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Title Page

Title: Abortion by telemedicine in the European Union

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Keywords: telemedicine; early medical abortion; abortion pills; mifepristone; misoprostol; EU law; trade law; free movement of services.

Synopsis: Where offered by accredited doctors within the EU, telemedical early medical abortion services are potentially protected by EU free movement laws.

Abstract: This paper analyses an important set of legal issues raised by the telemedical provision of abortion pills. Focusing on the case of EU law, it suggests that a properly accredited doctor seeking to treat a patient with abortion pills is entitled, in principle, to rely on EU rules of free movement to protect her access to patients in other member states and women facing unwanted pregnancies likewise have legal rights to access the services thus offered. EU countries seeking to claim an exception to those rules on the basis of public health or the protection of a fundamental public policy interest (here, the protection of fetal life) will face significant barriers.

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Abortion by telemedicine in the European Union

Tamara Hervey and Sally Sheldon

Introduction

This article explores one set of legal challenges raised by the interplay of two technologies. First, reliance on electronic media opens up the possibility of telemedicine, involving the provision of healthcare services in situations where the health professional and the patient are not in the same location. Second, safe, effective treatment protocols now exist for medical abortion (where a pregnancy is ended using mifepristone and misoprostol – collectively referred to below as ‘abortion pills’). Combined, these two technologies open up the possibility of telemedical abortion services. The clinical issues raised by this possibility have been widely considered [1, 2] but the regulatory issues far less so [3]. Much discussion of abortion law has – quite properly – been framed within international human rights norms. Here we consider something different and far less well explored. How does transnational trade law apply to the situation when telemedical abortion services cross national boundaries to enable a woman resident in a country where abortion is illegal or highly restricted to end an unwanted pregnancy? Can residents of these countries rely on transnational trade law to assert rights to receive telemedical abortion services? And can health professionals claim a legally protected right to treat them?

While this discussion raises issues which resonate in other regional contexts and other regulatory frameworks, here we focus on how these issues might play out within the European Union. The EU has a highly developed set of uniform regulations governing transnational trade and wide variation in domestic abortion laws. While there has been a gradual trend towards more permissive regulation of abortion within Europe, there nonetheless exists significant variation, with termination of pregnancy available on request within specified gestational limits in some countries (including the Netherlands, Sweden, and France) to others where it is permitted only in highly restricted circumstances (such as Northern Ireland, Malta, and Poland) [4]. Where legal local abortion services are not available, women will either travel to access services in other countries or end pregnancies outside of formal healthcare settings [5]. Many of these women will seek to have abortion services travel to them, through the online purchase of abortion pills.

Abortion pills are readily available on the internet from a range of suppliers. Some will supply pills without a medical prescription; and some of the pills thus supplied will not contain the indicated quantity of the active medical ingredient [6]. We do not consider those situations here. Rather, we focus just on the case where authentic pills are supplied on prescription by an appropriately accredited doctor based in another EU country. This brings legal issues of free movement of medicines and services into particularly sharp focus. When articulated in the language of EU law, these issues can appear very technical and far removed from the fundamental moral issues which underpin them. This should not conceal what is at stake here: the responsible conduct of medical practice in supporting women’s reproductive health; the proper role of telemedical services in allowing women to escape domestic criminal prohibitions that reflect religious and moral concerns for the protection of embryonic and fetal life (hereinafter fetal life); and the reach of EU law into sensitive moral matters.

Abortion using pills purchased online

The safety, effectiveness and patient acceptability of abortion pills is well established [7, 8], including in cases when the pills are used in the patient's home [9, 10] transforming the way that abortion services can be offered. Here, we focus on the work of two online collectives of doctors and trained volunteers, who are motivated by concerns for social justice, reproductive health and solidarity with women facing unwanted pregnancies [2, 11, 12]. Following an online consultation that screens for the small number of contraindications to early medical abortion and confirms that a woman's pregnancy has not exceeded nine weeks, Women on Web (WoW) and Women Help Women (WHW) each supply abortion pills to women in countries where abortion is legally restricted. Each group follows a well-established treatment protocol involving sequential administration of mifepristone followed by misoprostol. Clear instructions are provided both as to correct use and the symptoms that would require the woman to seek local aftercare, with advice and support available by e-mail for as long as the woman needs it. In return, a donation of €60-90 is requested from those who can afford it (or waived for those who cannot), with those who can afford more asked to contribute to supporting the provision of services for others.

While evidence suggests that the service offered by these groups is very safe and highly acceptable to those who use it [13] it is subject to one important limitation: the medical treatment offered necessarily ends with provoking a miscarriage. This means that women must seek medical treatment locally for any complications that arise. Serious infections requiring hospitalization are very rare and it is only in the most extreme circumstances (estimated at 0.03% of cases) that women require transfusion to replace excessive blood loss [14]. However, haemorrhage can be life-threatening if left untreated and women are advised to plan for it. WoW and WHW emphasize that this makes a planned miscarriage considerably safer than if the same thing occurs spontaneously and that women often manage spontaneous miscarriages by themselves at home, with limited medical supervision. Research suggests that, given appropriate information, women can safely self-assess to confirm whether the termination is complete or whether further care is needed [15].

It is also important to remember that the risks of a telemedical abortion be measured against the risks implicit in the other options available to women. First, alongside the social, emotional, and financial harms that come with continuing an unwanted pregnancy to term are the very real clinical risks of so doing: pregnancy and childbirth carries a significantly higher risk of morbidity and mortality than a safely performed abortion, particularly in early pregnancy [16, 8]. Second, while less well documented, the need to travel to obtain an abortion has negative emotional, financial and health consequences [17], not least in delaying access to services resulting in later, higher risk procedures. Third, where unable to access safe abortion services, some women will try other extreme measures to end a pregnancy, which are often either exceedingly dangerous, likely to be ineffective, or both. It is noteworthy that the availability of abortion pills is credited with making a contribution to the global reduction in the number of women dying or seeking aftercare for severe complications following illegal abortion each year [18, 19].

There is thus good reason to believe that the telemedical abortion services offered by WoW and WHW meet the best standards of patient care and safety available, given the context in which they are offered. Indeed, an Austrian court has recognised that WoW's work has made a material contribution to women's health and survival [20]. The groups offer women a choice that allows them to avoid the risks of other, often unsafe, methods of abortion and the significant physical, emotional, social and financial burdens of continuing an unwanted

pregnancy. However, highly controversially, they also enable women to avoid domestic legal prohibitions on abortion [21].

The EU law on patient choice and professional services

EU law, like other trans-national trade agreements, on services, may cover situations where the service itself crosses a border, rather than the person who receives or provides the service. The provision of a medical consultation online and the prescription of abortion pills which are then shipped to the patient is that kind of service. The provider (health professional) and the receiver (patient) remain in their different states: the service crosses a border. In the language of trade law, non-tariff barriers to trade are, potentially, any domestic rules that impede the access of service providers established in one country that is part of a trade agreement to those in another country also bound by that trade agreement. [3], [22] Legal restrictions on the provision of abortion services across borders are thus non-tariff barriers to trade. Trade agreements seek to ban or reduce the number of non-tariff barriers, in the name of securing free trade, which is understood to be in the interests of consumers and economies generally. [22] [23]

EU law is a particularly dense example of this kind of trade agreement. First, it includes not only the trade agreement itself (the 'Treaty on the Functioning of the EU') but also a significant web of legislation adopted by the EU institutions that applies to trade within the EU. Second, EU law includes mechanisms whereby individual traders (service providers and receivers, or in our case, health professionals and their patients) may enforce their rights using courts. This is relatively unusual: trade agreements usually provide only for inter-state dispute settlement, and/or arbitration. Third, EU law adopts a highly restrictive approach to rules that have the effect of trade protectionism. Any restriction of access to markets is treated as suspect. Impeding market access must be carefully justified, and must be a proportionate restriction on trade [22].

From the point of view of those seeking to provide and receive telemedical abortion services, EU law offers a number of important potential protections. So long as a health professional complies with the domestic law within the country in which she works when treating her patients, the starting principle is that she can use rights to trade in order to reach patients in other countries who wish to be treated by her. EU law gives enforceable rights to the health professional to offer the service, and to the patient to receive it. Attempts to prosecute either can also be met with a defence that the prosecution breaches EU law [23].

What specific EU laws might apply in this situation? While the most obvious legislation – the Directive on Patients' Rights to Cross Border Healthcare [24] – does not cover remote prescribing, the e-commerce Directive [25] covers medical consultations undertaken through a website. And the general provision of the Treaty on the Functioning of the EU, Article 56, applies if the e-commerce Directive does not. Both prohibit 'restrictions' on cross-border trade in services unless those restrictions are justified by an objective public interest in the state intervening in that free trade. Because a 'restriction' is anything that makes it harder to receive the service across borders, the important question here is whether a state intervening by its abortion laws is a justified trade restriction.

Justified state interventions

No trade agreement, even one of the depth, intensity and enforceability of EU law, removes entirely states' sovereign entitlements over important matters of public policy or morality, promoting or protecting health, or securing human rights. Non-tariff barriers do not breach EU law if they are necessary to protect such public interests. One might thus assume that it would be easy for European states to argue that their abortion laws protect the broad purposes for which they were generally historically intended – to protect women's health and/or to recognise the special moral status of the fetus – and thus avoid any application of EU law to cross-border abortion by telemedicine. However, several features of EU law suggest that it would not be as straightforward as one might expect to assert such an exemption, thus leaving scope for doctors providing or patients receiving such services successfully to rely on EU law to defend their activities.

In general, EU law respects national decisions about acceptable risks to human health and national articulations of morality and human rights. However, the EU's Court of Justice gives considerably less discretion to national decision-makers than does the European Court of Human Rights in Strasbourg. The starting point for the EU Court is that public interest reasons for departing from trade law are *exceptions*, and thus should always be narrowly interpreted. Further, derogations from free movement of services must mutually respect equivalent protections, including professional qualifications, in another EU country. Finally, exceptions must be part of proportionate, consistent and evidence-based national law and policy.

This has several implications. First, an argument that fails to treat the doctor established in another EU country as an equivalently competent and trusted health professional to those in the state where the patient is based would fail under EU law. Second, an argument that protecting women's health requires a restriction on services of abortion by telemedicine would have to show that the domestic law actually works to protect health, or to prevent a risk of harm to women seeking abortion by telemedicine. As explained above, the treatment protocol used by reputable abortion service providers (such as WoW) is both safe and effective and any negative health consequences of telemedical use of abortion pills are outweighed by the health consequences of the alternative options available. There is overwhelming evidence that restrictive abortion laws are very harmful to women's health and good public health arguments to believe – in the terms of the Austrian court cited above – that these groups' work makes a material contribution to women's health and survival [20]. An argument restricting cross-border abortion by telemedicine for public health reasons would, we think, be difficult to make convincingly.

States seeking to justify their restrictive policies would thus need to rely on a 'public policy' argument, based on a recognition of the moral status of the fetus. But these restrictions also have to be proportionate, taking into account equivalent protections of the relevant interests in the other state. All EU countries recognise and protect the special moral status of the fetus, for instance, through restricting access to abortion later in pregnancy. Further, while there is a wide divergence in relevant domestic laws, there is a clear trend towards legislation that permits greater access to services, and a majority of member states allow some access to abortion within early pregnancy (the period within which WoW offer treatment) [4]. In such a context, what might be considered outlier legal positions – such as harsh criminal penalties, a failure to offer any access to services even very early in pregnancy, a refusal to offer abortions for fatal fetal abnormality or where there is risk to a woman's health and so on – all tend to suggest the disproportionality of the policy.

Relying on the moral status of the fetus to restrict cross-border telemedicine services also goes to the question of whether protecting fetal life justifies a restriction not only on trade, but also on the rights of the pregnant woman to dignity and autonomy, and the freedom of the WoW and WHW doctors to pursue a profession. EU countries do not enjoy unrestrained discretion over standards of public morality. The impact of the exercise of that discretion has to be considered proportionate, taking account of its effects on entitlements of individual women to exercise not only trade rights, but also human rights, across EU borders. Women's rights such as the right to integrity of the person, freedom from inhuman and degrading treatment, and human dignity, are all potentially engaged.

In short, we regard as far from legally certain that an EU country could successfully defend a policy or law that restricted the receipt of abortion services involving telemedicine by women in its territory, where the doctor offering the service operates lawfully from another EU country.

Conclusions

To recap: a doctor seeking to treat a patient with abortion pills is entitled, in principle, to rely on EU rules of free movement to protect her access to patients in other member states and women facing unwanted pregnancies likewise have legal rights to access the services thus offered. EU countries seeking to claim an exception to those rules on the basis of public health or on the protection of a fundamental public policy interest (here, the protection of fetal life) will face significant barriers. The legal burden of establishing that a derogation from free movement rules can be justified lies on the EU country concerned. While again we have had no space to consider this further here, similar protections may be available under other trade agreements.

It is important to emphasise again that the focus of our argument is restricted to the case of properly accredited doctors, acting within the law of the country from which they operate, to supply authentic abortion pills on prescription. Within those limited circumstances, we believe that EU trade law is properly interpreted so as to offer important protections both to doctors and their patients. How the protections thus offered would translate into enforceable rights raises a further set of complexities that will depend in part on the specific national context and go far beyond the scope of this paper (and we have offered a more detailed exploration of one national context elsewhere[3]). However, they are likely to offer a basis for legal challenge to any attempt by local authorities to prevent the physical importation of abortion pills; and to require that, insofar as possible, domestic law be interpreted so as to render it consistent with these international trade obligations. This is not to deny that any relevant litigation would raise a range of difficult legal questions, which have not been fully tested in the courts. As such, the legal pathway to challenging an attempt to prevent the prescription of abortion pills for a patient in one country from a prescribing doctor in another would inevitably be long, expensive, and contested.

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