-exposure-minors-alcohol-advertising-tv-and-online-services>> accessed 8 July 2016.

Member States and the Commission shall encourage the development of self- and co-regulatory codes of conduct regarding inappropriate audiovisual commercial communications for alcoholic beverages. Those codes should be used to effectively limit the exposure of minors to audiovisual commercial communications for alcoholic beverages.¹²⁴

Once again, the Commission merely reasserts its dogmatic belief in the virtues of self-regulation. To make matters worse, it simultaneously proposes to further liberalise a range of provisions, which could increase the exposure of children to alcohol marketing. Two points are worth noting here. First, Article 23(1) would be amended to contain a daily limit on television advertising to replace the existing hourly limit: ‘The daily proportion of television advertising spots and teleshopping spots within the period between 7:00 and 23:00 shall not exceed 20%.’ This means that a broadcaster would have more flexibility to decide when to insert advertising and teleshopping spots in television programmes within the limits set by the Directive. One could venture the hypothesis that this would lead to more marketing in programmes with high audience thresholds, and less in programmes with low audience thresholds – with an overall increase in exposure to marketing and alcohol marketing more specifically.¹²⁵ Second, product placement would be liberalised under Article 11. In the current version of the AVMSD, Member States have an option to ban product placement.¹²⁶ One positive change is that the ban on product placement would remain in ‘children’s programmes’ (as is currently the case) and would be extended to ‘programmes with a significant children’s audience’. This takes into account the fact that children can be – and often are – exposed to marketing even in programmes that are not classified as children’s programmes. Unfortunately, however, the notion of ‘significant’ seems to lay down a high threshold which will in turn allow industry operators to continue to promote their alcohol beverages when children are watching. This is particularly insidious in light of the report published alongside the proposed revision of the AVMSD that children are affected by embedded marketing even though they do not always recognise it and that they openly declare not to like it.¹²⁷ The fact that the AVMSD is a minimum harmonisation directive only partially alleviates these concerns, as Member States who will want to seize the opportunity to implement stricter provisions than those contained in the AVMSD may be challenged on the ground that these measures are not compatible with the general free movement provision on the free movement of goods. Furthermore, the freedom which Member States have to regulate audiovisual commercial communications more strictly is limited by the country of origin principle.¹²⁸ Overall, therefore, the Commission has not sufficiently taken on board all the evidence that has accumulated over the years on the exposure of children to alcohol marketing.

¹²⁴ Commission, ‘Proposal for a directive of the European Parliament and of the Council amending Directive 2010/13/EU’ COM (2016) 287/4.

¹²⁵ It is worth noting that the 20% limit does not apply to: 1) announcements made by the broadcaster in connection with its own programmes; 2) sponsorship; and 3) product placement. Exposure to various forms of marketing will therefore exceed 20% overall if programmes are sponsored and include product placement.

¹²⁶ On the regulation of product placement in the AVMSD, see A Garde, ‘Towards the Liberalisation of Product Placement on UK Television?’ (2011) 16 Communications Law 93.

¹²⁷ Study on the impact of marketing through social media, online games and mobile applications on children’s behaviour, published on 25 May 2016: Commission, ‘Study on the impact of marketing through social media, online games and mobile applications on children’s behaviour’ (European Commission, 25 May 2016) <http://ec.europa.eu/consumers/consumer_evidence/behavioural_research/impact_media_marketing_study/index_en.htm> accessed 8 July 2016.

¹²⁸ O Bartlett and A Garde, ‘Time to seize the (red) bull by the horns: the EU’s failure to protect children from alcohol and unhealthy food marketing’ 38(4) European Law Review 498.

Bearing in mind 1) existing evidence supporting strong alcohol policies, 2) the EU's public health mainstreaming obligations and 3) the Court's case law on the compatibility of national alcohol control measures with general free movement provisions, it is indeed extremely difficult to comprehend why the EU has not done more in areas with a clear cross-border effect, if this is not for its chronic lack of political will.

III.ii The Principle of Subsidiarity as a Cloak for the EU's Chronic Lack of Political Will to Adopt an Evidence-based EU Alcohol Policy

The principle of subsidiarity has traditionally been invoked to guard against excessive EU regulatory intervention. In this instance, however, the EU has relied on this principle to significantly limit its regulatory intervention. The way the European Commission has interpreted the principle of subsidiarity in its EU Alcohol Strategy is to avoid using the Union's competences at all, insisting that 'there is no intention to substitute Community action to national policies ... in accordance with the principle of subsidiarity ... In particular the Commission does not intend as a consequence of this Communication to propose the development of harmonised legislation in the field of the prevention alcohol-related harm.'¹²⁹ We argue that this position is misconceived in that it ignores the fragmentation resulting from the Court's case law and the impact such fragmentation has had on Member States' freedom to adopt alcohol control policies.

The principle of subsidiarity constrains EU action by requiring that:

in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.¹³⁰

Despite 'its lack of conceptual contours',¹³¹ the principle of subsidiarity was never intended to be relied upon as a way out of the EU's obligation to ensure that a high level of public health protection should be ensured in the development and implementation of all its policies, and more specifically its internal market policy. If it admittedly lays down a presumption in favour of decentralisation,¹³² it does not lay down an irrefutable presumption. In fact, paragraphs 6 and 7 of the Protocol on Subsidiarity and Proportionality require that the EU should legislate only to the extent necessary and that EU measures should leave as much scope for national decisions as possible, while securing the aim of the measure and observing the requirements of the Treaty.¹³³ In other words, a rigorous subsidiarity analysis may not necessarily result in EU action being altogether avoided. The principle of subsidiarity may rather lead to an 'extension of the activities of the Union within the framework of its powers when circumstances so require'.¹³⁴

¹²⁹ Commission (n 83) 4.

¹³⁰ Consolidated version of the Treaty on European Union [2012] OJ C326/01 (TEU), Article 5(3).

¹³¹ For a criticism of the wording of Article 5(3), see R Schütze, *European Constitutional Law* (CUP 2012) 178.

¹³² M Pollack 'The end of creeping competence? EU policy-making since Maastricht' (2000) 38(3) *Journal of Common Market Studies* 519, 520.

¹³³ Protocol (No 2) on the Application of the Principles of Subsidiarity and Proportionality [2010] OJ C83/206.

¹³⁴ European Parliament, 'Resolution of 13 September 2012 on the 18th report on Better Legislation – Application of the Principles of Subsidiarity and Proportionality (2010)' (European Parliament, 13 September 2012) <<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2012-340>> accessed 8 July 2016, para 15. See further I Maletic, 'The role of the principle of subsidiarity in the EU's lifestyle risk policy' in Alemanno and Garde (n 35) 197.

As Lyon-Caen noted shortly after the principle of subsidiarity was first introduced in the EU Treaty, ‘subsidiarity can cut both ways’.¹³⁵ Furthermore, Article 3 of the Protocol also emphasises that:

Subsidiarity is a dynamic concept and should be applied in the light of the objectives set out in the Treaty. It allows Community action within the limits of its powers to be expanded where circumstances so require, and conversely, to be restricted or discontinued where it is no longer justified.

The Court’s growing case law on the compatibility of national measures with EU free movement provisions strongly suggests that EU legislation is necessary if the EU is to achieve the dual objective of establishing and ensuring the functioning of the internal market, while ensuring a high level of public health protection. Internal market objectives are better served if cross-border issues affecting all Member States are regulated by the EU at EU-level. This is the case even if Member States have suffered from the lack of harmonised rules to varying degrees, depending in particular on the extent to which they have attempted to develop national comprehensive, multisectoral and evidence-based alcohol control policies. Writing in relation to tobacco products, the Court recently stated:

Even if the second of those objectives might be better achieved at the level of the Member States, the fact remains that pursuing it at that level would be liable to entrench, if not create, situations in which some Member States permit the placing on the market of tobacco products containing certain characterising flavours, whilst others prohibit it, thus running completely counter to the first objective of Directive 2014/40, namely the improvement of the functioning of the internal market for tobacco and related products.

The interdependence of the two objectives pursued by the directive means that the EU legislature could legitimately take the view that it had to establish a set of rules for the placing on the EU market of tobacco products with characterising flavours and that, because of that interdependence, those two objectives could best be achieved at EU level.¹³⁶

It is concerning that the Commission purports to respect the principle of subsidiarity – a legal principle subject to judicial review – to hide its utter lack of political will to adopt evidence-based standards with a view to addressing inherently cross-border issues that the free movement of goods and services has increased rather than alleviated and that the Court’s case law has put in sharp focus. Why would the fact that drinking patterns vary from one Member State to another, in itself, lead to the conclusion that regulating the labelling and the marketing of alcoholic beverages is more effectively done at national rather than at EU level? The fragmentation of the internal market will only be increased if Member States are left to regulate the labelling and marketing of alcoholic beverages at national level. As discussed above, such measures are classified for the purposes of Article 34 TFEU as either product requirements or certain selling arrangements that may not apply equally in law and in fact, leaving it to the CJEU to determine whether these measures are proportionate. As the Council Conclusions of December 2015 specifically emphasise, ‘an EU strategy can further support and complement national public health policies’,¹³⁷ calling specifically on the Commission to

¹³⁵ G Lyon-Caen, ‘Subsidiarity’ in P Davies and others (eds), *European Community Labour Law: Principles and Perspectives*. Liber Amicorum Lord Wedderburn of Charlton (Clarendon Press 1996) 49.

¹³⁶ Philip Morris (n 114) paras 221 and 222. See also Case C-508/13 *Estonia v European Parliament and Council* ECLI:EU:C:2015:403, paras 47 and 48.

¹³⁷ Council Conclusions (n 79) para 13.

‘focus on initiatives on the reduction of alcohol-related harm with a cross-border dimension and an EU added value as a follow-up to the first EU Alcohol Strategy’.¹³⁸

By failing to apply the internal market logic to alcoholic beverages as it has in relation to tobacco products, the EU has instrumentalised the principle of subsidiarity to reach pre-determined outcomes.¹³⁹ This can only lead to increased regulatory fragmentation within the EU, thus depriving Member States from the certainty they should be able to hope for as to the compatibility of their alcohol control measures with EU free movement rules, and making it more difficult for them to uphold the international commitments they have made to reduce the burden of NCDs, and in particular the harm resulting from the consumption of alcoholic beverages.

IV. CONCLUSION: THE EU’S FAILURE TO ENGAGE WITH EVIDENCE

The necessity of engaging with evidence when making policy on public health issues such as alcohol control, is emphasised throughout the literature.¹⁴⁰ Alcohol control will not be fully effective if the evidence on, among other things, how consumers behave in purchasing situations¹⁴¹ and the socio-economic environment in which alcohol consumption takes place,¹⁴² are not taken into account when developing and implementing policy. The desirability of factoring the latest evidence into public health policymaking is also reflected in Article 114(3), where internal market legislative proposals relating to health must ‘take as a base a high level of protection, taking account in particular of any new development based on scientific facts’.

It is therefore all the more regrettable that the Commission has largely failed to engage with existing evidence which suggests that measures affecting the price,¹⁴³ availability and accessibility¹⁴⁴ of alcoholic beverages, as well as their advertising,¹⁴⁵ will have the most impact in decreasing rates of excessive consumption. It is striking that the EU Alcohol Strategy prioritised the types of policy measures that have been found to have the

¹³⁸ *ibid* para 21.

¹³⁹ Alemanno and Garde (n 5).

¹⁴⁰ See for instance: RC Brownson, JF Chiqui, and KA Stamatakis, ‘Understanding Evidence-Bases Public Health Policy’ (2009) 99(9) *American Journal of Public Health* 1576; R Room, T Babor and J Rehm, ‘Alcohol and public health’ (2005) 365(9458) *Lancet* 519; P Anderson, D Chisholm and DC Fuhr, ‘Effectiveness and cost-effectiveness of policies and programmes to reduce the harm caused by alcohol’ (2009) 373 *Lancet* 2234.

¹⁴¹ J Janson and D Kysar, ‘Taking Behaviouralism Seriously: Some Evidence of Market Manipulation’ (1999) 112(7) *Harvard Law Review* 1420; A Alemanno and A Sibony (eds), *Nudge and the Law: A European Perspective* (Hart 2015).

¹⁴² M Marmot, *The Health Gap: The Challenges of an Unequal World* (Bloomsbury 2015); J van Oers and others, ‘Alcohol consumption, alcohol-related problems, problem drinking, and socioeconomic status’ (1999) 34(1) *Alcohol and Alcoholism* 78.

¹⁴³ A Wagenaar, MJ Salois and KA Komro, ‘Effects of beverage alcohol price and tax levels on drinking: a meta analysis of 1003 estimates from 112 studies’ (2009) 104(2) *Addiction* 179.

¹⁴⁴ C Campbell and others, ‘The effectiveness of limiting alcohol outlet density as a means of reducing excessive alcohol consumption and alcohol-related harms’ (2009) 37(6) *American Journal of Preventive Medicine* 556.

¹⁴⁵ L Smith and D Foxcroft, ‘The effect of alcohol advertising, marketing and portrayal on drinking behaviour in young people: systematic review of prospective cohort studies’ (2009) 9 *BMC Public Health* 51.

least impact, namely information and education,¹⁴⁶ or harm reduction policies (which do not aim to reduce consumption of alcohol but its associated harms).¹⁴⁷

A comprehensive statement of the evidence base, funded by the Commission, was produced specifically to support the EU Alcohol Strategy.¹⁴⁸ However, as one expert noted in evidence given to the European Union Committee of the House of Lords on the EU Alcohol Strategy, ‘a lot of that evidence did not get through into the strategy itself’.¹⁴⁹ This is all the more curious in light of the fact that during the drafting process for the Strategy there were multiple references to evidence-based policymaking and many evidentially effective interventions were on the table – for example in June 2004 Member State representatives pushed to keep the option for legislation on commercial communications open, for an EU minimum purchase age, and for the role of industry operators to be more clearly defined, while in March 2005 the informal draft of the strategy proposed for example that the Commission would assess the possibility of placing special rates of excise duty on specific beverages that caused harm among young people.¹⁵⁰ The fact that the final consensus on the main themes and content of the Strategy,¹⁵¹ as well as the final text, bore little relation to earlier work on the Strategy strongly suggests that a significant ‘watering down’ influence was exerted on the Commission’s work, highlighting its failure to engage properly with evidence – or perhaps its failure to resist those who lobby against an evidence-based approach when such an approach negatively impacts on their private economic interests.

Most of the evidence on self-regulation and partnership with the alcohol industry points to its inefficacy, due to the inherent conflicts of interest, and merely supports the use of self-regulatory mechanisms if it is part of a wider legislative approach to alcohol control.¹⁵² The Commission however has relied almost exclusively on the self-regulation and Forum commitments to drive the work of the EU Strategy, being so blind as to praise its work in assessments of the progress of the Strategy,¹⁵³ and ignore the conflicts of interest such governance mechanisms unavoidably promote.¹⁵⁴

Nobody would dispute the complexity of designing an effective EU alcohol policy. What is more controversial is that the EU has hardly engaged with this complexity, despite its strong mandate to do so, and the plethora of evidence at its disposal. This will unavoidably make it much more difficult for Member States to uphold their commitment to reducing the

¹⁴⁶ Anderson and Baumberg (n 1).

¹⁴⁷ A Ritter and J Cameron, ‘A review of the efficacy and effectiveness of harm reduction strategies for alcohol, tobacco and illicit drugs’ (2006) 25 *Drug and Alcohol Review* 611.

¹⁴⁸ Anderson and Baumberg (n 1).

¹⁴⁹ Health and Education Sub Committee of the European Union Committee, ‘A new EU Alcohol Strategy? – Evidence’ (HL 2014–15, 123) 78.

¹⁵⁰ See respectively: Working Group on Alcohol and Health, ‘Draft Minutes of the Meeting of the Working Group on Alcohol and Health’ (Luxembourg, 9–10 June 2004), 8-9; Working Group on Alcohol and Health, ‘Discussion Paper on the EU Strategy on Alcohol’ (2005), 8.

¹⁵¹ M Renstrom, ‘Commission activities to prevent alcohol-related harm’ (Bridging the Gap, 3rd Meeting, Barcelona 2006).

¹⁵² Moodie and others (n 34); S Casswell, ‘Vested interests in addiction research and policy. Why do we not see the corporate interests of the alcohol industry as clearly as we see those of the tobacco industry?’ (2013) 108(4) *Addiction* 680; A Gilmore, E Savell and J Collin, ‘Public health, corporations and the New Responsibility Deal: promoting partnerships with vectors of disease?’ (2011) 33(1) *Journal of Public Health* 2.

¹⁵³ T Zamparutti, G Hernández and K Bolt, ‘Assessment of the added value of the EU strategy to support Member States in reducing alcohol-related harm’ (Report for DG SANCO, 2012) 15.

¹⁵⁴ Bartlett and Garde (n 35).

burden of NCDs by 2025.¹⁵⁵ Nothing will ever replace the political motivation and courage which are currently lacking. The suggestion that the Commission should adopt evidence-based policies, which limit the purely economic private interests of alcoholic beverage operators, in order to comply with its Treaty obligations to ensure a high level of public health protection for all, is unlikely to meet with any sympathy in Brussels – at least for the time being.

¹⁵⁵ By approving the WHO Global NCD Action Plan for 2013–2020, Member States have undertaken to attain nine voluntary global targets, including that of a 25% relative reduction in premature mortality from NCDs and that of at least a 10% relative reduction in the harmful use of alcohol by 2025.

PART 5

THE EXTERNAL DIMENSION

17. Trade and health in the European Union

Holly Jarman and Meri Koivusalo*

I. INTRODUCTION

This chapter focuses on the implications of the European Union's (EU) external trade policies, including the negotiation of trade agreements, for EU internal policies that affect health. The EU's internal policy context has been strongly shaped by the development of international trade law under the World Trade Organisation (WTO) and its predecessor, the General Agreement on Tariffs and Trade (GATT).¹ WTO treaties affect EU internal policies both directly, as the result of trade disputes affecting the EU or its Member States, as well as indirectly, on the basis of required legislative changes to Member States' domestic laws. It is therefore important to consider the changing context of trade decision-making when examining the EU's internal health policies. While historic WTO decisions concerned largely issues of food safety and environmental health (and these remain core issues that dominate public discourse on trade negotiations), extrapolating solely from existing WTO decisions to draw lessons for current EU health policymaking ignores a raft of potential problems associated with newer areas of trade policy that are currently under negotiation.

The earliest trade disputes between the EU and the United States (US) under the GATT were often concerned with the more stringent regulatory requirements of the US, for example, in areas of environmental health. This changed in the 1990s with the introduction of the WTO dispute settlement process.² From then onwards, discussions about the link between the EU's health policies and its trade policies centred on the substantive area of food regulation and the legal issue of the precautionary principle. They were shaped by two dispute settlement cases in particular: a Canadian challenge to the EU regarding occupational health and asbestos regulation³ and an American challenge to the EU regarding hormones in beef production.⁴ The EU was also subject to a WTO dispute settlement claim in relation to the banning of antimicrobial treatment of poultry in 2009.⁵ A potential case concerning the use of antibiotics in animal production was high on the policy agenda when the CJEU upheld a

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¹ General Agreement on Tariffs and Trade (adopted 30 October 1947, entered into force provisionally 1 January 1948) 55 UNTS 194 (GATT), Marrakesh Agreement Establishing the World Trade Organisation (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154 (WTO Agreement).

² Vogel D, *The Politics of Precaution: Regulating Health, Safety and Environmental Risks in Europe and the United States* (Princeton University Press 2012) 7.

³ WTO, *EC Measures Affecting Asbestos and Asbestos-Containing Products – Report of the Appellate Body* (5 April 2001) WT/DS135/AB/R [2001] 7 DSR 3243.

⁴ WTO, *EC Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States – Panel Report* (13 February 1998) WT/DS26/R/USA, as modified by Appellate Body Report (13 February 1998) WT/DS26/AB/R and WT/DS48/AB/R [1998] 3 DSR 699.

⁵ WTO, *EC Certain Measures Affecting Poultry Meat and Poultry Meat Products from the United States – Request for Consultations* (20 January 2009) WT/DS389/1. The poultry case differs a bit from the others as it relates to different practices to lower the risk of contamination of poultry.

restriction (in Pfizer) and the US immediately threatened a challenge under trade law.⁶ Trade-related concerns regarding EU regulation of aflatoxins have also been addressed under the WTO, as EU standards on aflatoxins have remained much lower than international Codex Alimentarius standards and lower than, for example, aflatoxin standards required by the US.⁷

While the implications of these decisions for EU internal policies have been somewhat limited,⁸ the decisions directly challenged the place of the precautionary principle within the EU's broader policy framework.⁹ These past dispute settlement cases also go some length to explain why public attention has been drawn to the potential impacts on food safety and environmental health regulations from a new era of transatlantic negotiations on trade. In many EU States, the impact on food safety and quality has been the subject of much polemic, especially in discussion of the Transatlantic Trade and Investment Partnership (TTIP).¹⁰

Direct trade policy-related challenges to EU health-related internal policies have been more limited in other fields under the WTO's purview, such as services and intellectual property rights.¹¹ However, reliance on past trade agreements and dispute settlements to draw implications for current and future health law as the only reference is problematic due to the changing trade policy context. Governments, including those of the EU, are seeking trade negotiations towards plurilateral and bilateral agreements with a very broad focus on services, investment, government procurement, intellectual property rights and regulatory cooperation.¹² Many health-related policies –from

⁶ Concern over antibiotic growth promoters (AGPs) dates back to the 1960s. WHO guidance from 1997 suggested that the use of AGP should be stopped or phased out. However, when the EU banned the non-veterinary use of antibiotics in animal feed in the late 1990s, implementation proved difficult. The initial ban of antibiotics with relevance to human health in 1998 was challenged by Pfizer in the Court of Justice of the European Union in 1999 (Case T-13/99 Pfizer ECLI:EU:T:2002:209, [2002] ECR II-3305). The challenge was unsuccessful due to an EU argument supporting the necessity of precautionary measures. The US immediately warned that the ban may violate WTO rules, see, eg, 'Scher Letter on EU Antibiotics Ban' Inside US Trade (Washington, 10 September 1999). See WHO Europe, Tackling Antibiotic Resistance from a Food Safety Perspective in Europe (WHO 2011).

⁷ F Cheng, 'Food Safety: The Case of Aflatoxin (3–11)' in P Pinstrup-Andersen and F Cheng (eds), *Case Studies in Food Policy for Developing Countries, Volume 1* (Cornell University Press 2009) (Also available at <http://cip.cornell.edu/dns.gfs/1200428161>).

⁸ The EU won the asbestos case on appeal, while the case on hormones in beef production is ongoing.

⁹ The political scars from these disputes can be seen in Commission, 'Communication from the Commission on the Precautionary Principle' COM (2000) 1 final and in Council, 'Council Resolution on the Precautionary Principle' (Annex III to the European Council Conclusions, Nice 7–9 December 2000). These documents provide guidance for the Commission and Member States when dealing with the WTO, in order to: 'ensure that the precautionary principle is fully recognised in the relevant international health, environment and world trade fora, in particular on the basis of the principles put forward in this Resolution; to pursue that aim and ensure that it is taken into account as fully as possible, particularly at the WTO, and at the same time help to explain it'.

¹⁰ H Jarman, 'Trade policymaking meets social policies: Public statements on healthcare and the Transatlantic Trade and Investment Partnership' (Paper Presented at the European Union Studies Association Annual Meeting, 2015)

¹¹ While the EU is defending a case regarding the transit of generic medicines against India and Brazil, this applies less to internal policies. See WTO, *European Union and a Member State – Seizure of Generic Drugs in Transit – Request for Consultations* (19 May 2010) WT/DS408/1.

¹² M Koivusalo and N Watt, 'Policy space for health in the context of emerging European trade policies' in M Freeman and J Orbinski (eds), *Law and Global Health: Current Legal Issues* (OUP 2014).

regulations designed to protect public health, to laws governing the distribution and sale of medicines and medical devices, to the financing and management of health systems – could potentially fall into those categories. It is only through two slow and relatively closed parallel processes – international trade negotiations on the one hand, and internal bargaining among the EU institutions and Member States on the other – that this policy space will be gradually defined.

The change in EU trade policy is in part a response to the faster and more aggressive US negotiation of free trade agreements with third countries, which allows some to argue that the EU is falling behind and letting the US gain both commercial advantage and a major role shaping trade law. The desire for further EU trade agreements can be seen as a response to an international trend for ‘competitive liberalization’ strategies in which developing free trade agreements is part of a broader economic policy strategy.¹³ Understanding the EU’s direction of travel thus requires us to focus also on the context, content and direction of current negotiations. Food safety might have dominated trade disputes in the past, but the new generation trade agreements currently under negotiation have the potential to constrain policy space for health in many more areas. The following sections focus first on the current authority of the EU to make trade law and policy and the impacts of this on health policy spaces, before turning to a discussion of recent EU trade negotiations and their impact on health.

II. CURRENT DIMENSIONS OF EU TRADE LAW AND POLICY AND THEIR IMPACT ON HEALTH

Current EU trade policy is a complex domain that can be mapped along two dimensions: changes in, and challenges to, the jurisdiction and competence of EU institutions; and the impact of those changes and related trade negotiations on the available policy space for health. EU and international law are not separate, but rather all of one piece, with mandates for trade negotiations dependent upon internal EU competences. While a series of treaty changes and court decisions, described elsewhere in this volume, has moulded available policy space for health at the EU level, a parallel series of international trade negotiations has constrained the political space available to enact public policies within the EU and its Member States, including those aimed at protecting and promoting health.

II.i Jurisdiction and Competence

Over time, EU trade policymaking has evolved from a closed process dominated by governments of Member States to a more open, multiparty decision-making process under the EU’s ordinary legislative procedure. The central EU institutions historically had exclusive competence over trade issues through the Common Commercial Policy (CCP), and the EU has long held exclusive competence over trade in goods. But as the subject matter of trade policy has become more complex, going beyond the governance of tangible products, questions of competence over trade have become more complex also – to the extent that not even the EU institutions themselves are always clear about matters of competence.¹⁴ In Opinion 1/94, the CJEU ruled that the EU and Member States shared competence over key aspects of the WTO’s new trade agenda – most of trade in services and matters of intellectual property. This meant that the core new agreements negotiated under the World Trade

¹³ A Sbragia, ‘The EU, the US, and trade policy: competitive interdependence in the management of globalization’ (2010) 17(3) *Journal of European Public Policy* 368.

¹⁴ E Steinberger, ‘The WTO Treaty as a Mixed Agreement: Problems with the EC’s and the EC Member States’ Membership of the WTO’ (2006) 17(4) *European Journal of International Law* 837.

Organisation in these areas (the General Agreement on Trade in Services¹⁵, or GATS and the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS) had to be concluded as ‘mixed’ agreements.¹⁶ Opinion 1/94 and similar decisions that followed were subsequently codified – but not really clarified – through the Amsterdam and Nice Treaties,¹⁷ leaving matters of jurisdiction far from clear.

The Lisbon Treaty¹⁸ attempted to fix this confusion, confirming that the EU institutions can exercise exclusive competence in all areas of trade in services (except transport) and trade-related aspects of intellectual property. The Treaty also allowed the EU to move towards competence in investment, although not without leaving some lingering legal questions.¹⁹ This is a matter where different views continue to co-exist, causing significant legal uncertainty that can only be countered by further judgments or treaty negotiations. For example, the European Commission consulted the CJEU with respect to its competence to conduct negotiations concerning investment protection in the recent EU-Singapore FTA Agreement.²⁰

In a significant departure from previous practice in which consensus was the rule, the architects of the Lisbon Treaty hoped to streamline decision-making on trade by emphasising the ability of the Council to make decisions by qualified majority. But again, the situation is more complex than it appears at first glance. Article 207(4)(b) TFEU, which sets out the scope of the Common Commercial Policy, requires the Council to act unanimously to negotiate and conclude agreements involving trade in social, education and health services, ‘where these agreements risk seriously disturbing the national organisation of such services and prejudicing the responsibility of Member States to deliver them’.

This carve-out for health, social and education services in the Lisbon Treaty deliberately follows the wording of CJEU decisions with respect to the sustainable financing of health services in the context of EU Treaty obligations.²¹ The initial Nice and Lisbon Treaty connection between unanimous decisions on audiovisual services and those on so-called ‘sensitive’ services (health, education and social services) has, however, become broken in the context of trade negotiations. This is clear, for example, in the now-declassified TTIP negotiation mandate, where audiovisual services

¹⁵ General Agreement on Trade in Services (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 183 (GATS); Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299 (TRIPS).

¹⁶ Opinion 1/94 Opinion Pursuant To Article 228(6) of the EC Treaty (WTO Agreement) ECLI:EU:C:1994:384, [1994] ECR I-5267.

¹⁷ Treaty of Nice, Amending the Treaty on European Union, the Treaties Establishing the European Communities and Certain Related Acts [2001] C80/01.

¹⁸ (As adopted by the Treaty of Lisbon) Consolidated version of the Treaty on the Functioning of the European Union [2012] OJ C326/01 (TFEU).

¹⁹ Questions persist around whether the exclusive competence concerns all investment or just Foreign Direct Investment (FDI), and whether it covers both the liberalisation of investment as well as investment protection.

²⁰ Commission, ‘Commission Decision requesting an opinion of the Court of Justice pursuant to article 218(11)TFEU on the competence of the Union to sign and conclude a Free Trade Agreement with Singapore’ C(2014) 8218 final.

²¹ For further discussions, see Chapters 1 and 2 in this book.

are excluded, but health services are not.²² Health, social or educational services thus remain in a legal grey area.

The role of the European Parliament (EP) in trade policymaking was also strengthened by the Lisbon Treaty, with the EP gaining a more significant say in the approval process on the basis of Article 218 TFEU.²³ The potential power of the EP to derail trade deals was shown in the context of the Anti-Counterfeiting Trade Agreement (ACTA).²⁴ Using the powers conferred on them by the Lisbon Treaty for the first time, MEPs voted to reject ACTA, preventing the deal from becoming law in the EU and scuppering it globally. Despite the EP's new role, however, the negotiation of trade agreements still mostly occurs under the purview of the Member States and the Commission. Talks on the recent Trade in Services Agreement (TiSA), for example, were initiated before impact assessments were conducted and without the EP approving a mandate for the negotiations.²⁵ The EP responded to this in its assessment of and guidance regarding TiSA in 2016 by including clear red and green lines as well as many detailed recommendations.²⁶

The 'mixity' of trade agreements also continues to matter because it determines the process by which such agreements can be ratified. Non-mixed agreements, where competence falls entirely under the purview of the central EU institutions, need to be approved in the Council, usually by qualified majority, and by the European Parliament. Mixed agreements, however, have to be approved not only by the Council and the European Parliament, but also voted through by national parliaments – a significant complication given the number and diversity of legislatures as well as frequent hostility towards the European project.

Since negotiating a mandate for the EU-Japan Free Trade Agreement of 2012, the Council has implemented a workaround for this problem.²⁷ Using a 'double-decision' mechanism, the Council provides two separate authorisations for the Commission to negotiate trade deals – one which refers to matters of exclusive competence, and another for matters of shared competence.²⁸ This uncertainty around competences in 'sensitive' areas such as health and the workarounds implemented to circumvent them have important consequences for trade policy outcomes. Controversial 'mixed' areas of negotiation (such as investment protection in the CETA agreement) may be claimed by negotiators

²² In particular, cf paragraphs 15 to 25 in Council, 'Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America' 11103/13 (2013)

²³ TFEU, Article 218.

²⁴ European Parliament, 'European Parliament Rejects ACTA' (European Parliament, 4 July 2012) <www.europarl.europa.eu/news/en/news-room/20120703IPR48247/European-Parliament-rejects-ACTA> accessed 20 June 2016.

²⁵ This was explicitly brought up in European Parliament, 'Resolution of 4 July 2013 on the opening of negotiations on a plurilateral agreement on services' (European Parliament, 2013) <www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2013-325> accessed 20 June 2016.

²⁶ European Parliament, 'Draft report containing the European Parliament's recommendations to the Commission on the negotiations for the Trade in Services Agreement (TiSA)' PE 567.814 (Rapporteur: Viviane Reding, 25 September 2015).

²⁷ M Emerson and others, 'British Balance of Competence Reviews, Part II: Again, a huge contradiction between the evidence and Eurosceptic populism.' 'British Balance of Competence Reviews, Part II: Again, a huge contradiction between the evidence and Eurosceptic populism' (European Policy Institutes Network Papers No 40, 2013).

²⁸ HM Government, 'Review of the balance of competences between the United Kingdom and the European Union: Trade and Investment' (2014).

to be part of the overall trade deal, but this may not be the case in practice once all the actors have had their say.

In short, the EU's competence to conduct trade negotiations and conclude trade agreements draws from its internal competences to shape the European internal market.²⁹ This implies two kinds of challenges for EU governance. First, in terms of substantive policy areas, where the European Commission requires competence in order to negotiate trade agreements on those topics. Second, on how changing internal policies and actors' understanding of competence affects trade negotiations. EU law is not distinct and separate from external international trade law – rather, both are created and developed in connection with trade negotiations. This can be seen in the context of the new transparency directive³⁰ or the importance of TTIP negotiations for the Commission's political guidelines,³¹ work-programme,³² and recent internal market strategy,³³ but also as a longer-term policy development within EU trade policy.³⁴

Internal policies matter also to the extent that health care reforms within EU Member States establish new healthcare markets. In many EU Member States in recent years, the role of contractual relationships between government agencies, funders and private actors has increased within healthcare systems. The 2011 Directive on Patients' Rights in Cross-border Healthcare³⁵ and updated legislation affecting the mobility of health professionals³⁶ have also created their own dynamics within the EU with potential relevance, in particular, for trade in professional services and health tourism. Health tourism has gained attention in the context of trade in services as a potential future avenue for business development and it is also sought as part of negotiation of trade agreements. Greater portability of social security benefits could potentially increase trade in health services

²⁹ H Jarman, 'Trade in Services and the Public's Health: A "Fortress Europe" for Health?' in SL Greer and P Kurzer (eds), *European Union Public Health Policy: Regional and Global Perspectives* (Routledge 2013).

³⁰ European Parliament and Council Directive 2013/50/EU of 22 October 2013 amending Directive 2004/109/EC of the European Parliament and of the Council on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market, Directive 2003/71/EC of the European Parliament and of the Council on the prospectus to be published when securities are offered to the public or admitted to trading and Commission Directive 2007/14/EC laying down detailed rules for the implementation of certain provisions of Directive 2004/109/EC [2013] OJ L294/13.

³¹ JC Juncker, 'A New Start for Europe: My agenda for jobs, growth, fairness and democratic change, political guidelines for the next European Commission' (Opening Statement in the European Parliament Plenary Session, Strasbourg, 15 July 2014).

³² Commission, 'Commission Work Programme 2016: No Time for Business as Usual' (Communication) COM (2015) 610 final.

³³ Commission, 'Upgrading the Single Market: more opportunities for people and business' (Communication) COM (2015) 550 final.

³⁴ The Commission will examine how to 'strengthen the mutual links between internal and external regulatory actions and to explore how to improve coordination between the two in areas like government regulation and *international standards, with a particular focus on future legislation*'. Commission, 'Trade, Growth and World Affairs: Trade Policy as a Core Component of the EU's 2020 strategy' COM (2010) 612 final, 7.

³⁵ European Parliament and Council Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L88/45 (Patients' Rights Directive).

³⁶ European Parliament and Council Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22, as amended by the European Parliament and Council Directive 2013/55/EU of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation') [2012] OJ L354/132.

between the EU and middle- and lower-income countries. It has also been proposed that US patients could seek out care in Europe, as costs of care remain lower in the EU. It may not be solely accidental that the European Commission has included text regarding the mobility of patients in its trade agreements.³⁷ In the CARIFORUM agreement between the EU and Caribbean countries, for example, the mobility of patients was enabled for privately-funded health services.³⁸ With the exception of few Member States' reservations, health tourism (mode 2) was also further expanded in the EU-Korea FTA for privately-funded trade in health services.³⁹ Despite these aspirations, the volume of trade in health services still remains low for all EU Member States.⁴⁰ Nevertheless, health tourism provides a perfect example of the linkages between the EU's internal market and the policies that govern it, and the ability of the EU Commission to negotiate regarding those sectors as part of its trade policy. Dealing with health issues as part of trade negotiations immediately places health in the background and brings economic issues to the fore, impacting available policy space for health.

II.ii Policy Space for Health

Since the late twentieth century, as more complex regulatory and services issues have come to be considered 'trade' issues, questions of competence have become more complex and uncertain. The so-called 'new generation' trade agreements – such as the EU-Canada Comprehensive Economic and Trade Agreement (CETA), the EU-Singapore Free Trade Agreement (SSFTA), the plurilateral Trade in Services Agreement (TiSA) and the EU-USA Transatlantic Trade and Investment Partnership (TTIP) – extend much further into national regulatory contexts and so-called 'beyond-border' measures. While most of these agreements apply to services, government procurement and investment as new areas of focus, the TTIP is the broadest.

Governing tariffs and trade in goods as it applies to medicines, medical devices, alcohol or tobacco, while far from problem-free, remains a simpler matter than governing intellectual property rights, regulatory cooperation, investment protection, government procurement, State-owned enterprises or, more broadly, the context of trade in health services – which include the provision of health services across borders (e.g., electronic delivery of services, consultation, or surveillance), the movement of patients across borders, rules governing the commercial presence of health-oriented foreign companies, or the movement of medical professionals into and out of the EU. Add to this cross-border complexity the sensitivity of EU Member State governments and Europeans themselves to changes in their health systems and it is not difficult to see why trade and health issues are both politically fraught and legally uncertain.

EU policies designed to promote and protect its large internal market do not always mesh well with its collective social and health policies or the health systems of its Member States. This is apparent not only in the context of external trade, but as well with respect to internal policies. The challenges of maintaining policy space for health apply at both the EU level (e.g., food security, standard-setting) and in national policy spaces with respect to the governance and financial sustainability of national health systems. While some accommodations can be made within EU policies in order to maintain governments' ability to plan for and maintain capacity within their health systems in the areas of government procurement service provision, this 'wiggle room' can be lost as part of trade policies.

³⁷ A Mattoo and R Rathindran, 'How health insurance inhibits trade in health care' (2006) 52(2) *Health Affairs* 358.

³⁸ Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part [2008] OJ L289/I/3.

³⁹ Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part [2011] OJ L127/1.

⁴⁰ OECD, 'Trade in health services', in OECD, *Health at a Glance: Europe 2012* (OECD Publishing 2012).

Policy space for health can be defined as the ‘freedom, scope, and mechanisms that governments have to choose, design and implement public policies to fulfil their aims’.⁴¹ Trade agreements restrict this policy space as part of the negotiation process. The further and deeper trade-related obligations reach into national policies, the greater their impact upon policy space for health tends to be. This has become reflected, in particular, in the focus on exceptions and exclusions aiming to protect health policy space and by debates emphasising the right to regulate for health.

III. THE ROLE OF GENERAL AND HEALTH AND PUBLIC SERVICES EXCLUSIONS IN THE CONTEXT OF NEW-GENERATION TRADE AGREEMENTS AND TRADE LAW

Exceptions in trade policy are of importance for health systems both in the context of EU internal markets as well as in relation to the negotiation of trade agreements themselves. Policy space for health is shaped by the necessity of maintaining existing policy space under internal market and treaty obligations, including for measures on sustainable financing of health systems and government procurement, and also of ensuring that trade negotiations do not expose national legislation to additional measures, such as requirements for investment protection in all sectors.

In practice, exceptions for healthcare are based on general exceptions in the core of trade agreements and specific exclusions as part of Member State schedules. General exceptions for services are usually based on GATS Article 1.3, which applies to services chapters. Chapters of trade agreements regarding financial services usually have a similar exclusion for social security. This general exception is particularly important in States where private actors are involved as part of a national social security system. The GATS Article 1.3 exclusion is, however, drawn very narrowly, and does not include services in competition with publicly-provided services. This narrow definition is problematic, as described by Arena:⁴²

if governmental services under Article I:3(b) GATS are identified exclusively by reference to the two negative criteria in Article I:3(c) GATS, virtually all public services could be subject to the GATS, thus making the exemption meaningless.

Practically every health system has some element of competition between public and private services, so this principle, if not qualified, could make the healthcare exception almost meaningless.

Another route to exclusion is through specific schedules, which can be based on positive listing (in the GATS agreement, for example) or negative listing (such as in the CETA agreement). The EU has, for example, included an EU-level general exclusion for health services receiving any public funding. However, this exclusion covers only ‘sensitive’ services and not all public services. The positive news in terms of policy space is that this new exclusion is broader than previous EU exclusions for public utilities as it covers all modes and ‘any measures’, however, it also allows the European Commission to change what is included under this exclusion for health services. As complexity in trade agreements has increased, what has been excluded under Annexes may become

⁴¹ M Koivusalo, T Schrecker and R Labonté, ‘Globalization and Policy Space for Health and Social Determinants of Health’ in R Labonté and others, *Globalization and Health: Pathways, Evidence and Policy* (Routledge 2009).

⁴² A Arena, ‘The GATS notion of public services as an instance of intergovernmental agnosticism: comparative insights from EU supranational dialectic’ (2011) 45(3) *Journal of World Trade* 489, see as well M Krajewski ‘Public Services Exemptions in EU free trade and investment agreements’ in M Krajewski (ed), *Services of General Interest Beyond the Single Market* (Springer 2015).

undermined on the basis of textual provisions in other chapters or provisions that define whether exclusions apply and how they are applied.⁴³ The case of investment liberalisation is of importance as foreign investors already in a Member State can gain access to investor-State-dispute settlement if national regulations put foreign investors in less competitive positions than their domestic counterparts.⁴⁴ To date, foreign investors have often been deterred by the strength and complexity of healthcare regulation, so giving them extra-territorial means to challenge regulations could change both relevant markets and policy space.

In addition, excluding health services is useful only if it gives additional policy space for governments to act in the future – preserving the status quo is not enough. Particularly challenging are circular statements sometimes found in trade agreements that bind the right to regulate to compliance with provisions of the negotiated agreement as these are of little value in providing more policy space and merely state the obvious.

The emphasis in these agreements and public statements on not lowering existing standards is relevant, but slightly compromised by the fact that trade agreements tend to be based on existing legislation in any case. The real policy space issues emerge when governments seek to impose new measures, that are more trade- and investment-restrictive than anticipated or in other countries or intentionally or unintentionally put foreign providers or investors in a worse competitive situation than local service providers or investors. It is not that hard to write trade law that freezes existing policies; it is harder to write trade law that preserves policy space for future policies. Bearing this in mind, the next section reviews the new generation of trade agreements currently under negotiation.

IV. THE STATE OF CURRENT TRADE NEGOTIATIONS: SHAPING THE WAY FORWARD

IV.i Current Trade Negotiations and their Likely Impact on Health

Driven by the EU's severe economic problems, the consequent need to preserve political unity among its Member States, and perceived competition from other big global markets such as China, the EU has negotiated a series of large trade deals with key partners. These include the EU-Canada Comprehensive Trade and Economic Agreement (CETA), the Transatlantic Trade and Investment Partnership Agreement (TTIP) and the Trade in Services Agreement (TiSA). All three of these agreements are likely to be considered 'mixed' agreements for the purposes of ratification. They are all considered as 'new generation' trade agreements, covering not only tariffs and trade in goods, but also trade in services, investment and other areas of regulation. As part of a new generation of

⁴³ A suitable example is the EU services proposal for TTIP negotiations as Member State exclusions no longer apply to operational aspects of national treatment of investors, which now cover only establishment. Without further discussion Member States have given foreign investors within the country a substantial advantage as they will have access to investor-State-dispute settlement if national treatment obligations are breached. Commission, 'Transatlantic Trade and Investment Partnership: Trade in Services, Investment and E-Commerce' (Proposal for Discussion 12–17 July 2015).

⁴⁴ *ibid*, this draws from the Articles concerning the scope of investment protection. See Commission, 'Transatlantic Trade and Investment Partnership: Trade in Services, Investment and e-Commerce: Chapter II – Investment' (Commission TTIP Draft Text, made public 12 November 2015) and Commission, 'Comprehensive Economic and Trade Agreement (CETA) Between Canada, of the One Part, and the European Union' (Consolidated Text) <http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf> accessed 20 June 2016.

agreements that will impact all future negotiations, their importance goes way beyond their current structure and substantive content.

IV.i.a The EU-Canada Comprehensive Trade and Economic Agreement (CETA)

The EU-Canada Comprehensive Trade and Economic Agreement (CETA)⁴⁵ was the first fully-negotiated new-generation trade agreement to introduce negative listing for excluded services as well as negotiation on investment protection. From the perspective of European health systems, potential implications from CETA arise from both of these features.

Canadian negotiators made a commitment not to include health and social services under the agreement, as reflected in the scope of the exclusion of health services from investment liberalisation and from domestic regulation under CETA. However, this is not the case in relation to investment protection, where the agreement's provisions cover health services. In practice, the governments were also restricted by their past commitments as part of scheduling services under WTO General Agreement on Trade in Services as CETA negotiations built on and expanded what had already been agreed to under WTO.

A crucial aspect of CETA for EU Member States is thus whether investment protection and investor-State-dispute settlement should be part of the agreement. CETA has also been seen as the 'Trojan horse' agreement – bringing in investment protection by stealth under the guise of an ordinary trade agreement. The EU's recent public consultation on investment protection, which made headlines for the scale and negativity of the responses, focused on CETA provisions.⁴⁶ The EU has since negotiated a similar investment chapter as part of the EU-Singapore Free Trade Agreement. This includes investment protection as well as extensive provisions for investment liberalisation, suggesting that pushing liberalisation to cover all foreign investment within countries (national treatment) is on the European Commission's offensive, rather than defensive agenda. It seems, in other words, that the Commission views the economic advantages of investment liberalisation as outweighing potential threats to internal EU public policies.

CETA is not expected to have substantial implications for the EU in other fields of negotiation, but the agreement has also gained less scrutiny in other aspects. Regarding medicines, the agreement has implications for Canada due to the increased delay of entry of generic medicines to Canadian markets and no possibility of imposing a requirement for innovativeness as part of data exclusivity requirements.⁴⁷ While, from a public health point of view, the EU could have applied Canadian measures to limit the cost of medicines, such liberalisation is not the direction of travel.

CETA will remain particularly influential on future trade policy due to its inclusion of negative listing and investment protection, but also because the European Commission negotiated a

⁴⁵ CETA agreement has been negotiated and was signed on 30 October 2016. It will need to be ratified by all Member States and approved by the European Parliament. As a result of several Belgian sub-national parliaments threatening to veto the deal, further requirements were made. These included, inter alia, that the European Court of Justice should assess the compatibility of the Investment Court System (ICS) with European law.

⁴⁶ The consultation received almost 150,000 replies, of which 97% were negative, leading to recognition by Commissioner Malmström that 'The consultation clearly shows that there is a huge scepticism against the ISDS instrument'. Commission, 'Report presented today: Consultation on investment protection in EU-US trade talks' (European Commission, 13 January 2015) <http://europa.eu/rapid/press-release_IP-15-3201_en.htm> accessed 20 June 2016.

⁴⁷ J Lexchin and MA Gagnon, 'CETA and Pharmaceuticals: impact of the trade agreements between Europe and Canada on the costs of prescription drugs' (2014) 10(1) Global Health 30.

new version for an investment court system as part of the CETA investment protection provisions in late stages of negotiations.⁴⁸ The EU claims that this new multilateral investment court system, though yet to be constituted, would be more permanent and adhere to a better code of ethics, addressing some of the common complaints targeted at existing ad hoc, secretive investor-State dispute settlement mechanisms.⁴⁹

IV.i.b The Trade in Services Agreement (TiSA)

Receiving far less scrutiny to date is the Trade in Services Agreement (TiSA), which is currently being negotiated by the EU and 22 other members of the WTO. The agreement seeks to extend the General Agreement on Trade in Services (GATS) in a number of service areas, and is likely to form the global template for rules governing trade in services, since once it is complete other countries will be encouraged to participate. The countries included under TiSA negotiations are diverse, ranging from Pakistan to the US. It is likely that TiSA negotiations will also form the basis for TTIP negotiations on services. Little is known publicly about the content of the negotiations, however, we do know that Turkey proposed to include trade in health services, including patient mobility and the portability of health insurance, on the TiSA agenda in a document that was leaked in 2014.⁵⁰

The EU has already expanded mode 2 commitments (which cover patient mobility and health tourism) for privately-funded health services in the EU-Caribbean and EU-Korea Free Trade Agreements. The inclusion of health tourism under trade agreements creates a concern also for the TTIP as the only restriction that US has made under GATS applies to reimbursement of costs from health tourism,⁵¹ and a number of EU Member States have not excluded health tourism at all in WTO negotiations. The extent to which the European Commission can negotiate in the area of patient mobility is likely to define how and on what basis this will be negotiated and dealt with under TiSA and TTIP.⁵² It is important to note that obligations with respect to national treatment in services trade are made in the context of the comparative competitive positions of foreign and domestic industry rather than the content of legislation as such. Under national treatment provisions, trade-related considerations generally extend to legislation which is the same (de jure) for foreign and national providers, but may put foreign providers in competitive disadvantage (de facto). The GATS dispute settlement case under the WTO on anti-gambling laws in the US implies that banning a service could also become understood as a market access quota of zero, and thus become incompatible with trade policy commitments.⁵³ This is a slightly different concept of non-discrimination than the equivalent found in much EU law, and one that is more favourable to foreign investors in the regulated industry.

⁴⁸ This was done during so-called legal scrubbing and released on 29 February 2016, Commission, Consolidated CETA Text (n 44).

⁴⁹ H Jarman, 'Public Health and the Transatlantic Trade and Investment Partnership' (2014) 24(2) European Journal of Public Health 181.

⁵⁰ Wikileaks, 'TiSA Market Access – Turkey' (Wikileaks, 2015) <<https://wikileaks.org/tisa/market-turkey/>> accessed 20 June 2016.

⁵¹ United States International Trade Commission, 'US Schedule of Commitments Under the General Agreement on Trade in Services' (Investigation No 332–354, 1998).

⁵² This is currently negotiated on behalf of Member States. However, considering that the Commission is enhancing the implementation of the patient directive and mobility of patients, it is likely that taking up this competence more strongly as part of trade policies may be restricted more on the ground of political, rather than legal or jurisdictional matters.

⁵³ On US-Gambling see, for example, F Ortino, 'Treaty Interpretation and the WTO Appellate Body Report in US-Gambling: A Critique' (2006) 9(1) Journal of International Economic Law 117.

TiSA negotiations also include proposals on like treatment of mutualities (mutual societies).⁵⁴ The role of mutualities, public-private partnerships and non-profit organisations in service provision as well as requirements for local contracts or presence may come to be affected by trade negotiations as well as government measures seeking to restrict or limit profiteering. While investment protection is likely to be the main context for profit-related matters, negotiations on trade in services may also push towards commercialisation through imposition of the same regulatory context to all healthcare providers irrespective of their background and focus. There are particular questions with respect to domestic regulation in trade agreements such as TiSA which can be drawn to the potential and scope of excluding a public 'option' on the basis of domestic regulation. Doing so involves fulfilling related criteria on 'impartiality' or through explicit reference of government roles as complementary and residual as has been made in the context of some TiSA negotiation proposals in other services areas (postal services).⁵⁵

Although TiSA negotiations have not included investment protection provisions or investor-State dispute settlement mechanisms, it does include a push towards expanding inclusion of services through horizontal inclusion of national treatment and negotiations on intra-corporate personnel transfers and activities.⁵⁶ The role, transparency and mobility of data is a matter for TiSA negotiations. Data governance is likely to have implications for health systems, privacy and access to information, yet is unlikely to be discussed under health services restrictions. TiSA also includes negotiations on government procurement and financial services, which are likely to have implications for health services. In contrast to TTIP, the broad participation of countries in TiSA brings up concerns over different regulatory contexts in healthcare as well as potential consequences from health tourism such as the spread of antimicrobial resistance across healthcare systems for countries where multi-resistant strains have been found in their healthcare systems.⁵⁷ While the 'portability' of health insurance or mobility of patients could be seen as part of the European Commission's agenda, it is clear that the consequences of insurance portability and patient mobility could have implications for the sustainability of financing of healthcare, which is clearly a Member State competence.

IV.i.c The Transatlantic Trade and Investment Partnership (TTIP)

TTIP is the most comprehensive of the trade agreements currently under negotiation, with the broadest regulatory implications for health systems. While the EU and US both represent high-income populations, their health systems differ substantially in terms of their financing and organisation. Services negotiations under TTIP will build on what is agreed under TiSA. However, it is generally assumed that the greatest implications from TTIP for health systems will result from its intellectual property rights (IPR) provisions, pharmaceutical pricing policies and investment protections. Under TTIP's IPR provisions, further implications could emerge from potential trade secret provisions already under discussion within the EU.⁵⁸ Biologicals and issues with respect to biosimilars can become important for access to medicines, but some aspects of negotiations such as Good Manufacturing Practice inspections for drugs and devices producers are more geared towards addressing third parties. However, as a result of sensitivities and scrutiny around pharmaceuticals and

⁵⁴ Commission, 'TiSA Schedule of Specific Commitments & List of MFN Exemptions' (EU Initial Offer, September 2013).

⁵⁵ *ibid.*

⁵⁶ One of the negotiation areas is mode 4, where there are a number of categories of which mobility of intra-corporate transferees is most likely to proceed as part of negotiations.

⁵⁷ K Kumarasamy and others, 'Emergence of a new antibiotic resistance mechanism in India, Pakistan, and the UK: a molecular, biological, and epidemiological study' (2010) 10(9) *The Lancet Infectious Diseases* 597.

⁵⁸ Commission, 'Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure' COM (2013) 813 final.

pricing policies, it is possible that more controversial aspects could come to be negotiated under other more general provisions, such as State-owned enterprises, regulatory cooperation, transparency or investment protection.⁵⁹ This being said, to the extent that the US and EU emphasise joint presentation of views and participation in regulatory forums and discussions, there will be limited scope for the EU to depart from US stances on pharmaceuticals in other global forums such as the World Health Organisation, United Nations or WTO.⁶⁰

Pharmaceutical pricing in the EU is also likely to be affected by TTIP negotiations. A crucial issue with respect to EU policies is to what extent negotiations will apply to pharmaceutical policies, reimbursement and pricing in Germany, where opposition to TTIP is higher than in many other countries.⁶¹

TTIP is likely to affect health systems through liberalisation of investment and in some Member States also as part of trade in services. If trade law on government procurement includes health services and government procurement provisions override exclusions as part of Annexes, this will have implications for health systems. Requirements for competition and pro-competitive regulation will have implications for health systems if regulatory cooperation and competition chapters cover all services and national policies. If the chapter on State-owned enterprises apply to all services, it will constrain regulation and organisation of public-private partnerships and publicly-funded organisations and institutions, when these operate in competition with commercial providers or engage with commercial activities, and can have major consequences for health systems.⁶² Underlining the connection between internal and external markets in the EU, it is likely that some issues to be negotiated, such as those related to standardisation, professional mobility or regulatory cooperation, will be initially discussed as part of the EU's new internal market strategy.⁶³

TTIP focuses heavily on regulatory cooperation, seeking to establish a new transatlantic regulatory dialogue between the EU and US.⁶⁴ Negotiations will apply to 'technical barriers to trade' (which often look like public policies to those who do not share the deregulatory perspective of trade lawyers) and sanitary and phytosanitary measures. The emphasis of the regulatory dialogue will be on procedural issues, rather than standard-setting as such. Nevertheless, by seeking to define onerous measures and make the regulatory environments of the EU and US more similar, as well as by including requirements to seek the views and presence of stakeholders before regulatory measures can be taken, any new dialogue may well restrict the capacity of governments to regulate alone.

TTIP also contains a new article on animal production and antibiotic resistance. While the inclusion of this article can be seen as a means of enhancing best practices for antibiotics use in animal production,⁶⁵ it can also be seen as legitimating the use of antibiotics in animal production in

⁵⁹ As the TTIP consolidated text and negotiation reports are not publicly available, this may not be confirmed.

⁶⁰ There is no reason to assume that the European Commission's future positions would be less industry-friendly than those of the US – although this has often been the case in practice, the Commission's stance towards industry has evolved over time.

⁶¹ Germany and Austria have been most critical towards the proposed TTIP agreement.

⁶² As the TTIP consolidated text is not publicly available, it is not possible to confirm this.

⁶³ These have been raised both in the context of external trade negotiations as well as in relation to the EU's new internal market strategy.

⁶⁴ F De Ville and G Siles-Brugge, *TTIP: The Truth about the Transatlantic Trade and Investment Partnership* (Polity 2016).

⁶⁵ Commission, 'EU proposal to include an article on Anti-Microbial Resistance within the SPS Chapter of TTIP' (2015).

Member States, where this has been banned. Furthermore, there is already EU-USA cooperation under the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) in relation to treatment policies.⁶⁶ There is thus a risk that overly-close cooperation could limit the scope of the EU's support for global measures and governance with respect to antibiotic resistance.

TTIP's intellectual property rights negotiations will also have implications for health systems, but the actual relevance of those sections of TTIP to health will be difficult to assess until a text is available. The likely impact from further enhancement of IPR protection would be reflected in the form of delay of entry of generics to EU markets. This would imply increased costs of new medicines. While no account of what has been negotiated so far has been made public, it is likely that some aspects would follow similar provisions in the Trans-Pacific Partnership (TPP), a trade deal recently concluded among 12 Pacific Rim countries, including the US.⁶⁷ Trade secret and transparency provisions may have implications to access to knowledge and governance, including with respect to clinical trials, where European measures to enhance transparency were highlighted in the influential US pharmaceutical industry report for the US Trade Representative in 2013.⁶⁸ However, the most controversial concern about the negotiation is with investment protection and arbitration measures.

IV.ii Investment Protection, Arbitration and Ongoing Legal Uncertainty

Investment protection remains the most controversial part of trade and investment agreements because investors can claim compensation from governments through private arbitration panels. Even if the investors lose, the cost of a case can be a deterrent to strong regulatory policy for poorer countries, and the extra hurdles it creates can slow policymaking anywhere. The need for investment arbitration between high income countries – where domestic courts likely provide transparent and fair means of redress – can also be questioned. Investment arbitration evolved as a way to protect foreign investors from the kinds of expropriation and nationalisation found in countries with a less pro-capitalist politics or a weaker rule of law, not as a way to challenge any regulations that interfere with a given investment's profitability, yet this is how some companies would like to characterise such mechanisms.

The role of investment protection in relation to European health law remains so far limited. However, the potential for further implications for national health law as well as more restrictive changes under EU health law could be substantial. It is anticipated that one of the main implications would arise from 'regulatory chill' as a result of claims and threat of claims as part of policy process. This is relevant, in particular, for public health measures, health promotion and health protection. The most well-known cases to date are against tobacco control measures in Australia and Uruguay, where tobacco firms launched investment disputes using bilateral investment treaties despite simultaneously pursuing their respective cases in domestic courts.⁶⁹ Although not currently subject to legal arbitration,

⁶⁶ European Union and United States, 'EU-US Summit Declaration' (3 November 2009) (The establishment of TATFAR).

⁶⁷ On implications from the TPP for access to medicines and pricing, see BK Baker, 'Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere' (2016) *PLoS Medicine* 13(3) e10011970 DOI: 10.1371/journal.pmed.1001970 <<http://dx.doi.org/10.1371/journal.pmed.1001970>> accessed 20 June 2016.

⁶⁸ Pharmaceutical Research and Manufacturers of America (PhRMA), 'Special 301 Submission' (2013).

⁶⁹ In both instances, the firms then lost the domestic cases. In *Philip Morris Asia Ltd v The Commonwealth of Australia*, UNCITRAL, PCA Case No 2012–12, Award (17 December 2015), the panel decided it had no jurisdiction to hear the claim. *Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v Oriental Republic of Uruguay*, ICSID Case No ARB/10/7 is still ongoing. See H Jarman, *The Politics of Trade and Tobacco Control* (Palgrave 2015); H Jarman, 'Attack on Australia: Attack on Australia: Tobacco Industry Challenges to Plain Packaging' (2013) 34(3) *Journal of Public Health Policy* 375.

similar issues exist with respect to alcohol policies and alcohol control. This is the case for both CETA and TTIP, as both Canada and the US maintain alcohol restrictions.⁷⁰

A number of other high-profile international arbitration cases (and corresponding cases in the highest domestic courts) currently contribute to the climate of political and legal uncertainty around trade and health issues in the EU. One of the cases is the so-called Micula-Brothers case, which is likely to have directly contributed to the explicit exclusion of subsidies from investment protection.⁷¹ There are several arbitration cases that are of relevance to health systems. These have been applied to government decisions to withdraw or limit privatisation. Achmea (Eureko) challenged Poland when the government withdrew from privatisation plans and Poland was required to compensate.⁷² Slovakia was challenged by the same company due to its requirement that in publicly-financed health insurance services the returns should be invested back into healthcare system.⁷³ However, the company lost a third case where it sought to influence the legislative process on the ground that it had no case as no legal action has taken place yet.⁷⁴ These specific cases are, under investment agreements, signed before EU accession and should be phased out since there is no space in EU law for bilateral investment treaties between Member States. Nonetheless, the cases show some of the options that bilateral investment treaties create for investors dissatisfied with government measures. In the light of commercialisation and contractualisation of healthcare systems across European countries it is likely that government efforts to contain costs could become a focus for investment arbitration, if these measures seriously limit the returns expected to be gained from the investment or end up putting foreign investors in a different position compared to local public, non-governmental or other forms of operators, such as mutualities.

Health systems spend substantial amounts on medicines and new health technologies. This implies that decisions concerning ICT and data systems, medical technologies and medicines are a potential focus for arbitration simply due to the fact that public contracting and spending is of crucial importance to respective markets and that these markets do involve health systems in practice. Particular attention should be drawn to intellectual property rights and approval, and reimbursement of new medicines. Eli Lilly has already challenged a Canadian court decision in the field of medicines.⁷⁵ In the Trans-Pacific Partnership, specific wording concerning medicines was established and clarified for investment protection provisions. It indicates major potential for claims in the field.⁷⁶

⁷⁰ On the relationship between alcohol control and trade, see DW Ziegler, 'The alcohol industry and trade agreements: a preliminary assessment' (2009) 104(s1) *Addiction* 13; T Babor and others, *Alcohol: No Ordinary Commodity* (1st edn, OUP 2003).

⁷¹ The Micula-Brothers case involved investor arbitration between Sweden and Romania on the basis of withdrawal of regional subsidies, which was a requirement for Romania as part of joining the EU. EU right to regulation proposals now make explicit that State subsidies are not affected by investment protection. See, Ioan Micula, Viorel Micula, S.C. European Food S.A, S.C. Starmill S.R.L. and S.C. Multipack S.R.L. v Romania, ICSID Case No ARB/05/20, Award (11 December 2013).

⁷² *Eureko B.V. v Republic of Poland*, ad hoc Partial Award (19 August 2005).

⁷³ *Achmea B.V. v The Slovak Republic*, UNCITRAL, PCA Case No 2008-13, Award (7 December 2012).

⁷⁴ *Achmea B.V. v The Slovak Republic*, UNCITRAL, PCA Case No 2013-12 (Number 2), Award (18 December 2014).

⁷⁵ *Eli Lilly and Company v The Government of Canada*, ICSID Case No UNCT/14/2 (Ongoing)

⁷⁶ Office of the United States Trade Representative, 'TPP Full Text', Chapter 9 – Investment (Office of the United States Trade Representative) <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> accessed 20 June 2016.

The European Commission has sought a new Investment Court System as part of TTIP and CETA negotiations.⁷⁷ However, the proposed system does not solve essential problems in relation to health policies and may, in fact, create new problems. An early version of the TTIP right to regulate introduced the word necessary, which is tied more to obligations of not restricting trade or investment.⁷⁸ However, it has now been removed from the CETA version.⁷⁹ While what is proposed as part of CETA agreement, in particular, is an improvement on the previous version, it is, however, not sufficient to remove problems and concerns with respect to compensation claims.⁸⁰ What is suggested by the European Commission does not limit scope for compensation claims in other areas than State subsidies and, from a health policy perspective, does thus not provide the watertight solution it seeks to introduce.

V. CONCLUSIONS

Trade and health provide many important examples of the interactions between political will and legal frameworks. The architects of the Lisbon Treaty were keen to confer exclusive competence on the EU institutions to negotiate agreements on trade in services, including trade in health services. Yet objections to establishing liberalised markets in health services from Member State governments, the public and health policy advocates resulted in a number of legal caveats and political workarounds being introduced. Furthermore, while recent treaty changes have made it more difficult for Member States to veto trade agreements, the ability of the European Parliament to disrupt the conclusion and ratification of trade agreements has increased.

The European Commission's efforts to provide negotiation documents for public consumption is a positive move beyond managed consultations with a limited number of civil society groups. However, this does put the Commission under more scrutiny in terms of what is promised and delivered. In this context, problems clearly emerge in the field of financial services, investment, intellectual property rights and investment protection.

The latest generation of trade agreements needs to be seen as a new framework with a purpose of shaping how governments can regulate to protect and promote health. The most crucial aspects of the negotiations do not apply to changes in current standards or maintaining current policies, but to the policy space for health in the future. Furthermore, the public need to know what is meant by EU officials when they speak of their intention to maintain high standards of regulation in areas such as health. In this regard, actual textual provisions achieved as part of negotiations are more important than aspirational statements, letters and reassurances.

⁷⁷ Commission, TTIP Draft Text (n 44); Commission, Consolidated CETA Text (n 44).

⁷⁸ G Van Harten, 'Key Flaws in the European Commission's Proposals for Foreign Investor Protection in TTIP' (Osgoode Legal Studies Research Paper No 16/2016, 2015).

⁷⁹ Commission, Consolidated CETA Text (n 44).

⁸⁰ Right to regulate provisions continue to allow for compensation claims on the basis of respective articles. While panels of the international court system can take into account aspects of right to regulate in their judgments, current provisions do not change the fundamental problems of investor protection in shifting decision-making to less transparent and democratic forums or its bias towards investor benefits without obligations. See, for example, G Van Harten and DN Scott, 'Investment Treaties and the Internal Vetting of Regulatory Proposals: A Case Study from Canada' (2016) 7(1) *Journal of International Dispute Settlement* 92; G Van Harten, 'Five justifications for investment treaties: a critical discussion' (2010) 2(1) *Trade, Law & Development* 1.

In addition to a more traditional trade context with the focus on market access or tariffs, the TTIP negotiations, in particular, have a more ideological focus on creating a market- and investor-driven regulatory environment. The architects of the agreement see an expanding role for markets and investors, and a more contested and limited role for public services and government interventions. While these negotiations can be seen to take place in parallel to how the EU and US govern their internal markets, the ideological shift is shaped further by the particular aspects of the internal policy process within the US and the EU.

The WHO Director-General has warned Ministries of Health in the TPP context that if they are not at the negotiation table, they will be on the menu.⁸¹ The message to EU Member States responsible for the financing of healthcare systems should be the same. The European Commission has so far failed to convince the public and concerned advocates that trade negotiations will not affect national health systems and their financing. This could have been possible and entirely in the scope of negotiations, but it was not the political choice of the Commission to do so in relation to investment liberalisation, investment protection or explicit exclusion of social security and pension systems from financial services.

On the other hand, the Lisbon Treaty leaves scope for Member States to use their powers to apply political pressure and to veto on the basis of implications of negotiations to the organisation and financing of their healthcare systems. Furthermore, it is also possible that crucial decisions concerning health systems and trade negotiations are taken at European level as part of European Parliament scrutiny, rather than national level. The ultimate fate of the new generation of trade agreements may well be determined by political will as much as by legal frameworks.

⁸¹ M Chan, 'Keynote address to the Regional Committee for the Western Pacific, Sixty-fourth session Manila, Philippines' (Manila, 21 October 2013).

18. The EU's (emergent) global health law and policy

Tamara K Hervey

I. INTRODUCTION

Research in EU health law has largely focused on the *internal*: how EU health law operates *within* the EU. Without overstating the EU's capacity to engage in global health law and policymaking, this chapter, along with the previous chapter, takes the position that the EU's *external* or *global* health law and policy is becoming increasingly important,¹ and tracks some of its substantive and conceptual effects.

The first holistic treatment of the EU's external or global health law is in Hervey and McHale's *EU Health Law*.² That analysis brings together, in a thematic discussion, disparate areas of outward-facing EU health law, which are also among the topics that make up global health law. In a sense, therefore, Hervey and McHale define EU global health law, with a wide substantive focus: (non-exhaustively) medical tourism; communicable disease transmission; public health threats from globally traded products; regulation of global markets in pharmaceuticals and medical devices; global clinical trials regulation; global trade (and foreign direct investment) in health services; health professional migration; access to essential medicines; and the 'right to health'.

The concept of 'global health law' probably emerged at around the same time as the popularisation of the word 'globalisation', in the 1980s.³ While there is no fixed understanding of 'global health law', its core focus is both 'hard' and 'soft' international law which 'shapes norms, processes and institutions to attain the highest possible standards of physical and mental health for the world's populations'.⁴ A central plank of 'global health law' is global human rights law.⁵ Closely connected to global ethics, and justice,⁶ those who

¹ The EU is not a particularly powerful global health actor, see TK Hervey and JV McHale, *European Union Health Law: Themes and Implications* (CUP 2015) 530–1. Contrast policy areas such as security and defence, energy or the environment. There are significant gaps in the EU's external health law, such as the lack of EU law directly and explicitly concerned with global trade in human organs, Hervey and McHale 483.

² Hervey and McHale (n 2) 433–532.

³ M Freeman, 'Global Health: An Introduction' in M Freeman, S Hawkes and B Bennett (eds), *Law and Global Health: Current Legal Issues Volume 16* (OUP 2014); see also: LO Gostin, *Global Health Law* (Harvard University Press 2014); T Murphy, *Health and Human Rights* (Hart 2013); IG Cohen (ed), *The Globalisation of Healthcare: Legal and Ethical Issues* (OUP 2013); CM Flood and T Lemmens, 'Global Health Challenges and the Role of Law' (2013) 41(1) *Journal of Law, Medicine and Ethics* 9.

⁴ Gostin (n 3) 59.

⁵ TW Pogge, 'Human Rights and Global Health: A Research Program' (2005) 36(1–2) *Metaphilosophy* 182; J Harrington and M Stuttaford (eds), *Global Health and Human Rights: Legal and Philosophical Perspectives* (Routledge 2010); Gostin (n 3); P Eleftheriadis, 'Global Rights and the Sanctity of Life' in Cohen (n 3); M Stuttaford, J Harrington and G Lewando-Hundt, 'Sites for health rights: Local, national,

conceive global health law in this way focus on matters such as access to healthcare, and to essential medicines,⁷ and so consider institutional design and economic resourcing of health systems, as well as the ethics of medical research.⁸ A second central building block of global health law is the many ways in which the global trading system affects health, given the relationships between economic development and health.⁹ These aspects of global health law are wide ranging. They include the obligations of developing and least-developed countries ('the global South') which are supported by mechanisms such as those of the IMF and World Bank. They cover the free trade conditionality of access by traders in those countries to markets in the developed world, for instance expressed through legal instruments overseen by the World Trade Organisation (WTO). Such bigger picture legal concepts are supplemented and supported by detailed, sector-specific, international instruments covering trade in organs, human tissue and cells, human blood;¹⁰ pharmaceuticals¹¹ and medical devices; and products

regional and global' (2012) 74(1) *Social Science and Medicine* 1; L London and H Schneider, 'Globalization and health inequalities: Can a human rights paradigm create space for civil society action?' (2012) 74(1) *Social Science and Medicine* 6; JM Mann and others, 'Health and Human Rights' (1994) 1(1) *Journal of Health and Human Rights* 6; CA Toebes, 'The Right to Health', in A Eide, C Krause and A Rosas (eds), *Economic, Cultural and Social Rights* (2nd edn, Martinus Nijhoff Publishers 2001); CA Toebes, *The Right to Health as a Human Right in International Law* (Intersentia 1999).

⁶ See, eg, MJ Sandel, *What Money Can't Buy: The Moral Limits of Markets* (Allen Lane 2012); JP Ruger, *Health and Social Justice* (OUP 2010); N Daniels, *Just Health: Meeting Health Needs Fairly* (CUP 2008); J Coggon, 'Global Health, Law, and Ethics: Fragmented Sovereignty and the Limits of Universal Theory' in Freeman, Hawkes and Bennett (n 3).

⁷ See, eg, the discussion in: J Harrington, O Aginam and P Yu (eds), *The Global Governance of AIDS: Intellectual Property and Access to Essential Medicines* (Edward Elgar 2012); E Jackson, *Law and the Regulation of Medicines* (Hart 2012) 193–8; J Harrington, 'Access to Essential Medicines in Kenya: Intellectual Property, Anti-Counterfeiting, and the Right to Health' in Freeman, Hawkes and Bennett (n 3).

⁸ See, for instance, discussions of global bioethics governance, such as through the UNESCO Universal Declaration on Bioethics (adopted 19 October 2005); eg, J Montgomery, 'Bioethics as a Governance Practice' (2016) 24 *Health Care Analysis* 3; R Ashcroft, 'The troubled relationship between bioethics and human rights' in M Freeman (ed), *Law and Bioethics* (OUP 2008); R Brownsword, *Rights, Regulation and the Technological Revolution* (OUP 2013). There is also the (unethical) '10/90 gap' – 'health problems which affect 90 per cent of the world's population attract only 10 per cent of the global funding for health research', Jackson (n 7) 191; see: Global Forum for Health Research, 'The 10/90 Report on Health Research' (GCFR 1999). See further Chapter 6 in this book.

⁹ Global health inequalities are related to stages of economic development, as health and poverty are inter-related, although the correlation between poverty and health is not a perfect or direct one. Many studies show that poverty is a key indicator for poor health, and vice versa. For some global research see World Bank, WHO and Voices of the Poor, 'Dying For Change' (c 2001) <<http://siteresources.worldbank.org/INTPAH/Resources/Publications/Dying-for-Change/dyifull2.pdf>> accessed 21 June 2016; for European examples see, WHO, *Poverty, Social Exclusion and health systems in the WHO European Region* (WHO Europe 2010); and WHO, *Poverty and Social Exclusion in the WHO European Region: health systems respond* (WHO Europe 2010).

¹⁰ See, eg, the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (adopted 4 April 1997, entered into force 1 December 1999) CETS 164, Article 21, and Council of Europe Protocol on Transplantation of Organs and Tissues of Human Origin (adopted 24 January 2002, entered into force 1 May 2006) CETS 186; Council of Europe Convention against Trafficking in Human Organs (adopted 25 March 2015) CETS 216.

that have important effects on the health of populations (in particular food, chemicals, alcohol and tobacco).¹²

All of these key aspects of global health law (trade, development, human rights) are also important aspects of the EU's external relations law. The focus for this chapter is therefore those substantive areas. To set the scene, the chapter first explains a little more about the legal and institutional architectures within which EU external health law and policy is developed. For more detail on the trade aspects, readers are referred to Chapter 17.

II. INSTITUTIONAL ARCHITECTURES

Literature on the institutional architectures of global health law, particularly its trade and human rights aspects, tends to focus either on the institutions supporting global health law's notion of the 'right to health', or on those supporting global trade as it affects health, particularly in populations on the global South. Institutions supporting global development are often subsumed within one or the other, especially the latter.

This is also true of the literature on aspects of EU external health law and policy. It is not surprising. The European Commission's attempt to bring the two together in its 2010 Communication *The EU Role in Global Health*¹³ proved over-ambitious. Rather, the EU's external health law and policy has continued to be developed, in the main, through the distinctive institutional architectures that support EU external trade law and policy, EU development law and policy, and EU external human rights law and policy. This is reflected, for instance, in the rotating chair of the European Commission's Global Health Forum, which is organised by the DGs for Health and Consumers, Development and Cooperation, and Research and Innovation, in turn.¹⁴

The general context for the EU's external health law and policy is as follows. The EU has international legal personality.¹⁵ It is party to hundreds of international treaties, some of which are concluded by the EU acting on behalf of its Member States (where the EU has 'exclusive competence'), many of which are concluded by the EU and its Member States

¹¹ See, eg, instruments adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which was launched in 1990 as a joint regulatory/industry project to make new pharmaceutical development and registration processes more efficient in the interests of patients, public health and cost-effectiveness.

¹² See, eg, the WHO Framework Convention on Tobacco Control (adopted 21 May 2003, entered into force 27 February 2005) 2302 UNTS 166; or the WHO and UN Food and Agricultural Office's *Codex Alimentarius* Commission established in 1963.

¹³ Commission, 'The EU Role in Global Health' (Communication) COM (2010) 128 final.

¹⁴ Commission, 'Global Health Policy Forum in 2014' (*European Commission*, 21 February 2014) <http://ec.europa.eu/health/eu_world/global_health/events_2014_en.htm> accessed 21 June 2016. Five events took place in 2014, but apparently only one in 2015 and one in 2016.

¹⁵ Consolidated version of the Treaty on European Union [2012] OJ C326/01 (TEU), Article 47.

(known as ‘mixed agreements’).¹⁶ The EU also participates in numerous international organisations. In its global health policy, the EU’s institutional relationships with other actors are those of *cooperation*,¹⁷ representing the non-hierarchical nature of global health law and policymaking.¹⁸

On the trade side, the main international organisations relevant to global health law and policy are the WTO and the UN’s World Health Organisation (WHO). The World Trade Organisation brings together more than 150 countries, and the EU itself, through a series of trading agreements,¹⁹ supported by an institutional infrastructure. The WTO’s infrastructure is among the most highly developed of international organisations, and includes the quasi-judicial arrangements under the Dispute Settlement Understanding, through which WTO members (including the EU) agree to resolve trade disputes. As many trade disputes are about protecting human health, these structures are a central part of the institutional arrangements of EU external health law, and of global health law. However, the position of the WTO as the organising structure for global trade law and policy has been challenged recently by several multi- and bi-lateral trading agreements, in particular the Transatlantic Trade and Investment Partnership (TTIP).²⁰

The WHO is not obviously a trade organisation, but actually many of its activities involve global trade. Many of these concern risks to health through the movements of people, products and/or services in global trading chains. For instance, the WHO’s International Health Regulations cover public health risks and emergencies of international concern.²¹ The EU’s Centre for Disease Prevention and Control works with those systems, for instance, to control migration of health workers as seen recently during the Ebola outbreak in East Africa,

¹⁶ P Eeckhout, *EU External Relations Law* (2nd edn, OUP 2011) 117; B Van Vooren and RA Wessel, *EU External Relations Law: Text, Cases and Materials* (CUP 2014) 55–63. For instance, in Opinion 1/94 *Opinion Pursuant To Article 228(6) of the EC Treaty (WTO Agreement)* ECLI:EU:C:1994:384, [1994] ECR I-5267, the CJEU held that the EU did not at the time have exclusive competence over external trade in services, hence the EU could not join the WTO except through a ‘mixed agreement’.

¹⁷ Consolidated version of the Treaty on the Functioning of the European Union [2012] OJ C326/01 (TFEU), Article 168(3).

¹⁸ Contrast those who argue for a hierarchical ‘global health constitution’, eg, Ruger (n 6); K Buse, L Gostin and E Friedman, ‘Pathways towards a Framework Convention on Global Health: Political Mobilization for the Human Right to Health’ in Freeman, Hawkes and Bennett (n 3); A Krajewska, ‘Bioethics and Human Rights in the Constitutional Formation of Global Health’ (2015) 4(4) *Laws* 771.

¹⁹ General Agreement on Tariffs and Trade (adopted 30 October 1947, entered into force provisionally 1 January 1948) 55 UNTS 194 (GATT); Agreement on Technical Barriers to Trade (adopted 15 April 1994, entered into force 1 January 1995) 1868 UNTS 120 (TBT); General Agreement on Trade in Services (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 183 (GATS); Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299 (TRIPS).

²⁰ See further below.

²¹ See further: Gostin (n 3) Chapter 6; B Von Tigerstrom, ‘The Revised International Health Regulations and Restraint of National Health Measures’ (2005) 13 *Health Law Journal* 35; WHO, ‘Global Crisis – Global Solutions: Managing Public Health Emergencies of International Concern Through the Revised International Health Regulations’ (Revision of the International Health Regulations, WHO 2002).

or the earlier SARS, H1N1 or H4N1 outbreaks.²² The WHO's Framework Convention on Tobacco Control, to which the EU is a signatory, is another example. It seeks to disseminate best practice in tobacco regulation, through a model based on international environmental law.²³

Other important institutions through which EU external health law and policy is developed include the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which seeks to align technical rules for quality, safety and efficacy of novel pharmaceuticals. The pharmaceuticals market is of course a global market. The non-binding ICH guidelines have a 'hard' legal effect in the EU and elsewhere, because EU or national clinical trial or marketing authorisation rules require *de facto* compliance. For trade in food, the *Codex Alimentarius* Commission (a collaboration between the UN's Food and Agriculture Office and the WHO), of which the EU is also a member, determines internationally harmonised standards seeking to secure consumer safety and fair dealing in global food trade.

The international institutional contexts within which EU development law and policy²⁴ unfolds are even more disparate than those for trade. The main EU legislation on development cooperation²⁵ is focused around what are now the UN's Sustainable Development Goals.²⁶ The partnership model, which has been the mainstay of EU

²² See further Chapters 5 and 13 in this book. See European Centre for Disease Prevention and Control (ECDC), 'Partnerships' (ECDC) <<http://ecdc.europa.eu/en/aboutus/Partnerships/Pages/partnerships.aspx>> accessed 21 June 2016; see: SL Greer and M Mätzke, 'Bacteria without Borders: Communicable Disease Politics in Europe' (2012) 37(6) *Journal of Health Politics, Policy and Law* 887; SL Greer, 'The European Centre for Disease Prevention and Control: Hub or Hollow Core?' (2012) 37(6) *Journal of Health Politics, Policy and Law* 1001; HA Elliott, DK Jones and SL Greer, 'Mapping Communicable Disease Control in the European Union' (2012) 37(6) *Journal of Health Politics, Policy and Law* 935; M Liverani and R Coker, 'Protecting Europe from Diseases: From the International Sanitary Conferences to the ECDC' (2012) 37(6) *Journal of Health Politics, Policy and Law* 915; Gostin (n 3) Chapter 12.

²³ See I Kickbusch, 'Foreword' in W Hein, S Bartsch and L Kohlmorgen (eds), *Global Health Governance and the Fight Against HIV/AIDS* (Palgrave Macmillan 2007) xiii. See also: Shibuya and others, 'WHO Framework Convention on Tobacco Control: development of an evidence based global public health treaty' (2003) 327(7407) *British Medical Journal* 154; L Taylor and DW Bettcher, 'WHO Framework Convention on Tobacco Control: a global 'good' for public health' (2000) 78(7) *Bulletin of the WHO* 920; R Roemer, A Taylor and J Lariviere, 'Origins of the WHO Framework Convention on Tobacco Control' (2005) 95(6) *American Journal of Public Health* 936. Contrast Taylor and others, 'The impact of trade liberalization on tobacco consumption' in P Jha and FJ Chaloupka (eds), *Tobacco in Developing Countries* (OUP 2000).

²⁴ Some doubt that 'EU development policy' is even a meaningful category, certainly when it comes to development aid, see the project reported, 'Why we should stop talking about 'European' development aid' *EurActiv* (14 April 2014) <www.euractiv.com/sections/development-policy/why-we-should-stop-talking-about-european-development-aid-301551> accessed 21 June 2016; and the special issue of *European Politics and Society* (Various contributors, 'The Eurasian Project in Global Perspective' (2016) 17 (suppl.1) *European Politics and Society*) on The Europeanisation of Development Policy, which shows only modest levels of Europeanisation of domestic development policy.

²⁵ European Parliament and Council Regulation (EU) 233/2014 of 11 March 2014 establishing a financing instrument for development cooperation for the period 2014–2020 [2014] OJ L77/44.

²⁶ These 17 goals, adopted by 193 UN countries in September 2015, are the successors to the Millennium Development Goals, see UN, 'Sustainable Development Knowledge Platform' (*United Nations*) <<https://sustainabledevelopment.un.org/>> accessed 21 June 2016.

development policy for decades, means that the EU interacts with many State, private and especially ‘third sector’ institutions in pursuing its development policy, often on a project basis. Important examples for EU external health law include the Global Fund to fight HIV/AIDS, Tuberculosis and Malaria, working with the World Bank, WHO and the ‘Global Alliance for Vaccines and Immunisation’, an institutional framework for cooperation between public and private actors.²⁷

But actually the main mechanism for EU development law and policy is trade. This is succinctly expressed, for instance, in the recitals to the Council’s 2010 position on the Commission’s proposed amendment to the 2006 EU Development Cooperation Regulation:²⁸

Whereas:

- (1) The Union’s development policy aims to reduce and ultimately eradicate poverty.
- (2) The Union, as a member of the WTO, is committed to mainstreaming trade in development strategies and to promoting international trade in order to advance development and reduce – and, in the long term, eradicate – poverty worldwide.

So the institutional architecture for EU external trade law and policy also represents at least part of the architecture for EU external development law and policy.

On the human rights side, the key relevant international institutions also operate through the auspices of the UN. The World Health Organisation tends not to express its work in human rights’ terms. But the UN’s various human rights instruments, particularly more recent instruments,²⁹ recognise the ‘right to health’ in several of its different meanings.³⁰ The EU’s own Charter of Fundamental Rights acknowledges these international instruments as sources

²⁷ See Hervey and McHale (n 1) 491, 498; S Bartsch, ‘The Global Fund to Fight AIDS, Tuberculosis and Malaria’ in Hein, Bartsch and Kohlmorgen (n 23); J Clemens and others, ‘Ten years of the Global Alliance for Vaccines and Immunization: challenges and progress’ (2010) 11(12) *Nature Immunology* 1069; S Nwaka and RG Ridley, ‘Virtual drug discovery and development for neglected diseases through public-private partnerships’ (2003) 2 *Nature Reviews Drug Discovery* 919.

²⁸ Council, ‘Position (EU) 4/2011 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1905/2006 establishing a financing instrument for development cooperation Adopted by the Council on 10 December 2010’ [2011] OJ C7E/17.

²⁹ Such as the Convention on the Rights of Persons with Disabilities UNGA Res 61/106 (13 December 2006) UN Doc A/RES/61/106.

³⁰ See, eg, Toebes (1999) (n 5); Toebes (2001) (n 5); B Toebes, ‘Right to Health and Health Care’, *Encyclopaedia for Human Rights* (2009) Vol 2, 365; K Buse, L Gostin and E Friedman, ‘Pathways towards a Framework Convention on Global Health: Political Mobilization for the Human Right to Health’ in Freeman, Hawkes and Bennett (n 3); J Montgomery, ‘Recognising a Right to Health’ in R Beddard and DM Hill (eds), *Economic, Social and Cultural Rights: Progress and Achievement* (Macmillan 1992); A Hendriks, ‘The Right to Health’ (1998) 5 *European Journal of Health Law* 389; J Harrington, ‘Access to Essential Medicines in Kenya: IP, Anti-Counterfeiting, and the Right to Health’ in Freeman, Hawkes and Bennett (n 3); P Eleftheriadis, ‘A Right to Health Care’ (2012) 40 *Journal of Law, Medicine & Ethics* 268; U Baxi, ‘The Place of the Human Right to Health and Context Approach to Global Justice’ in J Harrington and M Stuttford (eds), *Global Health and Human Rights: Legal and Philosophical Perspectives* (Routledge 2010); A Den Exter and H Hermans, *The Right to Health Care in Several European Countries* (Kluwer Law International 1995).

of inspiration for its provisions, with at least potential implications for their interpretation and implementation.³¹

The EU's Charter of Fundamental Rights is also inspired by the instruments of European regional human rights organisations, particularly the Council of Europe. For instance, the EU's Charter, Article 3 on the 'right to integrity of the person',³² draws on the Council of Europe's Oviedo Convention on Human Rights and Biomedicine in its prohibitions of eugenic practices, reproductive cloning and 'making the human body and its parts a source of financial gain'. Article 8(1) of the EU's Charter³³ draws on the European Convention on Human Rights, Article 8 and the Council of Europe Convention on Data Processing 1981. When courts (national or the CJEU) interpret the EU's Charter of Fundamental Rights, they must take account of the Council of Europe's instruments and their interpretations in that context.³⁴ EU legislation and policy must be compliant with those instruments.³⁵ So, for example, the EU's Data Protection Regulation explicitly refers to the CFREU as expressing the legal concepts underpinning the proposal.³⁶ The geographical scope of that Regulation extends beyond the EU's borders to those who handle data of people residing in the EU, where the data processing relates to 'offering of goods or services to such data subjects in the Union'.³⁷ So, for instance, a provider of genetic testing services established outside the EU³⁸ will have to comply with EU data protection law if it contracts with anyone within the EU.

³¹ See TK Hervey and JV McHale, 'Article 35 – The Right to Health Care' in S Peers and others (eds), *The EU Charter of Fundamental Rights: A Commentary* (Hart 2014); TK Hervey, 'We Don't See a Connection: The 'Right to Health' in the EU Charter and European Social Charter' in G De Búrca and B De Witte (eds), *Social Rights in Europe* (OUP 2005).

³² See S Michalowski, 'Article 3 – Right to Integrity of the Person' in Peers and others (n 31).

³³ See H Kranenborg, 'Article 8 – Protection of Personal Data', in Peers and others (n 31).

³⁴ Charter of Fundamental Rights of the European Union [2012] OJ C326/391 (CFREU), Article 52(3). See further Chapter 4 in this book.

³⁵ TFEU, Article 263.

³⁶ See European Parliament and Council Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L119/1, Recital 1; and see also Commission, 'Safeguarding Privacy in a Connected World, a European Data Protection Framework for the 21st Century' (Communication) COM (2012) 9 final, '5. DATA PROTECTION IN A GLOBALISED WORLD Individuals' rights must continue to be ensured when personal data is transferred from the EU to third countries, and whenever individuals in Member States are targeted and their data is used or analysed by third country service providers. This means that EU data protection standards have to apply regardless of the geographical location of a company or its processing facility.'

³⁷ European Parliament and Council Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L119/1, Article 3(2)(a). See further Chapter 10 in this book.

³⁸ Such as, for instance, California-based 23andMe. The European Commission, using its delegated powers, has a list of countries regarded as ensuring an adequate level of data protection, see Commission, 'Commission decisions on the adequacy of the protection of personal data in third countries' (*European Commission*) <http://ec.europa.eu/justice/data-protection/international-transfers/adequacy/index_en.htm> accessed 21 June 2016. So far, it includes Andorra, Argentina, Canada (commercial organisations), Faeroe Islands, Guernsey,

This brief overview shows some of the ways in which the EU interacts with the institutional architectures supporting global health law. The key feature of these arrangements is the centrality of trade as the organising legal and policy idea behind global health law and policy initiatives. As a consequence, the institutions of most significance are not ‘global health’ institutions per se. The EU’s contributions to global health law are not, in the main, pursued through institutions which have as their central mission or guiding ideology the aim of seeking to ‘attain the highest possible standards of physical and mental health for the world’s populations’.³⁹

III. TRADE/DEVELOPMENT

Although EU development law has different legal bases and institutional arrangements from EU trade law, both in general and when it comes to health, the two are inextricably intertwined.⁴⁰ The relationships between trade and health are not straightforward, but, as a broad generalisation, economic development improves population health.⁴¹

Where the EU creates its external or global health law and policy, it must accommodate two competing constitutional requirements. The EU is constitutionally required to liberalise world trade, and foreign direct investment.⁴² It is also constitutionally required to ‘mainstream’ health in all its policies and activities.⁴³ The EU’s development law and policy achieves this accommodation through the notion of modified or *embedded* liberalism, also associated with the WTO.⁴⁴

From its origins, EU development policy has proceeded on the basis that development is best promoted through integration of economies, trade liberalisation and market access. Initially the focus of EU development law was on relations with former colonies of EU Member States,⁴⁵ and international agreements embodied both free trade and development aid provisions.⁴⁶ Development aid, over time, came to include a range of social matters,

Israel, Isle of Man, Jersey, New Zealand, Switzerland, Uruguay and the US Department of Commerce's Safe Harbour Privacy Principles.

³⁹ Gostin (n 3) 59.

⁴⁰ See Hervey and McHale (n 1) 463–9.

⁴¹ See above, n 9.

⁴² TFEU, Article 206.

⁴³ TFEU, Article 9; TFEU, Article 168.

⁴⁴ G Ruggie, ‘International Regimes, Transactions and Change: Embedded Liberalism in the Postwar Economic Order’ (1982) 36(2) *International Organization* 379; Gostin (n 3) Chapter 9, 272–289.

⁴⁵ See L Bartels, ‘The Trade and Development Policy of the European Union’ in M Cremona (ed), *Developments in EU External Relations Law* (OUP 2008); M Broberg, ‘The EU’s Legal Ties with its Former Colonies – When Old Love Never Dies’ (2011) DIIS Working paper 2011:01 <<http://diis.dk/en/research/the-eus-legal-ties-with-its-former-colonies>> accessed 21 June 2016.

⁴⁶ Yaoundé I Convention between EAMA (Associated African and Malgache Countries) and EEC (adopted 20 July 1963, entered into force 1 June 1964); Yaoundé II Convention between EAMA and EEC (1969); Lomé

including health, but especially human rights and democracy.⁴⁷ By 2006, the EU's *Global Europe* strategy⁴⁸ had made explicit links between trade, development, and the EU's economy and global competitiveness of EU industries. The EU's novel health technologies industries are often explicitly mentioned. These links are set to continue.⁴⁹ Attempts in 2010–2014 to move away from the central focus on free trade,⁵⁰ especially to recognise the need to treat differently the world's poorest populations,⁵¹ have been mothballed. The EU's contributions to global health through its development law and policy are and will continue to be based on the logics of economic development through trade. But this is a particular variant of a free trade ideology.

In the context of the WTO, the EU accommodates free trade and the need to protect health and the WTO's recognition of a series of exceptions⁵² to the rule of trade in goods,⁵³ services⁵⁴ and intellectual property, particularly in the case of pharmaceuticals.⁵⁵ Most

Convention I (adopted 28 February 1975, entered into force April 1976), II (1979), III (1984) and IV (1990); Cotonou Agreement (signed 23 June 2000, entered into force 1 April 2003).

⁴⁷ See Hervey and McHale (n 1) 464–9; Bartels (n 45); M Cremona, 'Human Rights and Democracy Clauses in the EC's Trade Agreements' in D O'Keefe and N Emiliou (eds), *The European Union and World Trade Law* (Wiley 1996).

⁴⁸ Commission, 'Global Europe Competing in the World: A contribution to the EU's growth and jobs strategy' (Communication) COM (2006) 567 final.

⁴⁹ Commission, 'Trade, Growth and World Affairs: Trade Policy as a Core Component of the EU's 2020 strategy' COM (2010) 612 final.

⁵⁰ European Parliament, 'Resolution of 27 September 2011 on a New Trade Policy for Europe under the Europe 2020 Strategy' [2013] OJ CE56/87; see: European Global Strategy, B Fägersten and others, 'Towards a European Global Strategy: Securing European Influence in a Changing World' (European Global Strategy Project, The Swedish Institute of International Affairs 2013); [G Grevi](#), 'A progressive European Global Strategy' (Policy Brief No 140, FRIDE 2012).

⁵¹ Approximately 1.2 billion people (that is around 17% of the world's population) live in extreme poverty, defined by the UN as existing on less than \$1.25 a day, United Nations, 'The Millennium Development Goals Report 2014' (UN 2014) 8-9.

⁵² Governments retain the right, in the international economic law of the WTO, to regulate markets to secure non-economic goals, including health protection and promotion.

⁵³ For instance, Article XX (b) of the GATT permits measures 'necessary to protect human ... life or health', and Article 2.2 of the TBT provides that States parties must ensure that mandatory requirements concerning product characteristics must not be more restrictive of trade than necessary to meet a legitimate objective, such as human health protection. So, for example, national rules on the ingredients, packaging and labelling for pharmaceuticals, covered by EU pharmaceutical law, fall within Article 2.2 TBT. The health measures of Article XX(b) GATT have been elaborated in the Agreement on the Application of Sanitary and Phytosanitary Measures (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 493 (SPS Agreement). If such a measure is in conformity with the SPS Agreement, it is presumed to conform with the GATT, see Article 2.4, SPS Agreement.

⁵⁴ The scope of WTO rules on trade in services is such that global trade in health services is not mandated by WTO membership, and the EU has pursued a policy of both protecting European health services from external competition, and securing maximum flexibility for Member States who wish to open up certain aspects of the health services sector to non-European providers or investors. See Hervey and McHale (n 1) 453–4; H Jarman, 'Trade in Services and the Public's Health: A 'Fortress Europe' for Health?' in SL Greer and P Kurzer (eds), *European Union Public Health Policy: Regional and Global Trends* (Routledge 2013); M Krajewski, 'Patient Mobility Beyond Calais: Health Services Under WTO Law' in JW Van de Gronden and others (eds), *Health*

importantly, the Doha Declaration 2001 reaffirms ‘TRIPS flexibilities’: the rights of WTO member countries to interpret and apply TRIPS in ways which ‘protect public health and, in particular ... promote access to medicines for all’.⁵⁶ Some aspects of EU global health policy, such as EU provision of technical assistance to developing countries in intellectual property matters, support these TRIPS flexibilities.⁵⁷

Embedded liberalism and the rule-exception relationship between free trade and health in WTO law, and in EU development law and policy, are problematic for global health policy activists. They see health and trade as inverted in this rule-exception: why should trade be valued more highly than human health? In the EU, these types of concerns are often directed against the US, which has a different regulatory settlement and approach for many aspects of trade which directly affect health, such as pharmaceuticals, chemicals, environmental and food regulation.⁵⁸ The ‘received wisdom’ is that the EU is more precautionary⁵⁹ than the US, which adopts a more ‘science-based’ and therefore liberal

Care and EU Law (Springer 2011); L Reynolds and others, ‘Competition-based reform of the National Health Service in England: A One-Way Street?’ (2012) 42(2) *International Journal of Health Services* 213.

⁵⁵ TRIPS obliges member countries to bring into force intellectual property laws, including patent protections for inventions. For new pharmaceuticals, TRIPS global patent protection excludes generic equivalents from the market place for 20 years. Before TRIPS entered into force in 1995, many developing countries (and especially India, known as ‘the developing world’s pharmacy’ provided a place where generics could be made, much more cheaply, both for home markets, and for markets in other developing and least developed countries. See Oxfam India, ‘Oxfam calls on EU not to shut down ‘pharmacy of the developing World’ (*Oxfam*, 9 February 2012) <www.oxfam.org.uk/media-centre/press-releases/2012/02/oxfam-calls-on-eu-not-to-shut-down-pharmacy-of-the-developing-world> accessed 22 June 2016. See further: Hervey and McHale (n 1) 486–492; Gostin (n 3) 285–295; Jackson (n 7) 193. In the context of WTO law on intellectual property, some general rules which would potentially have far-reaching negative effects for global health, such as the global patent protection for new pharmaceuticals, have been modified by a series of mechanisms within the WTO arrangements. Developing countries, such as India, had a 10-year transitional period, and least developed countries were not required to be fully TRIPS-compliant until 2016, TRIPS, Article 65(4).

⁵⁶ See further W Hein, ‘Global Health Governance and WTO/TRIPS: Conflicts between ‘Global “Market Creation” and “Global Social Rights”’ in Hein, Bartsch and Kohlmorgen (n 23) 49; A Bozik, ‘Essential Medicines: The Crisis in Developing Countries’ (2011) 7(2) *Yale Journal of Medicine and Law* at 13; C Correa and D Matthews, ‘The Doha Declaration Ten Years on and its Impact on Access to Medicines and the Right to Health’ (Discussion Paper, UNDP 2011); O Aginam and J Harrington, ‘Introduction’ in Harrington, Aginam and Yu (n 7).

⁵⁷ Under Article 61 TRIPS, see: D Matthews and V Munoz-Tellez, ‘Bilateral Technical Assistance and TRIPS: The US, Japan and the EC in Comparative Perspective’ (2006) 9(6) *Journal of World Intellectual Property* 629.

⁵⁸ Some of the most protracted and difficult instances of use of the WTO dispute settlement procedures involve disputes about how best to protect human health.

⁵⁹ See, eg, D Vogel, *The Politics of Precaution: Regulating Health, Safety and Environmental Risks in Europe and the United States* (Princeton University Press 2012). The WTO instruments recognise the precautionary principle. See, eg, Article 5.7 SPS Agreement, which allows provisional measures where scientific information is insufficient, see: WTO, *EC Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States – Appellate Body Report* (13 February 1998) WT/DS26/AB/R and WT/DS48/AB/R [1998] 3 DSR 699. For further discussion, see: J Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (OUP 2007); C Button, *The Power to Protect: Trade, Health, Uncertainty in the WTO* (Hart 2004) 113–162; B Mercurio and D Shao, ‘A Precautionary Approach to Decision Making: The Evolving Jurisprudence on Article 5.7 of the SPS Agreement’ (2010) 2 *Trade, Law and Development* 195.

approach to health regulation. While this is the case in some instances, it is not true across the board.⁶⁰ So far, the EU has managed to defend its more precautionary approach within WTO structures, indirectly therefore making this approach legally acceptable and available to other countries, for instance in the global South, should they wish to adopt such an approach. If traders wish to access EU markets, they must comply with (precautionary) EU trading rules which seek to protect health.⁶¹ One important question for the future of health law and policy is whether the EU will retain this global ‘rule maker’ position, exporting those health values through its ‘embedded liberalism’ approach to trade rules to the rest of the world, in the context of international agreements outside the WTO context.

Alongside the WTO agreements and institutional arrangements, the EU pursues its trade and development policies through a range of bi- and multi-lateral agreements with other countries. Usually classified as ‘first’,⁶² ‘second’,⁶³ ‘third’⁶⁴ and ‘fourth generation’⁶⁵ international agreements, those which affect global health law and policy the most are those in the latter categories agreed with countries such as Chile,⁶⁶ or under negotiation with countries such as India,⁶⁷ and as well as agreements with the EU’s former colonies, such as the CARIFORUM agreements.⁶⁸

⁶⁰ See Hervey and McHale (n 1) Chapters 12–15; Scott (n 59) 77–79, 150–151; D Collins, ‘Health Protection at the World Trade Organization: The J-Value as a Universal Standard for Reasonableness of Regulatory Precautions’ (2009) 43(5) *Journal of World Trade* 1071; Button (n 59) 102–113.

⁶¹ The EU is an important ‘rule maker’ for instance in global food law – see Hervey and McHale (n 1) 517–526; AR Young, ‘Europe as a global regulator? The limits of EU influence in international food safety standards’ (2014) 21(6) *Journal of European Public Policy* 904; E Vos and M Weimer, ‘The Role of the EU in Transnational Regulation of Food Safety: Extending Experimentalist Governance?’ (2013) GR:EEN Working Paper No 35 <www2.warwick.ac.uk/fac/soc/csgr/green/papers/workingpapers/no.35_vos_and_weimer.pdf> accessed 22 June 2016.

⁶² Covering only trade in goods.

⁶³ Covering trade in goods, services, public procurement and investment.

⁶⁴ Covering trade in goods, services, public procurement, investment, intellectual property rights, and anti-competitive regulatory measures.

⁶⁵ Sometimes also known as ‘DCFTAs’ (deep and comprehensive free trade agreements). There are a few such agreements, which go even further, and seek to attain some kind of economic integration between the States parties. The EU agreed DCFTAs with Ukraine, Georgia and Moldova in June 2014.

⁶⁶ Agreement establishing an association between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part [2002] OJ L352/3.

⁶⁷ Commission, ‘Countries and Regions: India’ (*European Commission*) <<http://ec.europa.eu/trade/policy/countries-and-regions/countries/india/>> accessed 22 June 2016. See on general EU-India relations, PJ Cardwell and N Samanta, ‘What Brexit would mean for relations between India and the UK’ *The Conversation* (2 May 2016) <<http://theconversation.com/what-brexit-would-mean-for-relations-between-india-and-the-uk-58374>> accessed 22 June 2016; and on health, R Chanda, ‘India-EU Relations in Health Services: Prospects and Challenges’ (2011) 7 *Globalization and Health* 1.

⁶⁸ Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part [2008] OJ L289/I/3.

Generally speaking, this dense web of international law⁶⁹ forms a less high-profile site for EU global health law-making than the WTO instruments. But the low political salience of trade law for global health has been challenged by civil society attention drawn to several more recent trade agreements, in particular the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada; the Trans-Pacific Partnership (TPP);⁷⁰ the Trade in Services Agreement (TiSA);⁷¹ and, above all, the Transatlantic Trade and Investment Partnership (TTIP) between the EU and the US.⁷²

Comprehensive trade agreements, such as these, could be a potential instrument for improving global health. It is worth exploring, therefore, what the effects on global health in terms of development might be if, for instance, the model of third- and fourth-generation

⁶⁹ A list of agreements in force is available here: Commission, 'Agreements' (*European Commission*) <http://ec.europa.eu/trade/policy/countries-and-regions/agreements/#_europe> accessed 22 June 2016.

⁷⁰ The Trans-Pacific Partnership (TPP), obviously not involving the EU, agreed in October 2015 between the US, Canada, Australia, New Zealand, Japan, Singapore, Malaysia, Brunei, Vietnam, Chile, Mexico and Peru, covers a range of matters pertinent to health, including intellectual property rights. A 12-year data exclusivity clause (used to prevent the generics industry from accessing clinical trial data, to support marketing authorisations applications) on biologics (a type of pharmaceutical manufactured from living organisms, such as proteins, cells and tissues) in the original negotiating texts was 'watered down' to eight years, a longer period than in force in nine of the 12 TPP countries. The remaining three being Japan, Canada and the US, see: M Davey, 'Trans-Pacific Partnership could pose risk to public healthcare, leaked draft shows' *The Guardian* (6 August 2015) <www.theguardian.com/global-development/2015/aug/06/trans-pacific-partnership-could-pose-risk-to-public-healthcare-leaked-draft-shows> accessed 22 June 2016; *Medicins sans Frontières* described the agreement as 'the most harmful trade pact ever for access to medicines in developing countries', because it requires member countries to enforce patent protections on pharmaceuticals and squeeze out generics, see MSF, 'Trading Away Health: The Trans-Pacific Partnership Agreement (TPP)' (*Medicins sans Frontières USA*, 3 March 2013) <www.doctorswithoutborders.org/news-stories/briefing-document/trading-away-health-trans-pacific-partnership-agreement-tpp> accessed 22 June 2016; A Corderoy, 'Trans-Pacific Partnership: Health groups say TPP will cost lives' *Sydney Morning Herald* (Sydney, 6 October 2015) <www.smh.com.au/national/health/transpacific-partnership-health-groups-say-tpp-will-cost-lives-20151005-gk229t.html> accessed 22 June 2016. However, Australia's ability to negotiate protections for its anti-tobacco laws (including its plain packaging laws which lead the global field in tobacco regulation) demonstrates that such trade agreements need not necessarily be worse for health than WTO law. The problem is, of course, that most countries do not enjoy Australia's geo-political/geo-economic position when negotiating trade agreements. The TTP was not used as a mechanism for *improving* tobacco regulation in the other States parties.

⁷¹ The Trade in Services Agreement, TiSA, is being negotiated by 23 countries (including China, Japan, Korea, Mexico, Chile, Peru) plus the EU. The agenda is essentially deregulatory, and the TiSA would take its member countries beyond the WTO's GATS framework. The EU Negotiating mandate is published here: Council, 'Draft Directives for the Negotiation of a Plurilateral Agreement on Trade in Services' (2015) <<http://data.consilium.europa.eu/doc/document/ST-6891-2013-ADD-1-DCL-1/en/pdf>> accessed 22 June 2016, and should be read in context with the EU's 'revised offer': http://trade.ec.europa.eu/doclib/docs/2016/may/tradoc_154590.pdf accessed 15 November 2016; other documents are here: Wikileaks, 'Trade in Services Agreement' (*Wikileaks*) <<https://wikileaks.org/tisa/>> accessed 22 June 2016; and see D Dayen, 'The Scariest Trade Deal Nobody's Talking About Just Suffered a Big Leak' *New Republic* (4 June 2016) <<https://newrepublic.com/article/121967/whats-really-going-trade-services-agreement>> accessed 22 June 2016.

⁷² See further Chapter 17 in this book; and F de Ville and G Siles-Brügge, *The Truth about the Transatlantic Trade and Investment Partnership* (Polity 2016).

trade agreements were to be applied in the EU's trade relations with the rest of the world. Three main observations are pertinent:

First, comprehensive trade agreements do not pursue the type of regulatory approach pursued (sometimes in spite of the European Commission's 'better regulation' agendas) by the TFEU. Much of EU law that protects health is based on health-respecting *harmonisation*: the development of EU-level rules that apply across the whole of the single EU market. Granted, these rules do not always express the highest possible protections for health, in spite of the obligation in the TFEU to that effect.⁷³ But neither do they always express a lowest common denominator: far from it. One of the surprising things about EU health law is that it does not always operate through a deregulatory imperative, and the adopted regulatory standards are sometimes the product of a 'race to the top', not the bottom. The EU's health law articulates the idea of the EU market as a particularly safe, particularly ethical market.⁷⁴ And it protects the specificities of European health systems.⁷⁵

If the EU were to use comprehensive trade agreements to pursue a harmonisation (or even an *erga omnes* mutual recognition of national standards) agenda that embodies high levels of protection for human health, there would be an incentive for producers outside the market created by such trade agreements to align their practices so as to access that market, by compliance with harmonised (or mutually recognised) standards. That would support a push towards higher regulatory standards in other countries, and represent an opportunity to improve health law in those countries. But, for instance, the TTIP will not allow access to the whole TTIP market through compliance with either EU or US regulatory standards. So this opportunity is lost.

Second, although there is to be a 'sustainable development' chapter of TTIP, the EU negotiating text is very light on anything to do with development, and does not include anything to do with health and global development.⁷⁶ So as things stand, that is a lost opportunity too.

Third, and perhaps the most important in the longer term, the effects of these types of agreements look set to permanently destabilise the WTO – with its embedded liberalism model – as the institutional site for global regulation of trade, and, consequently, of development through trade.⁷⁷ The implications for non-EU States are significant. Take, for instance, a State that seeks to enter into third- or fourth-generation trade agreements with both the EU and the US to develop its economy (with the consequent indirect effects on

⁷³ TFEU, Article 168(1).

⁷⁴ See, for instance, G Bache, ML Flear and TK Hervey, 'The Defining Features of the European Union's Approach to Regulating New Health Technologies' in ML Flear and others (eds), *European Law and New Health Technologies* (OUP 2013).

⁷⁵ See Hervey and McHale (n 1) Chapters 9–11; TK Hervey, 'The National Health Service, TTIP and the EU Referendum' (*EU Law Analysis*, 17 April 2016) <<http://eulawanalysis.blogspot.co.uk/2016/04/the-nhs-ttip-and-eu-referendum.html>> accessed 22 June 2016.

⁷⁶ It is mainly about preserving European labour rights, and about environmental protection see: Commission 'Trade and Sustainable Development Chapter /Labour and Environment: EU Paper outlining key issues and elements for provisions in the TTIP' (EU Position Paper for negotiating round 19–23 May 2014) <http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153024.pdf> accessed 22 June 2016.

⁷⁷ See n 71.

health of its population). This is the case for many EU eastern neighbourhood and southern Mediterranean countries, with whom the EU is negotiating such agreements.⁷⁸ Matters such as justifiable technical barriers to trade, sanitary and phytosanitary measures – all of which have implications for health protection – are relatively settled within the WTO structures. But bi- and multi-lateral agreements reopen those debates, and unless they adopt a common EU-US standard (for, say, GM food) – which is highly unlikely – countries outside the EU/US will struggle to reconcile the opposing approaches in their hoped-for trading partners.⁷⁹ Opportunities to improve health through economic development supported by such comprehensive trade agreements will be lost.

More importantly for global health, bi- and multi-lateral treaties destabilise the TRIPS settlement, and in particular its approach to access to essential medicines in the context of a global proprietary pharmaceutical industry relying on patent protection to freeze out the generics industry. The TPP negotiations show how the pharmaceutical industry was able to use this opportunity to reopen matters, such as the ‘evergreening’ of patents,⁸⁰ that were ‘on their way to being settled’ through the WTO.⁸¹ Patent terms are extended beyond the WTO’s 20-year period through provisions such as Articles 18.46 and 18.48 of the Intellectual Property Chapter of the TPP. This provides that patent owners may require States to adjust the term of patents to compensate for ‘unreasonable delays’ in issuance of patents, and that for pharmaceutical products, patent terms must be adjusted to compensate for ‘unreasonable curtailment’ of the patent term ‘as a result of the marketing approval process’.

The hegemony of the WTO is fundamentally challenged by the new global phenomenon of third- and fourth-generation free trade agreements. Of course, it would be a mistake to overstate the ways in which WTO mechanisms and institutions have been used to pursue global health agendas. But there is no doubt that, at least to some small extent, they have been. The opportunity for the EU to continue to pursue global health through trade and development law and policy based on the WTO’s ‘embedded liberalism’ looks set to be lost, unless it can be brought within those new bi- and multi-lateral trade agreements.

IV. HUMAN RIGHTS

The other principal global institutional setting through which civil society has been able to pursue a global health agenda is that of international human rights institutions. There is a

⁷⁸ Negotiations are concluded in DCFTAs with Ukraine, Georgia, Moldova. Morocco, Egypt, Jordan and Tunisia all in the frame for future negotiations.

⁷⁹ T Kovziridze, ‘Differences in Regulatory Approach between the EU and the US: Transatlantic Trade and Investment Partnership and its impact on trade with third countries’ in D Cardoso and others (eds), *The Transatlantic Colossus: Global Contributions to Broaden the Debate on the EU-US Free Trade Agreement* (Berlin Forum on Global Politics 2014) (also available free online).

⁸⁰ Various practices of the pharmaceutical industry that seek to extend their patent rights, see H Moir and D Gleeson, ‘Evergreening and how big pharma keeps drug prices high’ *The Conversation* (5 November 2014) <<https://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623>> accessed 22 June 2016; F Chaudhry, ‘The TAFTA/TTIP and Treatment Access: What does the Agreement mean for Intellectual Property Rights over Essential Medicines’ in Cardoso and others (n 79).

⁸¹ Chaudhry (n 80).

significant literature on global health and human rights.⁸² This ranges from the wildly optimistic through to the deeply critical/pessimistic. There is no doubt, though, that human rights ideas have been used to promote global health, at least in some high-profile instances, such as access to HIV/retroviral medication in developing countries,⁸³ or regulation of organ donation by donors in developing countries.⁸⁴ There is also no doubt that human rights represents a powerful counter-narrative, or alternative framing, to the trade/development framing of global health law.

This is seen, for instance, in the EU's regulation of organ donation,⁸⁵ which is based on human rights-inspired principles of non-commodification of the human body. However, as Hervey and McHale observe, the EU legislation is 'blind' to the realities of global markets in human organs. In general, legislation across the globe has proved ineffective in tackling persistent human rights breaches, given the demand and supply drivers in the context of such disparities of wealth between donors and their eventual recipients.⁸⁶

⁸² See above n 81; J Biehl and A Petryna (eds), *When People Come First: Critical Studies in Global Health* (Princeton University Press 2013); JM Zuniga, SP Marks and LO Gostin (eds), *Advancing the Human Right to Health* (OUP 2013).

⁸³ The best-known example involving South Africa, see *Minister of Health v Treatment Action Campaign (TAC)* 2002 (10) BCLR 1075 (CC). See eg Hein, Bartsch and Kohlmorgen (n 23); EB Kramer, "No one may be refused emergency medical treatment" – ethical dilemmas in South African emergency medicine' (2008) 1 *South African Journal of Bioethics and Law* 53; CR Sunstein, 'Social and Economic Rights – Lessons from South Africa' (1999) 11 *Constitutional Forum* 123; P O'Connell, *Vindicating Socio-Economic Rights: International Standards and Comparative Experiences* (Routledge 2012); M Tushnet, 'Social Welfare Rights and the Forms of Judicial Review' (2003) 82 *Texas Law Review* 1895; MS Kende, 'South African Constitutional Court's Embrace of Socio-Economic Rights: A Comparative Perspective' (2003) 6 *Chapman Law Review* 137; T Roux, 'Principle and pragmatism on the Constitutional Court of South Africa' (2009) 7 *International Journal of Constitutional Law* 106; EC Christiansen, 'Adjudicating Non-Justiciable Rights: Socio-Economic Rights and the South African Constitutional Court' (2006) 38(2) *Columbia Human Rights Law Review* 321; J Dugard, 'Court of first instance? Towards a pro-poor jurisdiction for the South African Constitutional Court' (2006) 22 *South African Journal on Human Rights* 261; L Forman, 'Ensuring Reasonable Health: Health Rights, the Judiciary, and South African HIV/AIDS Policy' (2005) 33(4) *Journal of Law, Medicine & Ethics* 711.

⁸⁴ See, eg, IG Cohen, *Patients with Passports: Medical Tourism, Law and Ethics* (OUP 2015); S McGuinness and JV McHale, 'Transnational crimes related to health: How should law respond to illicit organ tourism?' (2014) 34(4) *Legal Studies* 682; D Sperling, 'Human Trafficking and Organ Trade: Does the Law Really Care for the Health of People' in Freeman, Hawkes and Bennett (n 3); WHO, 'WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation' Sixty-third World Health Assembly (May 2010) Resolution WHA63.22; Council of Europe, 'Committee of Ministers Recommendation 2004(7) to member states on organ trafficking' (Council of Europe, 19 May 2004) <<https://wcd.coe.int/ViewDoc.jsp?id=744621>> accessed 22 June 2016.

⁸⁵ European Parliament and Council Directive 2010/45/EU of 7 July 2010 on standards of quality and safety of human organs intended for transplantation [2010] OJ L207/14. This is the correct number, see Corrigendum to Directive 2010/45/EU OJ [2010] L243/68. See further Chapter 9 in this book; Hervey and McHale (n 1) 358-60, 478-483.

⁸⁶ eg, Cohen (n 84); Sperling (n 34); IG Cohen, 'Transplant Tourism: The Ethics and Regulation of International Markets for Organs' (2013) 41(1) *Journal of Law, Medicine and Ethics* 269; and see the studies cited in Hervey and McHale (n 1) 472-477.

In the instance of access to essential medicines, where this aspect of the human right to health is impeded by global intellectual property law, the EU's legal approach in general is to acknowledge TRIPS' flexibilities in its legal texts, but also to insist on effective, proportionate and dissuasive intellectual property rights enforcement. Candidate examples include the EU's Economic Partnership Agreement with the CARIFORUM States, and its 2010 free trade agreement with Korea. The EU has done almost nothing to provide incentives to the pharmaceutical industry to develop medicines for the global South.⁸⁷ That said, the EU has provided technical assistance to developing countries in intellectual property matters, to help those countries to incorporate TRIPS' flexibilities in national law, including flexibilities protecting public health.⁸⁸

The EU's development policy, including access to budget support for developing countries, and support for projects and programmes within the EU's development themes, has long been subject to human rights conditionality.⁸⁹ This is also expressed in the most recent versions of EU development policy, see for instance the Council's Conclusions on *A New Global Partnership for Poverty Eradication and Sustainable Development after 2015*.⁹⁰ But in the context of law and policy relevant to 'the right to health' this human rights conditionality is theoretical, rather than having any practical effects.

The essential problem with global human rights law as a mechanism for pursuing global health is that international law, with its underpinning assumptions of State sovereignty

⁸⁷ Hervey and McHale (n 1) 498–501; Jackson (n 7) 199–204.

⁸⁸ Matthews and Munoz-Tellez (n 57)

⁸⁹ Budget support from EU development funds – human rights conditionality (see Commission, 'Budget support and dialogue with partner countries' (*European Commission*) <https://ec.europa.eu/europeaid/how/delivering-aid/budget-support/index_en.htm_en> accessed 22 June 2016; and see European Parliament and Council Regulation (EU) 233/2014 of 11 March 2014 establishing a financing instrument for development cooperation for the period 2014–2020 [2014] OJ L77/44, Recital 7, 'Respect for human rights, fundamental freedoms, the promotion of the rule of law, democratic principles, transparency, good governance, peace and stability and gender equality are essential for the development of partner countries, and those issues should be mainstreamed in the Union's development policy, particularly in programming and in agreements with partner countries' and Article 3(1)(1), 'The Union shall seek to promote, develop and consolidate the principles of democracy, the rule of law and respect for human rights and fundamental freedoms on which it is founded, through dialogue and cooperation with partner countries and regions.'

⁹⁰ Council, 'A New Global Partnership for Poverty Eradication and Sustainable Development after 2015 – Council conclusions' (2015), Part II 'Guiding principles for a new global partnership', para 6, 'The December 2014 Council conclusions set out a number of guiding principles for a new global partnership. We affirm those principles of universality, shared responsibility, mutual accountability, consideration of respective capabilities, and a multi-stakeholder approach. The new global partnership should also be based on and promote human rights, equality, nondiscrimination, democratic institutions, good governance, rule of law, inclusiveness, environmental sustainability and respect for planetary boundaries. Women's rights, gender equality and the empowerment of women and girls, as well as being ends in themselves, are a key means of implementation and should be promoted at all levels.'

See also (same document) para 9, 'The EU and its Member States consider the following to be key components of a comprehensive approach to means of implementation in the context of a new Global Partnership: (i) establishing an enabling and conducive policy environment at all levels; (ii) developing capacity to deliver; (iii) mobilising and making effective use of domestic public finance; (iv) mobilising and making effective use of international public finance; (v) mobilising the domestic and international private sector; (vi) stimulating trade and investments; (vii) fostering science, technology and innovation; and (viii) addressing the challenges and harnessing the positive effects of migration.'

and State equality, is insufficiently attentive to the differences in geo-political and geo-economic power between ‘sovereign’ States. Where trade is global and is conducted on terms dictated by not only the WTO, and bi- and multi-lateral trade agreements with powerful (Western) countries, but also the IMF and World Bank, States may be frustrated where they seek to improve the health of their populations through, for instance, building health infrastructure and systems.⁹¹ All of this lies far from the revised approach to geo-economics implied by the root-and-branch reform to global trade law that it would take to tackle global health disparities.

The solution, according to authors such as Mukherjee, is civil society action to assert a collective notion of ‘right to health’, such as that seen in the AIDS movement and the movement for debt relief. Such a collective ‘right to health’ is variously taken to mean, for instance, a general right to be healthy; a right to a basic package of medical treatments; and a right to social insurance or tax-based access to healthcare (either in general, or a specific set of healthcare entitlements, such as emergency treatment).⁹² But conceiving of human rights as a matter for collective action also carries with it certain risks as a strategy for using law to improve global health. Collective social rights such as the right to health are seen as aspirational and programmatic only. In particular, conceptualising human rights as *collectively* enjoyed and therefore to be collectively enforced risks throwing away one of the most powerful aspects of human rights as an asset in tackling inequalities: their individual judicial enforceability. As it constitutes a positive claim on the State, rather than a freedom from State interference, the collective ‘right to health’ is not seen as being an enforceable claim or entitlement.⁹³ The movement for debt relief, in particular, is framed much more in terms of ethics, justice and even charity than the human rights framing of *entitlement*.

It is particularly sobering to contrast what the EU has been able to achieve using a human rights approach to health rights *within* the EU. Although the overarching ‘DNA’ of internal EU law is trade and creation of the ‘internal market’, the EU has been able to secure not insignificant protection for human rights, as individual patients’ rights, as well as relationships of solidarity and equality embodied in collective arrangements for healthcare within EU national health systems.⁹⁴ By contrast, even taking into account the EU’s

⁹¹ JS Mukherjee, ‘Financing governments: towards achieving the right to health’ in Zuniga, Marks and Gostin (n 82).

⁹² It is not necessary that a right be entirely determinate in order to be classed as a human right: few would argue that the right to life is not a human right, yet the right to life clearly does not mean the right to eternal life, and there is significant disagreement about when it begins and ends. Civil and political rights may be (or have been) under-determined in terms of their substantive content, but they become more determinate through human rights practice. See further, TK Hervey, ‘Health Equality, Solidarity and Human Rights in European Union Law’ in A Silveira, M Canotilho and P Madeira Froufe (eds), *Citizenship and Solidarity in the European Union: From the Charter of Fundamental Rights to the Crisis, the State of the Art* (Peter Lang 2013) 341–66.

⁹³ Many civil and political rights also involve a claim on the State, see further, A Eide and A Rosas, ‘Economic, Social and Cultural Rights: A Universal Challenge’ in A Eide, K Krause and A Rosas (eds), *Economic, Cultural and Social Rights* (2nd edn, Martinus Nijhoff Publishers 2001) 3. Further, it has been pointed out forcefully that such economic and social rights are in practice *more* important than the civil and political rights that are commonly assumed to be their superiors. ‘What permanent achievement is there in saving people from torture, only to find that they are killed by ... disease that could be prevented?’ Eide and Rosas, 7; HJ Steiner, P Alston and R Goodman, *International Human Rights in Context: Law, Politics, Morals: Text and Materials* (OUP 2008) 255, ‘Of what use is the right to free speech to those who are starving and illiterate?’.

⁹⁴ Hervey and McHale (n 1) Chapters 8–11.

constrained competence to develop its external or global health law, the EU has missed opportunities to tackle global health inequalities through human rights mechanisms.⁹⁵

V. CONCLUSIONS

The EU's external health law and policy, and the ways in which EU law intersects with global health law and policy, take place through three main institutional and conceptual vectors: trade; development; and human rights. The institutional structures and legal mechanisms supporting these are, in the main, quite distinct, although there are strong overlaps between development and trade, and also areas where human rights intersect with those other vectors, such as the concept of 'human rights conditionality'.

Some opportunities for improvements in global health have been opened up by the EU's pursuing of modified or embedded liberalism through global trade rules, particular through the WTO. The pursuing of TRIPS' flexibilities, for instance, has assisted in securing significantly the chances of access to essential medicines in developing countries. The public health protections from WTO rules recognising precaution in new technologies, such as in food law, are another example. But these examples show the potential for the EU to contribute to global health, a potential that remains largely unrealised.

Finally, although not discussed above, we should not forget two important practical aspects of EU contributions to global health law. First, as the EU has expanded its membership, especially to the east, it has improved population health in its new Member States. The mechanisms the EU has used to do so include the transfer of development aid and expertise, but also EU economic law – which is, of course, at heart based on an extremely comprehensive trade agreement, the Treaty on the Functioning of the European Union. For instance, taking one example where the EU is a global leader in health regulation, all consumers of tobacco within the EU are protected by stringent EU-level rules on composition of tobacco products, packaging and advertising.⁹⁶ By expanding its geographical scope, the EU improves health, including in developing and transitional countries.

Second, the *practical* reach of EU law extends outside its formal Member States, to include associated States (including former colonies) and neighbourhood States, as well as States which are trading partners. Companies in those countries seeking to access the EU market need to align their production practices, as well as their products, to EU regulatory standards. Where the EU's regulatory standards are more protective of health than those

⁹⁵ Hervey and McHale (n 1) Chapter 17, and summary, 501–2.

⁹⁶ See further Chapter 14 in this book; Hervey and McHale (n 1) 390–403; A Gilmore and M McKee, 'Tobacco control policy: the European dimension' (2002) 2(4) *Clinical Medicine* 335; A Gilmore and M McKee, 'Tobacco policy in the European Union' in EA Feldman and R Bayer (eds), *Unfiltered: Conflicts Over Tobacco Policy and Public Health* (Harvard University Press 2004); M McKee, TK Hervey and A Gilmore, 'Public health policies' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010); DT Studlar, 'Tobacco Control: The End of Europe's Love Affair with Smoking?' in Greer and Kurzer (n 54); A Alemanno and A Garde (eds), *Regulating Lifestyle Risks: The EU, Alcohol, Tobacco and Unhealthy Diets* (CUP 2015); A Alemanno and A Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets' (2013) 50(6) *Common Market Law Review* 1745; A Alemanno, 'Out of Sight, Out of Mind: Towards a New EU Tobacco Products Directive' (2012) 18(2) *Columbia Journal of European Law* 197.

elsewhere in the world, the effect is a ‘race to the top’, and the EU can be seen as a *de facto* global ‘rule-maker’. We have seen this process, for instance, in the improving of various aspects of health in the EU’s accession countries, as their economies develop and they align their economic laws to EU law in preparation for membership.⁹⁷ Governments outside the EU are not legally obliged to align their regulations to EU standards, but they face political pressure from domestic producers to do so. A candidate example is EU-led ethical rules about clinical trials, including privacy and data protection rules.⁹⁸

In conclusion, although the EU’s external or global health law and policy lacks the conceptual unity of its internal health law and policy, it is a discernible aspect of EU law and policy, which looks set to increase through patterns of Europeanisation, as was the case with its internal health law. However, in the final analysis, the current assessment of EU external or global health law is that it is full of missed opportunities to support global health, and the direction of travel looks set to continue to miss those opportunities.

⁹⁷ For instance, health indicators in Bulgaria and Romania improved as the economies developed.

⁹⁸ But see, eg, ML Flear, *Governing Public Health* (Hart 2015); ML Flear, ‘Offshoring Clinical Trials: The Mutable Ethics, Weak Protections and Vulnerable Subjects of EU Law’ (2015) 16 *Cambridge Yearbook of European Legal Studies* 75.

CONCLUSIONS

19. The impediment of health laws' values in the constitutional setting of the EU

Anniek de Ruijter*

(...) account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since the level may vary from one Member State to another, Member States should be allowed a measure of discretion¹

In the above-cited Perez case, the Court of Justice of the EU (CJEU) refers to health and life of humans to rank foremost among the interests protected under EU law. Hence the EU is to leave discretion to the Member States to determine the level of health protection in each Member State. However, the involvement of the EU, through law and policy in the field of human health is vast, regardless of limited specific legal competence in the field (Article 168 TFEU). On the basis of an array of other legal competences, especially Article 114 TFEU on the functioning of the EU's internal market, the importance and authority of the EU in the field of human health is ever-growing.²

What is the relationship between the role of the EU and the values central in the field of human health? By such 'health values', I mean the guiding principles whereby a society in general ensures the merit of a health policy or law. When a topic goes to the core of the manner in which humans shape mutual relationships and obligations (in the current case with respect to human health), there is a good argument to make that we need more justification than law, or a democratic rule, may be able to provide.³ Health values are often articulated through law, but they are self-standing. In the context of bioethics, they are understood as having an intrinsic importance that gives expression to

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¹ Joined Cases C-570/07 and 571/07 *Blanco Pérez and Chao Gómez* ECLI:EU:C:2010:300, [2010] ECR I-4629, para 44. And see further references Case C-141/07 *Commission v Germany* ECLI:EU:C:2008:492, [2008] ECR I-6935, para 51, and Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others (Doc Morris)* ECLI:EU:C:2009:316, [2009] ECR I-4171 para 19.

² A de Ruijter, *The Expansion of EU Power in the Field of Human Health* (OUP 2016) (forthcoming). DS Martinsen, *An Ever More Powerful Court?: The Political Constraints of Legal Integration in the European Union* (OUP 2015).

³ O O'Neill, *Autonomy and Trust in Bioethics* (CUP 2002) 73 (who explains that 'political legitimation is not enough for an ethical justification of fundamental rights). But see S Bagatur, 'Toward a Democratic Conception of Human Rights' (2014) 2(1) *Theoria and Praxis* <<http://theoriandpraxis.journals.yorku.ca/index.php/theoriandpraxis/article/view/39372>> accessed 22 June 2016.

standards for conduct in individual cases and in the organisation of public health and healthcare.⁴ However, my focus here is not on bioethics specifically, nor the particular ethical questions on the basis of health values as they emerge in the EU. Rather, to achieve the objective of navigating the intricacies of ‘European Union Health Law’ and related policies, in their constitutional setting, the focus of this chapter is the relationship between health values, fundamental rights and health law and policy.

The central document that may immediately come to mind to EU health lawyers on these topics is the 2006 ‘Council Conclusions on Common Values and Principles in health care’.⁵ These conclusions were adopted when Member States agreed that the domestic healthcare systems were highly affected by the CJEU case law affecting the individual access to medical care, and the core values of ‘universality, access to good quality care, equity and solidarity’ needed safeguarding.⁶ Noting the links between values and ethics, I propose a somewhat wider scope for ‘EU health values’, and thus include human dignity, which is a central value of health law in the Western world generally.⁷ Hence, my focus is the values of solidarity, universal access, equality and human dignity.

The chapter argues that due to the EU’s current constitutional setting – which refers generally to the legislative limitations on the exercise of EU public authority of its institutions for adopting health law, including the protection and promotion of fundamental rights in that respect – EU health law and policy is not able to promote and protect the values that are embedded in Member States’ national health law and policy fully. The chapter will proceed as follows: first, the chapter turns to the place of values in (EU) health law and policy. Second, the chapter looks at the manner in which these values are expressed in the context of specific EU fundamental rights that have particular bearing on EU health law and policy. Third, the chapter addresses the place of EU health law in the EU constitutional setting and how EU health law affects values. By way of conclusion the chapter proposes a new research agenda on the constitutional embedding of values in health law in the EU.

I. VALUES IN (EU) HEALTH LAW AND POLICY

In health law, values and human rights play an important role. Together they make up the central aspects that form the fabric of most health laws in the Western world, and beyond. By contrast, according to most accounts, EU health law developed as a side issue of internal market law. Furthermore, EU health law came about as national health laws and regulations became exceptions to the creation of the EU internal market (deregulation). A relevant famous and foundational CJEU decision is the *Cassis de Dijon* case, in which the CJEU ruled on the extent of national power to adopt health-related alcohol laws.⁸

⁴ TL Beauchamp and JF Childress, *Principles of Biomedical Ethics* (7th edn, OUP 2012).

⁵ Council Conclusions on Common values and principles in European Union health systems [2006] OJ C146/1.

⁶ *ibid.*

⁷ M Frischhut, “‘EU’: Short for “Ethical” Union, the Role of Ethics in European Union Law’ (2015) 75(3) *Heidelberg Journal of International Law* 531; C Foster, *Human Dignity in Bioethics and Law* (Bloomsbury 2011). TK Hervey and JV McHale, *European Union Health Law: Themes and Implications* (CUP 2015) 40, 95. The authors outline in the EU context: ‘The most we might expect is a change to the way courts express the discussion in such cases – a certain suppression of explicit consideration of ethical questions, replaced by a discussion of trade in goods or services.’

⁸ In Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)* ECLI:EU:C:1979:42, [1979] ECR 649, the public health exception for goods in the Treaty (currently Article 36

EU health law and policy have also been a means to re-regulate the EU market in areas where national regulatory barriers to trade were removed to create the internal single EU market. In the *Tobacco Advertising I* case it is established that the European legislator cannot create legislation with health as a central and single objective. There must be an internal market connection as a legal basis for most EU health law (Article 114 TFEU, but see certain paragraphs in Article 168 TFEU).⁹ There are numerous examples here in the area of food safety, medicines and access to medical benefits in another Member State, where the market connection is the basis for EU regulation. However, over the past half-century in the Member States, health law developed on rather different foundational bases.

Generally, in the Member States health law regulates relationships of solidarity, of ethics, professional trust and the protection of human physical dignity, in the face of shared risks and opportunities related to life, disease and mortality.¹⁰ Health laws in the Member States on the whole express the values of solidarity, universal access, equality and human dignity. These values are translated in national public health programmes and healthcare systems in various ways.¹¹ The values of equality and solidarity are expressed in the general rule that all citizens have ‘universal access’ to medical treatment.¹² Human dignity is expressed in rules regarding the protection of informed consent in medical research and medical treatment or in national laws that guarantee a ‘right to know and not to know’ and the right to inviolability and physical integrity. In a public health sense human dignity is expressed in rules about eugenics and other research-related regulations. Besides the general national laws and policies that express the values and principles of health law, these values are expressed in constitutional law and the application of (EU or Council of Europe ECHR) human rights.¹³

Hence, national health laws largely protect a number of specifically health and human dignity-related rights,¹⁴ such as informed consent, the protection of medical and health data, secrecy and professional medical standards, medical liability and the right to equal ‘universal’ access to medical care.¹⁵ The shared foundational basis of rights and objectives that can be found in national health laws, are the ‘values’ of health law. Given the EU’s constitutional order and the setting in which the growing role of the EU in human health regulation is taking place, the question is to what extent the EU is able to facilitate health values as EU values, or are they left behind at Member State level? One

TFEU) as broadened through the establishment of a Rule of Reason-doctrine that applies only to national measures that treat products from another Member State equally.

⁹ Case C-376/98 *Germany v European Parliament and Council (Tobacco Advertising I)* ECLI:EU:C:2000:544, [2000] ECR I-8419.

¹⁰ Hervey and McHale (n 7).

¹¹ ED Kinney and BA Clark, ‘Provisions for Health and Health Care in the Constitutions of the Countries of the World’ (2004) 37(2) *Cornell International Law Journal* 285. B Toebes, ‘Introduction: Health and Human Rights in Europe’ in B Toebes and others (eds), *Health and Human Rights in Europe* (Intersentia 2012).

¹² Nobody can be denied access to medical care.

¹³ Kinney and Clark (n 11). HJ Leenen, ‘Health Law in the Twenty-First Century’ (1998) 5(4) *European Journal of Health Law* 341; HJ Leenen, JKM Gevers and G Pinet, *The Rights of Patients in Europe* (WHO; Kluwer 1993); J Legemaate, ‘Integrating Health Law and Policy: A European Perspective’ (2002) 60(2) *Health Policy* 101; TK Hervey, ‘We Don’t See a Connection: The “right to Health” in the EU Charter and European Social Charter’ in G De Búrca and B De Witte (eds), *Social Rights in Europe* (OUP 2005); JV McHale, ‘Fundamental Rights and Health Care’, in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of EU Law and Policy* (CUP 2010).

¹⁴ Frischhut (n 7).

¹⁵ A de Ruijter, ‘EU Integration in the Field of Human Health, Review Article’ (2016) *Journal of European Integration* (forthcoming).

strategy for protecting the values of solidarity, equality, universal access and human dignity generally could be through the above indicated legal expression in fundamental rights. In the next section the relationship between values and fundamental rights, and the role of fundamental rights in EU health law is addressed.

II. THE EXPRESSION OF HEALTH VALUES IN EU FUNDAMENTAL RIGHTS

II.i Health Values and Fundamental Rights

Values in bioethical research and analysis have a separate meaning from fundamental rights or human rights. ‘Fundamental rights’, rather than the term ‘human rights’ does not define one body of rights as more ‘fundamental’ than the other, but it refers to rights with a similar meaning, applicable as EU law. It is the term used in EU law to describe these types of rights. ‘Fundamental rights’ in the jurisprudence of the CJEU refers to the legal *praxis* that is used in balancing the legitimacy of the EU’s policies, legal rights claims against the Member States, against institutions of the EU or in some cases even in horizontal, private relationships.¹⁶ Human rights usually have a broader (international) or more abstract connotation.¹⁷ In this more abstract connotation, human rights can also refer to what is understood here as ‘values’.

Bioethics and the human rights discourse in many ways grew up together after the Second World War, where particularly the Nuremberg Trials had an important and contested role to play.¹⁸ In the literature there are different approaches to the relationship between bioethical values –both in an individual health context, and with regard to population health – and rights. On the one hand, it has been argued that to speak of values or human rights in legal terms provides a universal language for ‘the development of international legal standards for biomedicine’.¹⁹ Values in this respect provide a normative basis for specific fundamental health-related rights. George Annas even refers to bioethics and law as ‘estranged twins’ in this respect.²⁰ On the other hand, there is also criticism of the immediate relationship between values and fundamental or human rights. Bioethicists have argued that rights have their own legitimacy problems and that it limits the moral concepts that are used and

¹⁶ Commission, ‘2013 Report on the application of the EU Charter of Fundamental Rights’ COM (2014) 224 final; C Mak, *Fundamental Rights in European Contract Law: A Comparison of the Impact of Fundamental Rights in Contractual Relationships in Germany, the Netherlands, Italy and England* (Wolters Kluwer 2008) 6. See further Chapter 3 in this book.

¹⁷ R Alexy, ‘Discourse Theory and Fundamental Rights’ in AJ Menendez and EO Eriksen (eds), *Arguing Fundamental Rights* (Springer 2006) 17.

¹⁸ E Fenton, ‘Bioethics and Human Rights’ in JD Arras, E Fenton and R Kukla (eds), *The Routledge Companion to Bioethics* (Routledge 2014).

¹⁹ R Andorno, ‘Human Dignity and Human Rights as a Common Ground for a Global Bioethics’ (2009) 34 *Journal of Medicine and Philosophy* 223, 224. Also see LP Knowles, ‘The Lingua Franca of Human Rights and the Rise of a Global Bioethic’ (2001) 10 *Cambridge Quarterly of Healthcare Ethics* 253.

²⁰ GJ Annas, ‘Human Rights and American Bioethics: Resistance Is Futile’ (2010) 19 *Cambridge Quarterly of Healthcare Ethics* 133.

relevant when referring to broader values that have a self-standing importance. Moreover, a rights-based approach is only one of the many perspectives in this regard.²¹

The innate plurality of the EU legal order and the growing importance of fundamental rights (CFREU) and the underlying 'ethical' (naturalistic) implications of rights, makes their impact controversial in the European context. Rights are increasingly used to legitimate important decisions that affect the autonomy of the Member States.²² In a political conception, rights in the EU are also controversial, given the absence of a formal EU constitution.²³ Furthermore, rights in the deeper sense of common humanistic values are particularly controversial in the health context.²⁴ The different underlying reasons for the regulation of abortions across Member States, is a striking example. It is therefore important to reconcile the 'legal', 'political' and the 'ethical' conceptions of values and human rights, for instance through democratic notions or on the basis of other theories.²⁵ This is particularly the case for the EU, where an actual 'fundamental rights policy',²⁶ including Article 2 TEU itself presupposes a preconceived idea of shared values, an idea in which direction to take the EU in this respect,²⁷ rather than merely taking the status quo of fundamental rights protection as a matter of social practice, and thus dependent on place and time, as implied by a political conception of human rights.²⁸ What remains is the expression of values in EU health law. In this respect, as will be outlined below, there are different aspects of EU health law that express various degrees of values of health law, yet EU fundamental rights and EU values and principles are the primary locus whereof EU values in health law are expressed.

II.ii Health Values in EU Fundamental Rights

In the context of health law, each Member State itself has formulated the values and principles that underlie its national healthcare system or systems.²⁹ When the Council adopted its Conclusions on

²¹ O'Neill (n 3). Other approaches could be the classical utilitarian or deontological approaches, or a capabilities perspective etc. M Freeman, *Law and Bioethics* (OUP 2008).

²² E Muir, 'The Fundamental Rights implications of EU Legislation: Some Constitutional Challenges' (2014) 51 *Common Market Law Review* 219.

²³ AJ Menendez 'Some elements of a theory of European fundamental rights' in Menendez and Eriksen (n 17) 156.

²⁴ Menendez and Eriksen (n 17).

²⁵ Bagatur (n 3); *ibid.* P Gilabert, 'Humanist and Political Perspectives on Human Rights' (2011) 39(4) *Political Theory* 439; SM Liao and A Etinson, 'Political and Naturalistic Conceptions of Human Rights: A False Polemic?' (2012) 9(3) *The Journal of Moral Philosophy* 327 and see Alexy (n 17).

²⁶ P Alston and JHH Weiler, 'An 'Ever Closer Union' in Need of a Human Rights Policy: The European Union and Human Rights' (1998) 9 *European Journal of International Law* 658; A von Bogdandy, 'The European Union as a Human Rights Organisation? Human Rights and the Core of the European Union' (2000) 37 *Common Market Law Review* 1307.

²⁷ This also shows in some of the CJEU's case law on the Charter where the interpretation is usually based on a preconceived idea of rights 'that were already protected' in the EU legal order, see on this point and a discussion of these cases, P Eeckhout, 'The EU Charter of Fundamental Rights and the Federal Question' (2002) 39 *Common Market Law Review* 945.

²⁸ R Forst 'The Justification of Human Rights and the Basic Right to Justification: A Reflexive Approach' (2010) 120 *Ethics* 711, 727, emphasising the 'internal' role (inside a political system) of human rights for assessing legitimacy and see further Bagatur (n 3) 9.

²⁹ Council Conclusions (n 5).

Common Values and Principles in EU Health Systems,³⁰ it referred to ‘common’ values and principles among the Member States. The legal status of those common values and principles, and their relationship to fundamental rights in the sense of EU law, depends on whether the Council was referring to these values and principles in the sense of Article 2 and 6 TEU.

Article 6(3) TEU holds that:

Fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms and as they result from the constitutional traditions common to the Member States, shall constitute general principles of the Union’s law.

The language of the Council’s 2006 statement of Common Values (referring to ‘values’, rather than principles of EU law) suggests that it is not intended to constitute a statement of general principles of EU law, that are on equal footing with fundamental rights. However, in combination with particular fundamental rights of the Charter of Fundamental Rights of the EU (CFREU),³¹ it could be argued that the Common Values in the 2006 Council Conclusions may help shape the interpretation of fundamental rights in the context of EU health law. The 2006 Common Values were a response to the CJEU line of case law at the time, in the field of cross-border healthcare. They were intended to feed into the legislative process that eventually resulted in the Patients Rights’ Directive.³² Therefore the 2006 Common Values represent an indication of the baseline of principles that are common to the Member States, and in that regard they could also at least be taken into consideration in the EU legislative process, although this is not legally required. At the same time, the 2006 Common Values were written so as to stress their importance in the context of the organisation of national healthcare systems, a matter over which the Treaty explicitly requires national competence. In the field of public health, where the EU enjoys greater competence, however, there is no explicit document that refers to for instance values of solidarity or equality. In the central legal provisions, Article 9 TFEU and Article 168 TFEU, the central objective is formulated as ‘a high level of human health’, which is difficult to determine.

The values of solidarity, equality, universal access and human dignity are addressed in the CFREU. For an outline of the importance and application of the CFREU, and also general principles of EU law, and how these different legal sources have gained importance in the EU legal order, readers are referred to Calum Young’s chapter.³³ The EU’s adherence to the protection and promotion of fundamental rights, on the basis of EU primary law, is expressed as a constitutional value. Article 2 of the Treaty on European Union (TEU) lays the foundation of the EU’s agreed ‘common values’ as the basis of the EU’s constitutional structure.

Article 2 TEU

*The Union is founded on the **values** of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities. These values are **common** to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail. [emphasis added]*

³⁰ *ibid.*

³¹ Charter of Fundamental Rights of the European Union [2012] OJ C326/391.

³² European Parliament and Council Directive 2011/24/EU of 9 March 2011 on the application of patients’ rights in cross-border healthcare [2011] OJ L88/45 (Patients’ Rights Directive).

³³ Also see McHale (n 13); TK Hervey, ‘The “Right to Health” in European Union Law’, in TK Hervey and J Kenner (eds), *Economic and Social Rights under the EU Charter of Fundamental Rights* (Hart 2003); Hervey and McHale (n 7).

Article 3 TEU

(1) *The Union's aim is to promote peace, its values and the well-being of its peoples.*

Importantly, the *respect for rights* in itself is taken to be a foundational value of the European Union, which is assumed to be a value that is *common* to the Member States. Arguably, given that the values in Article 2 TEU are taken to be common to the Member States,³⁴ this means that reference to national identity (Article 4(2) TEU) cannot be used in the case of infringements of the values held in Article 2 TEU.³⁵ Furthermore, Article 2 TEU refers to 'human rights' and not 'fundamental rights', which are protected under Article 6 TEU by reference to, for example, the CFREU. As mentioned 'human rights' as a term is usually used to connote a deeper meaning that goes to underlying, deeper values when speaking in terms of 'rights'. These deeper values are sometimes also referred to as 'rights' but rather in a particular ethical sense.

The fundamental rights in the CFREU that express the EU health law values of solidarity, equality, universal access and human dignity can be found as follows in Table 19.1.

Table 19.1 Overview of the health topics potentially affected by European fundamental rights

Value/human right	Fundamental right	European provisions	EU Health topics involved
Human dignity	Human dignity	1 CFREU	End of life issues, access to health care, long term care
Human dignity (Respect for human life/autonomy)	Right to life	2 CFREU	Access to abortion in another Member State End of life issues, euthanasia Protection of life through public health measures Environmental health threats
Human dignity	Informed consent	3 CFREU	Bodily integrity, inviolability of the human body, autonomy in medical decisions, the right to refuse medical treatment

³⁴ Article 49 TEU on membership to the Union also refers to adherence to its values in Article 2 TEU

³⁵ LFM Besselink, 'The Bite, the Bark and the Howl: Article 7 TEU and the Rule of Law Initiatives' in A Jakab and D Kochenov (eds), *The Enforcement of EU Law and Values: Ensuring Member States' Compliance* (OUP 2016). (Although given the status of the right to health as a principle in the CFREU it is unlikely that Article 7 TEU as an enforcement mechanism will easily be evoked in the case of health rights' violations in Member States.)

Human dignity	Prohibition of torture and inhuman and degrading punishment	4 CFREU	Confinement of persons with mental disabilities Rape, sexual abuse Undue delay of access to health care
Human dignity	Privacy and family life, data protection	7, 8 CFREU	Medical research Protection of personal data, confidentiality of medical files (ehealth) Medical files/psychological background Union civil servants
Human dignity	Information and participation	11 CFREU	Access to health-related information to services and public health. Informed consent
Dignity, equality, solidarity	Education	14 CFREU	Education as a social determinant of health Sex education as public health
Equality	Protection of mothers, children and of the family	24 CFREU	Paid and sufficient maternity leave Social and family benefits Equality directive, disabilities, gender etc.
Equality, solidarity and universal access	Non-discrimination	20-26 CFREU	Non-discrimination in access to health care services and preventive care
Equality, solidarity	Employment	32 CFREU	Occupational health Employment as a social determinant
Solidarity and Equality	Social security	33 CFREU	Social security as a social determinant of public health
Equality, universal access	Right to health Right to access health	35 CFREU	Access to health care and other (public) health services, Access to preventive care Protection of public health

care	Reproductive Health
	Protection of environment as it affects public health
	Occupational health
	Regulation of services of general interests
	Pharmaceuticals and medical devices

Yet, the fact that these shared and common values can be distinguished at EU level in the field of health, does not solve the puzzle of what effect the constitutional nature of the EU has on the protection and promotion of these values within EU health law. The values that underlie EU health law as common values are difficult to balance on their own, when they are competing – and losing – to other values or principles of the EU’s free market.³⁶ It is at least arguable that the internal market freedoms form the very reason for the EU health law’s existence.³⁷ The four freedoms as constitutional principles are even stronger than the EU constitutional principle of subsidiarity in the field of health, which explains the recurrent paradox that the internal market legal basis (Article 114 TFEU) forms the legislative ground for many aspects of EU health law, where Member States at the same time have limited EU powers (Article 168(5) public health and (7) healthcare TFEU).

III. HEALTH LAW IN THE EU CONSTITUTIONAL SETTING

The question regarding the role of the EU’s constitutional order brings into perspective a classical thesis by Fritz Scharpf. Scharpf proposes that the EU’s limited legislative competence in areas outside the internal market objectives create a constitutional asymmetry.³⁸ The institutional and legal constraints for the EU to adopt ‘market-correcting policies’ favour economically liberal interests and policies, which in turn constrain Member States at national level to pursue welfare goals. At the same time, as recently argued by Dieter Grimm, the EU’s legal order is ‘over-constitutionalized’. In most political systems, constitutions function to legitimise and limit political power. Constitutional rules form the ‘framework for politics, not the blueprint for all political decisions.’³⁹

The ‘over-constitutionalisation’ of the EU refers to the notion that the four freedoms and the

³⁶ See particularly Chapter 11 in this book which refers to the competing values of the common market in EU competition law.

³⁷ For an alternative position, see Hervey and McHale (n 7); TK Hervey, ‘Telling stories about European Union Health Law: The emergence of a new field of law’ (2016) *Comparative European Politics* DOI 10.1057/cep.2016.4 <www.palgrave-journals.com/cep/journal/vaop/ncurrent/full/cep20164a.html> accessed 1 June 2016.

³⁸ A de Ruijter and TK Hervey, ‘Healthcare and the Lisbon Agenda’ in P Copeland and D Papadimitriou (eds), *The EU’s Lisbon Strategy: Evaluating Success, Understanding Failure* (Palgrave 2012); see F Scharpf, ‘The Asymmetry of European Integration or why the EU cannot be a “Social Market Economy”’ (2010) 8(2) *Socio-Economic Review* 211.

³⁹ D Grimm, ‘The Democratic Costs of Constitutionalisation: The European Case’ (2015) 21 *European Law Journal* 460.

objective of the creation of an internal market overrides all other legitimate policy objectives, due to their constitutional status in the Treaties and their function as constitutional review standard for the CJEU. The field of health in the EU exemplifies Grimm's thesis, given that the CJEU has had a central role in reaffirming the recasting of national public health considerations as 'exceptions' even beyond those exceptions that are mentioned in the Treaties.⁴⁰ Importantly, however, in the field of human health, Member States' health law is directly impacted by EU inroads into this field.⁴¹ Liberalisation and privatisation, together with the effects of globalisation and the constitutional context of the EU make it difficult for the Member States to uphold their standards of social welfare in order to retain their economic competitiveness.⁴²

Furthermore, the EU does not have a budget that can be used to alleviate these effects in light of values such as equality, solidarity and universal access. The European public health programme only has a small budget that pales in comparison to the national budgets for public health and healthcare services and programmes.⁴³ Nevertheless the EU public health programmes are an example of positive integration at EU level that actually redistributes funds in the area of social welfare. And although the public health programmes over the years have had to make do on very low budgets,⁴⁴ they have links with the much larger budget of the EU research programme that allocates more than six billion Euros for health. The priorities defined in the Programme Committee for the public health programme filter through in the funding priorities that are chosen in the Programme Committee of the health programme under the heading of DG Research.⁴⁵ Moreover, much of the public health budget is distributed through co-funding, which means any activity or action usually needs at least 40 per cent funding from other sources. Another aspect that plays into this is that the EU public health programmes play a role in the distribution of EU structural funds, in that objectives of the public health programmes are mirrored with respect to the budget for health priorities in the structural funds.⁴⁶ However, EU macroeconomic policy has had a much deeper impact on the protection of values of health in the Member States.

In Chapter 12 Sokol and Mijatović outline how the EU facilitated the existence of the European Stability Mechanism (ESM), which is the governance structure established by (or for) the Eurozone countries. With regard to the countries that received financial aid during the Euro crisis, the ESM established Memorandums of Understanding (MoU), monitored by the European Commission. Non-compliance with these MoUs can result in sanctions. As a result, the healthcare systems of these Member States, and particularly the ability of Member States to determine their own budgets for healthcare spending, were immediately affected. Given that the ESM is outside the EU legal realm, the first question is whether EU law on fundamental rights even applies. Furthermore, Member States

⁴⁰ See *Cassis de Dijon* (n 8), 'The Rule of Reason'.

⁴¹ TK Hervey and JV McHale, *Health Law and the European Union* (CUP 2004). In this first edition, this dynamic is meticulously mapped.

⁴² Grimm (n 40); see further Chapter 12 in this book.

⁴³ See de Ruijter (n 2).

⁴⁴ Averaging 300 to 500 million Euros.

⁴⁵ This link with research and health at EU level goes back to the 1950s since the ECSC funded research programmes in the area of occupational diseases. Over the course of the 1970s and especially in the 1980s, research into communicable diseases was also funded by the Community – this was mainly in the context of the common market and agriculture. However, also in the field of research and technology biomedical research became funded at the European level in the area of biotechnology. Commission, 'Biology and Health Protection Programme: Research Programme 1976–1980' (Proposal) COM (75) 351 final. See de Ruijter (n 2).

⁴⁶ J Watson, 'Health and Structural Funds 2007–2013 (2013): Country and regional assessment' (Report for DG SANCO, 2009) and see *ibid*.

are subject to the European Semester, which is an EU governance mechanism for national macroeconomic and fiscal policies based on the Stability and Growth Pact. Also in this regard the Member States have been pushed towards cutting public spending in the field of health.⁴⁷

Aside from deregulation, (EU) macroeconomic policies and their impact on the Member States' abilities to sustain national health policies in accordance with the values of solidarity, equality and universal access, re-regulation of human health law and policy at EU level is a third factor to consider in terms of its effect on the upholding of health values. Particularly in the field of public health, a massive regulatory effort has been undertaken in the EU to create markets by ensuring health and safety. However, also in this respect as the tobacco advertising saga foretold, the EU has only a limited legislative basis for recreating health protection regulation at EU level. As Marjolein van Asselt, Ellen Vos and Michelle Everson have argued persuasively, the manner in which the EU re-regulates in the field of public health is also depoliticised through what Sheila Jasanoff calls the 'constitutional role of' science.⁴⁸ Their central thesis is that the EU obfuscates political disagreement about balancing health risks with economic aims, through science.⁴⁹ Moreover the EU constitutional order – similar to Dieter Grimm's observations – puts executive actors in the lead, particularly also in politically sensitive policy issues.⁵⁰ Van Asselt, Vos and Everson have shown how the EU regulators use public health regulation as a tool to enhance the EU's legitimacy. In their research they establish that for public health regulation, science is needed to align economies in order to limit market forces. However, the EU – in so doing – excludes the value or ethical considerations that are actually at play. Ethics, specifically bioethics, are formally still largely determined at Member State level.⁵¹ In some specific areas of EU secondary regulation, ethics committees are involved, however their contribution is fragmented and in a recent overview of the EU's approach to ethics it was outlined that many gaps remain at EU level, also in areas affected by EU internal market regulation.⁵²

Human dignity as a value lies at the basis of all elements of law and involvement in health, and can thus be taken as the foundation for a number of specific patients' rights.⁵³ At EU level, however, what human dignity requires is essentially left up to the Member States.⁵⁴ But the question of human dignity could also become a EU issue – in this regard Article 3 CFREU on the integrity of the person is closely related to the principle of human dignity.⁵⁵ Human dignity can refer both to the individual in terms of personal integrity and to protecting the society at large. The principles outlined in Article 3

⁴⁷ See Grimm (n 40). R Baeten and B Vanhercke, 'Inside the Black Box: The EU's Economic Surveillance of National Healthcare Systems' (2016) *Comparative European Politics* DOI: 10.1057/cep.2016.10 <<http://link.springer.com/article/10.1057/cep.2016.10>> accessed 7 July 2016.

⁴⁸ See S Jasanoff in M Weimer and A de Ruijter, *The Co-Production of EU Expert and Executive Power in the Field of Public Health and the Environment* (Hart) (forthcoming).

⁴⁹ Hervey and McHale (n 7). M van Asselt, M Everson and E Vos, *Trade, Health and the Environment: The European Union Put to the Test* (Routledge 2013). M van Asselt and E Vos, 'The Precautionary Principle and the Uncertainty Paradox' (2006) 9 *Journal of Risk Research* 313. See also Chapter 6 in this book.

⁵⁰ See Grimm (n 40). Also see D Curtin, *Executive Power of the European Union, Law, Practices and the Living Constitution* (OUP 2009).

⁵¹ Frischhut (n 7).

⁵² *ibid.*

⁵³ See McHale (n 13).

⁵⁴ See Case C-36/02 *Omega* ECLI:EU:C:2004:614, [2004] ECR I-09609 and see S Douglas-Scott, 'The European Union and Human Rights after the Treaty of Lisbon' (2011) 11 *Human Rights Law Review* 645.

⁵⁵ Case C-377/98 *Netherlands v Parliament and Council* ECLI:EU:C:2001:523, [2001] ECR I-7079, see paras 77 and 78 on the basis of human dignity for not allowing patentability of elements of the human body.

CFREU generally are also part of the Council of Europe's ECHR, except for informed consent, which has only been developed in the case law of the ECtHR on the basis of Article 8 ECHR.⁵⁶ The second paragraph of Article 3 CFREU specifically outlines that informed consent must be respected in the field of medicine and biology, and that eugenic practices, particularly those aiming at the selection of persons, making the human body and its parts a source for financial gain and reproductive cloning of human beings, are prohibited.⁵⁷ The prohibition of reproductive cloning reflects the value of human dignity at population level, for instance with regard to the regulation of clinical trials at EU level or even with the appropriation of funds for medical research from the EU.⁵⁸

Human dignity also plays a role in the context of EU regulation of medicines. For instance, take the authorisation of gene therapy with respect to the regulation of pharmaceuticals at EU level. In 2013, the European Commission approved the medicine Glybera. This medicine uses a virus to deliver DNA encoding a lipid-processing enzyme to patients that lack this gene mutation. Gene therapy alters the human genetic code; the question is how this is different from a 'eugenic practice' and to what extent this (should) affect the authorisation of these therapies at EU level.⁵⁹

The constitutional setting of the EU, where economic objectives (i.e. the policy content itself) is protected as constitutional values, affects the place and protection of values in EU health law, that are central to the health law of the Member States – values such as human dignity, equality and solidarity. At Member State level, the EU law also affects health law, as it is approached as a barrier to trade, whereas at EU level, health law is recreated, but its inherent values are depoliticised through science. The constitutional balance between the economic 'values of efficiency' as outlined in the chapter by van de Gronden and Rusu, and health values is – because of the constitutional setting of health law in the EU – more likely to favour economic aims rather than health values. However, these values are not always opposing. For example, as Hervey and McHale outline, EU competition law has likely contributed to consumer benefits and a lowering of prices in the healthcare sector, which is important in ensuring universal access and upholds the values of solidarity and equality.⁶⁰

IV. CONCLUSION: FUTURE RESEARCH

Comparing the status of health values in the Member States and at EU level would substantiate the claim that the EU impedes health values through EU health law. However, the argument is not that simple. On the one hand, Member States to a large extent retain their own competences in the field of

⁵⁶ See, eg, *Tysiąc v Poland* App No 5410/03 (ECtHR, 20 March 2007); *KH and others v Slovakia* App No 32881/04 (ECtHR, 28 April 2009); and *RR v Poland* App No 27617/04 (ECtHR, 26 May 2011), which are some of the more recent cases of the ECtHR on the forced sterilisation of Roma women and in the context of abortions for medical reasons.

⁵⁷ CFREU, Article 3(2)(d), this is also prohibited in the UN declaration on the Human Genome and Human Rights and in European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L213/13. See extensively Chapter 9 in this book.

⁵⁸ An example here is *Netherlands v Parliament and Council* (n 56), where although an appeal to human dignity is accepted, nevertheless the plea with respect to informed consent is rejected given that: 'The purpose of the Directive is not to replace the restrictive provisions which guarantee, outside the scope of the Directive, compliance with certain ethical rules which include the right to self-determination by informed consent;' see para 80.

⁵⁹ See n 59, to interpret this provision as an individual right would probably involve reference to human dignity.

⁶⁰ Hervey and McHale (n 7) 229.

health in the EU as the Court of Justice clearly outlines in the above-cited *Perez* case. On the other hand, deregulation, macroeconomic policies and reregulation also affect the values that are part and parcel of health law at national level. Member States' health law has not remained unchanged in the past decade, and this is in a large part due to EU health law and regulation.

EU health law has a bearing on the same health values that form the foundations of national health law and its backbone is formed not only by internal market law, but also by EU fundamental rights law. Yet the impediment of EU values underlying health law is arguably stronger at national level due to the constitutional setting at EU level. Given the constitutional order of the EU, in which the policy content is determined at constitutional level, mostly by competition law and economic free movement principles and values, EU health law is lacking in terms of its protection and promotion of the values of solidarity, human dignity and the protection of the plurality of Member States.

Besides the importance of the 'EU economic constitution' in this respect, another factor to consider is the role of science. Science in the EU has the important role of depoliticising and taking the discussion on its innately related values such as human dignity out of the political equation. Health law and policy related to science or new technologies and aspects such as the commodification of human body parts etc. are often not presented as political choices at EU level, but rather presented as necessary for competitiveness or innovation. The argument as put forward by many scholars is that the EU needs a more lively and real democratic debate. However also in this respect, the economic values and aims being a central connecting factor in the EU constitutional structure could prove to be problematic. As Mark Flear exemplifies in the field of citizens science,⁶¹ even when participative democratic procedures are used in order to politicise and legitimise political choices on values that are made in the field of science, also here democratic participation is captured by the dominant economic constitution in which the objectives of science have been predetermined (knowledge economy, competitiveness, innovation).

These problems are constitutional because they address the manner in which the EU is able to create health law. This is an inherently democratic problem, but also a problem of the nature of EU health law itself. Hence, it is up to future research in the field of EU human health law, legal scholars and political and social science to ask whether the constitutional order of the EU can be changed or set up in a manner in which EU health laws' values will not have to compete so hard with EU economic values.

⁶¹ See further Chapter 6 in this book.