

# Consequences of the EU Ker-Optika Case for e-commerce in Physical Medical Devices and Apps for eHealth Services

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## Abstract

This article analyses the reasoning of the European Court with respect to the interpretation of the e-commerce directive and the free movement of goods provisions to the Internet sale of medical devices as goods in the Ker-Optika case. It draws conclusions from that analysis for e-commerce in medical devices as goods in the EU, which are extrapolated to the sale of medical devices as services such as apps for home treatment or monitoring in the context of eHealth services.

The article finds that eHealth services constituting medical devices are regulated identically under EU law to physical medical devices and analyses the consequences of this.

## Keywords

apps, software, medical devices, e-commerce, on-line sales

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## 1 Introduction

As medical devices are becoming more of a commodity and self-care medical devices proliferate, the question arises to what extent EU member states can regulate clinical supervision of the delivery of medical devices. Just like with medicinal products there are medical devices that member states regulate as prescription medical devices (such as hip implants and pacemakers) whereas there is a growing category of medical devices that consumers purchase without prescription and apply for themselves, such as contact lens fluid. While European medicinal products regulation makes a clear distinction between prescription medicinal products and non-prescription medicinal products for the purpose of distribution and sales to consumers, the medical devices directives<sup>1</sup> presently do not.

This makes the regulatory freedom that member states have to define what clinical supervision they may exercise on the delivery of medical devices a subject of the free

movement of goods. The modalities of sale (e.g. online via website) are not prescribed for medical devices on a European level as they are in the level of detail of medicinal products. Consequently, the same questions come up as with regulation of delivery of medical devices: to what extent are EU member states allowed to regulate modalities of sale for medical devices? Both of these questions have been addressed in a judgment delivered by the European Court of Justice concerning online sales of contact lenses. This article will discuss the legal reasoning in this case and subsequently extrapolate it to another field of medical devices that is rapidly developing: that of apps used for treatment and diagnosis, whether or not in the context of provision of eHealth services.

This software represents a huge developing market<sup>2</sup> and the EU has put it beyond doubt that such apps are considered medical devices regulated under the medical devices regulations [2]. Software is not a good, however, especially not if it is purchased online and delivered online

<sup>1</sup>Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1–43, Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189, 20.7.1990, p. 17–36 and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331, 7.12.1998, p. 1–37

<sup>2</sup>For example, the global telemedicine market is expected to grow from \$9.8 billion in 2010 to \$11.6 billion in 2011, and to \$27.3 billion

in 2016, a compound annual growth rate (CAGR) of 18.6% over the next five years. The telehospital/clinic market segment was worth \$8.1 billion in 2011. This is expected to grow to \$17.6 billion in 2016, demonstrating a CAGR of 16.8% between 2011 and 2016. The tele-home segment is growing faster than the telehospital/clinic segment. This market segment was valued at \$3.5 billion in 2011, and this revenue is expected to grow at a CAGR of 22.5%, reaching \$9.7 billion in 2016. [source BCC Research, January 2012]

to a consumer's computer or handheld device. In that case the medical device would constitute a service for the purpose of EU internal market law. Given the developments of medical devices in the form of software as service, it is interesting to investigate if the reasoning applied in the case discussed also applies to medical devices as services.

## 2 Judgment of the Court

The Ker-Optika case [1] concerned a dispute about the legality of Hungarian legislation that reserves the sale of contact lenses to shops that specialise in the sale of medical devices and, consequently, prohibits the sale of contact lenses via the Internet. The European Court held that EU member states are not under all circumstances allowed to restrict the sale of medical devices to only physical outlets that specialise in medical devices. It ruled on two points of law important to members of the medical devices industry seeking to sell medical devices to consumers in the EU online:

1. the scope of the e-commerce directive with respect to the national rules prohibiting Internet sales of certain medical devices (in this case contact lenses),
2. the restrictions that general EU free movement of goods rules impose on national requirements to sell certain medical devices only from brick-and-mortar shops with qualified personnel.

## 3 Scope of the e-commerce Directive

First, the Court clarified the scope of the e-commerce directive [3] with respect to the national rules prohibiting Internet sales of contact lenses. It held that national rules relating to whether or not medical devices can be sold via the Internet fall within the scope of the e-commerce directive because medical devices are not excluded from its scope. However, national rules that seek to regulate how medical devices are supplied to the end user (e.g., only after a prior examination for fitting) fall outside the scope of the e-commerce directive and, consequently, cannot be assessed by the rules that the e-commerce directive imposes. Those national rules have to be assessed under the general EU internal market rules on free movement of goods. Given that the sale of medical devices via the Internet falls within the scope of the e-commerce directive, the European Court ruled that Internet sales as such cannot be prohibited, even in cases where a prior examination by qualified staff would be necessary, because that examination can be separated from the subsequent Internet sale.

## 4 Permitted National Law Restrictions under Free Movement Rules

What then are the restrictions that general EU free movement of goods rules impose on national requirements to sell certain medical devices only from shops with qualified personnel? First of all, these rules hinder access to the market of the member state that has those rules more for foreign traders than for local traders, the court reasoned, with reference to the *DocMorris* case [4] concerning Internet sales of medicinal products.

That restriction must therefore be justified if the member state wants to be able to maintain it. However, the European Court finds that the type of devices in question does not justify this type of restriction for three reasons (paraphrased wording from the judgment):

1. In regards to the requirement that the customer must be physically present to have his eyes examined by an optician at the sales outlet, it must first be observed that precautionary examinations carried out for investigative purposes can be undertaken by ophthalmologists in places other than opticians' shops. However, there was no requirement that an optician must make every supply of lenses dependent on a precautionary examination or on medical advice having first been obtained or that those conditions are imposed, in particular, on each occasion when there is a series of supplies of lenses to the same customer.

Accordingly, undergoing such examinations and obtaining such advice must be held to be optional, and consequently it is primarily the responsibility of each contact lens user to make use of them, while the task of the optician in that regard is to give advice to the users. If that is the case, customers can be advised, in the same way, before the supply of contact lenses, as part of the process of selling the lenses via the Internet, by means of the interactive features on the Internet site concerned, the customer's use of which must be mandatory before he can proceed to purchase the lenses.

2. Member states can require that the determination of which type of contact lenses is the most appropriate be undertaken by an optician, who is under an obligation, at that time, to check the positioning of the lenses on the customer's eyes and advise the customer on the correct use and care of the lenses. However, that is normally only required when contact lenses are first supplied. At the time of subsequent supplies, there is, as a general rule, no need to provide the customer with such services. It is sufficient that the customer advise the seller of the type of lenses which was provided when lenses were first supplied, the specifications of those lenses having

been adjusted, where necessary, by an ophthalmologist who has issued a new prescription which takes into account any change in the customer's vision.

3. While the extended use of contact lenses must be accompanied by supplementary information and advice, those can be given to the customer by means of the interactive features of the website of the Internet sales provider (e.g., through a qualified optician whose task is to give to the customer, at a distance, individualised information and advice on the use and care of the contact lenses). The provision of such information and advice at a distance may, moreover, offer advantages, since the lens user is able to submit questions that are well thought out and pertinent, and without the need to go out.

In summary, because the legislation in question was not proportionate for regulation of the sale of contact lenses via the Internet, it was contrary to the general rules on free movement of goods.

## 5 Consequences for e-commerce for Medical Devices as Goods

This judgment has important consequences for national rules governing Internet sales of medical devices in the EU. Any restriction on Internet sales, even if it is intended to protect consumer health, must also be proportionate to that goal, and whether that is the case will differ from device to device. Even in cases concerning devices for which initial clinical/fitting advice would be prudent, EU member states are not allowed to completely ban Internet sales of the devices. The same is true for national advertising rules that impact the advertising of medical devices sold via the Internet. Medical device companies that experience difficulties with their (intended) Internet sales in EU member states should now definitely have an interest in taking a good look at whether the legislation concerned is proportionate.

Another important point of this case is that the European Court seems to view medical devices (at least OTC devices) as different from medicinal products, because it held in the DocMorris case that a categorical ban on Internet sales of both prescription and non-prescription medicinal products could not be justified altogether, although it did state that the supply of prescription medicinal products needs to be more strictly controlled [5]. It will be interesting to see if the European Court rules along the same lines in the case of prescription or high-risk medical devices. This seems however likely to happen.

<sup>3</sup>Commission Communication on telemedicine for the benefit of patients, healthcare systems and society, 4 November 2008, COM (2008) 689

## 6 Intermezzo: Are Software and eHealth Services Medical Devices?

The foregoing analysis has important consequences for the eHealth services industry in the EU, because eHealth services and specifically the software provided for the therapeutic and/or diagnostic functionalities may very well constitute medical devices in the meaning of Directive 93/42 ("MDD") as amended [6]. In fact, many eHealth services and software provided for the provision thereof have characteristics that cause them to fall within the scope of the concept of 'medical device' as defined in the MDD. Any software provided as service or software application provided to an end user for diagnostic and/or therapeutic purposes will normally constitute a medical device caught with the scope of the MDD [7]. Indeed, with the adoption of Directive 2007/47 amending the MDD it has been clarified beyond doubt that standalone software can also constitute a medical device [8]. This has been recently supplemented by a new MEDDEV guidance document of the European Commission about standalone software under the MDD. That means that eHealth services constituting a medical device (software as service) or involving a medical device (locally installed app to provide the service) must be CE marked as required under the MDD and the local national implementation of that directive, because otherwise they are on the market illegally. In practice however many eHealth services and applications do not meet this requirement and the level of awareness of regulatory compliance on the part of developers of such products and physicians prescribing them is very low [9].

Typical candidates for inclusion in the scope of medical devices are for example remote monitoring tools that monitor the physical condition of a patient via the internet and include a software algorithm that warns a physician if the patient's parameters give cause for this. Another candidate would be remote readout and interpretation of blood values, like glucose or other critical values allowing a patient to adjust medication to the readout. As I have argued on other occasions, prime candidates are Internet websites that allow individuals to assess their health risks [10] or apps that psychiatric patients can use on their iPad to condition themselves for and report to their psychiatrist about otherwise threatening situations that may provoke panic attacks [11]. Another good example is a medical decision support system running on a central server provided to physician.

And finally many of the telemedicine applications mentioned in the Commission's Communication on telemedicine for the benefit of patients, healthcare systems and society<sup>3</sup> will fall within that scope. In my view therefore the legal situation with respect to telemedicine is a lot less unclear than the Commission states in its Communi-

<sup>4</sup>Commission Communication on telemedicine for the benefit of patients, healthcare systems and society, 4 November 2008, COM (2008) 689, p. 8

cation on telemedicine for the benefit of patients, healthcare systems and society<sup>4</sup>, because telemedicine services and their constituent software will largely be an information society service regulated under the e-Commerce directive and the MDD when provided at a distance. The software installed locally or running on servers will constitute standalone software in the scope of the MDD.

## 7 Consequences for eHealth Services Offered Online

Because the e-Commerce Directive also applies to the provision of services, it applies likewise to medical devices that are sold through the internet as an eHealth service, as has been confirmed by the European Commission in the Explanatory Memorandum to the Cross-Border Healthcare Directive<sup>5</sup> and in the Communication on telemedicine for the benefit of patients, healthcare systems and society<sup>6</sup>.

If we apply the reasoning in the Ker-Optika judgment, this means that EU member states cannot restrict the provision of eHealth services in general with the sole argument that the physical presence of the patient and the health professional in the same place is required at all times. This is for example one of the major obstacles to telemedicine mentioned in the Commission’s Communication on telemedicine for the benefit of patients, healthcare systems and society.<sup>7</sup> This obstacle seems to have been removed by the Ker-Optika judgment. However, an EU member state could prescribe that (certain) eHealth services can only be offered after initial expert clinical intervention, e.g. after initial prescription by a physician or after an initial consult to define the parameters of the eHealth service.

In addition, in case of cross-border eHealth services EU member states may restrict the freedom to provide those on grounds of the protection of public health [12], provided however that

- the eHealth service concerned prejudices public health or presents a serious and grave risk of prejudice to those objectives and that
- the measures taken are proportionate to those objectives [13] and that
- the EU member state has concerned has asked the member state in which the provider is established to take measures and the latter did not take such measures, or they were inadequate, and notified the European Commission and the EU member state in which the provider is established of its intention to take such measures [14].

<sup>5</sup>See the explanatory memorandum to the Cross-Border Healthcare Directive, COM(2008) 414 final, p. 6

<sup>6</sup>Commission Communication on telemedicine for the benefit of patients, healthcare systems and society, 4 November 2008, COM (2008) 689, p. 9

<sup>7</sup>Commission Communication on telemedicine for the benefit of

The Commission has indicated in its Communication on telemedicine for the benefit of patients, healthcare systems and society that

“for business-to-business (professional-to-professional) telemedicine services, such as telera-diology, the country of origin principle applies: the service offered by the professional must comply with the rules of the Member State of establishment. In the case of business-to-consumer activities (which might be relevant to telemonitoring services) the contractual obligations are exempted from the country of origin principle: the service might need to comply with the rules of the recipient’s country.”<sup>8</sup>

It is unclear to me why the Commission would want to make this distinction between B2B and B2C eHealth services, as there is no clear basis for that in the e-Commerce directive.

As explained above, national rules on how medical devices may be provided fall within the scope of the rules on the free movement of goods. This does not however apply to eHealth services in the same way. In the Ker-Optika case the Court held that this was an unregulated field under the e-Commerce directive because “requirements applicable to the delivery of goods” were explicitly stated to be outside the coordinated field pursuant to article 2 (h) (ii) e-Commerce directive [15]. Consequently, the Court held, the national rules which relate to the conditions under which goods sold via the Internet may be supplied within the territory of a Member State fall outside the scope of that directive [17]. Article 2 (h) e-Commerce Directive that defines the coordinated field of the e-Commerce Directive does not contain a similar limitation of the scope of the directive for information society services, so these are fully within the scope of the e-Commerce directive. This means that eHealth service providers are fully subject to the internal market clause in article 3 of the e-Commerce Directive (free provision of services provided that the provider meets the requirements for the activity concerned of the member in which it is established). Those member states may pose requirements with which the service provider has to comply in respect of:

- the taking up of the activity of an information society service, such as requirements concerning qualifications, authorisation or notification, and
- the pursuit of the activity of an information society service, such as requirements concerning the behaviour of the service provider, requirements regarding the quality or content of the service including those applicable to advertising and contracts, or

patients, healthcare systems and society, 4 November 2008, COM (2008) 689, p. 8

<sup>8</sup>Commission Communication on telemedicine for the benefit of patients, healthcare systems and society, 4 November 2008, COM (2008) 689, p. 9

requirements concerning the liability of the service provider [16].

This means that it is very attractive to engage in forum shopping in the EU, because an eHealth services provider would logically establish itself in the EU jurisdiction with the most favourable eHealth regime and subsequently export that to the other member states via the internal market clause. Larger companies can choose out of which of their subsidiaries they will conduct their activities.

In their implementation of EU directives, member states have to observe the basic freedoms granted under the TFEU and the requirements that they may impose within the coordinated field have to be proportionate (see for example [18]). Member states have to be able justify the proportionality of their rules. Since the provisions on the free movement of services are highly similar (and some might argue identical) on the point of restriction of market access and possible justifications for them, the reasoning of the European Court in the Ker-Optika case would arguably be similar when applied to eHealth services. Whether or not a restriction in the form of a prior mandatory examination in person by a physician (as opposed for example to a video conference consultation) is justified, will depend on the risks associated with the condition that the eHealth service seeks to treat. Conversely, the fact that there is a high safety risk for users and patients if the eHealth service fails, is not as such an argument to prohibit an eHealth service for a particular purpose altogether but rather to require better risk management.

Finally, since the EU is not entitled to regulate healthcare as such [19], the scope and content of healthcare services will remain member state competence.<sup>9</sup> However, the Commission has stated that as a general principle the classification of specific telemedicine services as medical acts should ensure that these meet the same level of requirements as equivalent non-telemedicine services (e.g. teleradiology vs. radiology).<sup>10</sup> This principle ensures that adequately regulated health services are not replaced by less regulated telemedicine services and it avoids discrimination between providers of the same service, which would be incompatible with the e-Commerce Directive.<sup>11</sup> This principle is also reflected in the intention of the EU to regulate diagnostic testing services provided from outside the EU in the new EU medical devices regulation which is currently in preparation [20].

One other important point is that any member states' rules that have an impact on eHealth services are most likely technical regulations caught under Directive 98/34/EC as amended by Directive 98/48/EC. This directive establishes a procedure which imposes an obligation on Member States to notify the Commission

and each other of all draft technical regulations "concerning products and Information Society Services, including telemedicine"<sup>12</sup>, before they are adopted in national law. If this has not taken place the European Court has ruled "that breach of the obligation to notify renders the technical regulations concerned inapplicable, so that they are unenforceable against individuals" (see for example [21] and [22]) As a result, eHealth providers have a strong instrument to use against technical measures impacting on eHealth services that have not gone through the notification procedure correctly and were duly scrutinized by the European Commission.

## 8 Conclusion

The Ker-Optika case confirms many of the legal assumptions that the Commission has previously made about the legal status of e-Health services. eHealth services that constitute medical devices fall within the scope of the e-Commerce directive. As a result, advertising and sales of these services are covered by that directive. Also the way the services are provided is harmonised under the e-Commerce directive and although it may still be regulated by EU member states in certain detail, such regulation must meet the proportionality requirements for restrictions on the free provision of services. If member states take measures to regulate e-commerce in eHealth services, they must notify these to the European Commission for them to be enforceable against companies and private persons.

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<sup>9</sup>Commission Communication on telemedicine for the benefit of patients, healthcare systems and society, 4 November 2008, COM (2008) 689, p. 9

<sup>10</sup>Commission Communication on telemedicine for the benefit of patients, healthcare systems and society, 4 November 2008, COM (2008) 689, p. 9

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