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Restrictions of the Sale of Pharmaceuticals and Medical Devices such as Contact Lenses over the Internet and the Free Movement of Goods

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Abstract

In the light of new case law development, this article examines whether national restrictions on the on-line sale of pharmaceuticals and medical devices such as contact lenses are consistent either with EU secondary law, either with Article 34 TFEU that prohibits measures having equivalent effect to quantitative restrictions on imports. In particular, this article focuses on an analysis of two judgments on this important issue delivered by the Court of Justice of the European Union in 2003 and 2010, namely the *Deutscher Apothekerverband* decision and the *Ker-Optika* decision.

Keywords

on-line sales of pharmaceuticals and medical devices; on-line sales of contact lenses; free movement of goods and services; information society services; Articles 34 and 36 TFEU; *Keck* formula; health protection; proportionality of the measures

1. Introduction

As well as offering greater visibility, the on-line offer and subsequent conclusion of electronic contracts release economic operators selling goods and services from the burden of operating costs for a warehouse or office. Indeed, in geographical terms, their customers are no longer limited to the restricted circle of people living close to their sales outlets. By way of illustration, for pharmacies not established in a particular Member State, the Internet provides a more significant way to gain direct access to the domestic market.

However, the sale of goods such as pharmaceuticals or medical devices over the Internet without doubt raises more difficulties from the health policy point of view than other product categories. Generally speaking, the sale, as well as the on-line sale of these goods, is restricted with a view to protecting the health of patients.

Considering the advantages which the Internet provides for the growth in cross-border trade, the domestic regulation on on-line sales — especially in order

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to guarantee patient security — will have the effect of hindering more undertakings located outside the Member State seeking to sell on-line, than those located within its territory. For instance, a prohibition of the sale of pharmaceuticals on Internet is likely to have a greater impact on pharmacies established outside the Member State's territory. In effect, foreign retailers will suffer from the fact that they are no longer able to access foreign markets with ease — on-line — whereas their competitors with domestic sales outlets will remain able to sell their products to national clients. As a result, such a prohibition could impede access to the market for products from other Member States more than it impedes access for domestic products.

Given the different regulatory approaches regarding the on-line sale of pharmaceuticals and medical devices such as contact lenses being developed across the EU, there has been a fear of emergence of new barriers to free trade. For some, a neo-protectionist policy underlies these national measures. Indeed, a better protection of public health through controlling the on-line sale of pharmaceuticals and medical devices might constitute a plausible alibi for reinforcing competitiveness of national firms. Such measures are all the more insidious on the account that they are likely to apply without distinction to both domestic and imported goods.

One cannot avoid taking a stand on the following questions. Should the national markets be opened up to the detriment of patient safety, or is it on the contrary convenient to maintain local trade due to the obligation upon patients to attend an authorised office? Or should such domestic rules be swept aside by the principle of free movement of goods, considered by the Court of Justice of the European Union (CJEU) as 'one of the fundamental principles of the Treaty'[1] and by most academic authors as a major component of the European integration process?

It is the aim of this article to examine whether national restrictions on the on-line sale of pharmaceuticals and medical devices such as contact lenses are consistent either with Article 34 of the Treaty on the Functioning of the European Union (TFEU), either with EU secondary law. The discussion will be structured as follows. Section 2 will be dedicated to two instructive judgments handed down by the Court of Justice. In its judgment delivered on 11 December 2003 in the *Deutscher Apothekerverband* case,[2] the Court of Justice was called upon to assess the validity of a German prohibition of on-line sale over the Internet of pharmaceuticals. In its judgment delivered on 2 December 2010 in the *Ker-Optika* case,[3] the Court of Justice was asked to rule on whether a regime prohibiting the sale over the Internet not of pharmaceuticals, as in *Deutscher Apothekerverband*, but

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1) See, e.g. Case 265/65 *Commission v. France* [1997] ECR I-6959.

2) Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887.

3) Case C-108/09 *Ker-Optika bt c. ÀNTSZ Dél-dunántúli Regionális Intézete* [2010], nyr, noted by A. Rigaux (2011)2 *Europe* 19-22. Insofar as the lenses are deemed to be medical devices and not pharmaceuticals, the findings of the *Deutscher Apothekerverband* judgment could not be applied as such to this new case.

this time of contact lenses, was consistent with the Directive on electronic commerce as well as with Treaty law. To sum up, the first case concerned pharmaceuticals, whereas the second concerned medical devices.

In Section 3, the lessons to be drawn from the case law of the CJEU, and in particular judgments regarding the on-line sales of pharmaceuticals and contact lenses, would help us to assess the Member States' room to manoeuvre in regulating such activities.

2. Case Law

The *Deutscher Apothekerverband* provides insights into the room of manoeuvre left to the Member States as regards the regulation of sale via internet of pharmaceuticals. The *Deutsche Apothekerverband*, an association aiming at the protection and promotion of the economic and social interests of pharmacists, challenged the Internet business carried out by DocMorris, a Dutch virtual pharmacy. In particular, the applicant contended that DocMorris had been offering for sale at its Internet address, prescription and non-prescription medicinal products for human use, in languages including German, for end-users in Germany. The CJEU was asked by the *Landgericht Frankfurt am Main* to answer the question whether Germany may restrict the supply of medicinal products by a pharmacy established in the Netherlands on the basis of individual orders placed by consumers on the Internet. In particular, the Court had to ascertain whether the German prohibition at issue was deemed to constitute a measure having an effect equivalent to a quantitative restriction on imports (MEE) within the meaning of former Article 28 EC (new Article 34 TFEU).

The Court drew a distinction between medicinal products which were not authorised in Germany and those which were. As regards the first category of products, the Court took the view that the German prohibition was consistent with the obligation laid down in Directive 65/65[4] which makes the placing on the market of medicinal products subject to prior authorisation by the Member State. Accordingly, national authorities are empowered to prohibit the placing on the market of medicinal products that have not yet been authorised by the Member State concerned, although their marketing has been authorised by other Member States. Consequently, such national prohibition cannot be characterised as a MEE within the meaning of former Article 28 EC.[5]

Then the Court moved on to assess the validity of the prohibition of supplying medicinal products which were authorised in Germany on the basis of individual

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[4] Article 3 of Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, now replaced by Article 6(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).

[5] Case C-322/01 *Deutscher Apothekerverband*, para. 52.

orders placed by consumers on the Internet. It is important to stress at the outset, that the national rules on the sale and delivery of authorised medicinal products had not yet been harmonised with regard to prescription requirement and Internet-based mail order trade. Accordingly, the Court had to resolve the case in the light of the Treaty provisions on the free movement of goods.

At the outset, the question arose as to whether the German prohibition on mail order could escape the scope of ambit of former Article 28 EC. As discussed below, in order to be covered by the exception laid down by the *Keck* formula, the measure had to be classified as a selling arrangement and satisfy the following requirements: on the one hand, they must apply to all relevant traders operating within the national territory, on the other, they must affect in the same manner, in law and in fact the marketing of domestic products and of those from other Member States.[6]

Given that the prohibition could not be covered by the exception laid down by the *Keck* formula, it was deemed to be classified as a MEE for the purposes of former Article 28 EC. The Court then had to rule on whether there was any justification for the prohibition on mail-order sales. Indeed, overriding reasons in the general interest, such as the protection of public health, can justify restrictions on the freedom of movement of goods guaranteed by the Treaty. In this respect, the Court issued a Salomon judgment. Although former Article 30 EC (new Article 36 TFEU) may be relied on to justify a national prohibition on the sale by mail order of pharmaceuticals whose sale is restricted to pharmacies in the Member State concerned, in as far as the prohibition covers medicinal products subject to prescription, on the other hand this provision "cannot be relied on to justify an absolute prohibition on the sale by mail order of medicinal products which are not subject to prescription in the Member State concerned".[7] Table 1 below summarises the findings of this judgment.

Table 1. Validity of National Regimes Regulating On-line Sale of Pharmaceuticals

<table>
<tr><th>Prohibition of on-line sale of pharmaceuticals which have not obtained the authorisation required by the importing Member State</th><th>Prohibition of on-line sale of pharmaceuticals which have obtained the authorisation required by the importing Member State</th></tr>
<tr><td rowspan="2">Not an MEE on the grounds that the prohibition is consistent with the Community Code relating to medicinal products for human use</td><td>Pharmaceuticals that are subject to prescription: MEE justified on the basis of Article 36 TFEU</td></tr>
<tr><td>Pharmaceuticals that are not subject to prescription: MEE not justified on the basis of Article 36 TFEU</td></tr>
</table>

[6] See *infra* section 2.4.1.2.

[7] Case C-322/01 *Deutscher Apothekerverband*, para. 124.

Seven years later, on 2 December 2010, the CJEU adjudicated the second case regarding the validity of a national regulation of on-line sale of medical devices. Seized of a dispute between the company under Hungarian law, Ker-Optika, which sold contact lenses over its website, and a public health body which prohibited it from selling them, a Hungarian national court sent a preliminary reference to the CJEU regarding the compatibility of the Hungarian measure with EU law. It should be noted that the Hungarian regulation at issue only authorised the sale of contact lenses in shops specialising in the sale of medical devices, which in this case amounted implicitly to a prohibition on the sale of these goods over the Internet. Moreover, the shops had to satisfy criteria in respect of floor areas and staff qualification. This measure was indeed likely to jeopardize the free movement of goods.

More specifically, the Court was asked to first answer the question as to whether the sale constituted medical advice, which would have the effect of precluding the application of Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (hereafter the "Directive on electronic commerce").[8] In short, the CJEU applied the following distinction. First of all, the rules concerning the procedures applicable to the supply of lenses fall outside the scope of the Directive[9] since it amounts more to a physical than an electronic operation.[10] On the other hand, where it is possible to dissociate the act of sale from the medical services, the Court concluded that the rules governing the sale over the Internet fell within the scope of the Directive.[11]

Given that the answer to the first question was negative, the Court was called on to consider the compatibility of the contested regulation with Article 34 TFEU.[12] According to the *Deutscher Apothekerverband* case law, in *Ker-Optika* the CJEU examined the prohibition solely with regard to the rules on the free movement of goods and discarded the application of the Treaty provisions on services.[13]

As in the *Deutscher Apothekerverband,* the question arose as to whether the implicit Hungarian prohibition on mail order could escape the scope of ambit of Article 34 TFEU on the grounds that it had to be classified as a selling arrangement. Again, the Court endorsed a narrow interpretation of the second *Keck*'s condition. Following its reasoning in *Deutscher Apothekerverband*, the Court held that the prohibition on the on-line sale of pharmaceuticals was more penalising for economic operators not located in national territory.[14] Given that the measure

8) OJ [2000] L *178/1.*
9) Case C-108/09 *Ker-Optika,* paras. 29 à 31.
10) Opinion AG Mengozzi in Case C-108/09 *Ker-Optika*, para. 46.
11) Case C-108/09 *Ker-Optika*, paras. 40 à 42.
12) Since the reference for a preliminary ruling reached the Court on 23 March 2009, the old numbering of the EC Treaty was used, though as a matter of convenience, this discussion will refer to Articles 34 and 36 TFEU rather than Articles 28 and 30 of the EC Treaty.
13) Case C-108/09 *Ker-Optika*, para. 44.
14) Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, para. 74.

at issue constituted *de facto* discrimination against imports, the national prohibition on the sale by mail order of medicinal products was deemed to be an MEE for the purposes of Article 34 TFEU.

Since the contested selling arrangements could not escape the reach of Article 34 TFEU, the Court was required to verify once again as to whether the Hungarian prohibition could be justified on the grounds of one of the public interest grounds of Article 36 TFEU. The importance that the CJEU granted to measures taken with a view to protecting public health, had led the Court to adopt a more lenient approach in the *Deutscher Apothekerverband* judgment regarding a German regulation in so far as the prohibition covered medicinal products subject to prescription.[15] Could the same apply in this case?

With respect to the proportionality of the Hungarian measure, the Court had to assess both its appropriateness and its necessity. First, for the Court, the regulation concerned was appropriate for securing the objective of a high level of protection of health.[16] While not entirely eliminating all risks incurred by the users of the lenses, the obligation at issue was likely to reduce those risks.

Second, following a somewhat convoluted reasoning that we shall analyse in the third section of this article, the Court nonetheless held that some restrictions brought to the initial supply of contact lenses were necessary to achieve the objective of health protection. However, the Court took the view that it was not the case of subsequent services on the grounds that they can be replaced by on-line services that are deemed to be as effective.

3. Comments

3.1. *Introduction*

The two cases commented upon above raise the question as to how to draw the line between positive and negative harmonization. In the absence of harmonization of the subject matter through directives or regulations, the provisions of the TFEU on free movement of goods, and in particular Article 34 TFEU, are applicable (*negative harmonization*). Accordingly, national courts and the CJEU are called upon to assess the compatibility of the contested measures in the light of the Treaty provisions on free movement of goods. The same reasoning must be followed if harmonization by EU measures adopted usually on the basis of Article 114 TFEU (former Article 95 EC) is not deemed to be complete.

However, it must be borne in mind that the regulation of sale of products is often governed by directives and regulations adopted by the EU institutions (*positive harmonization*), in the framework provided for in the TFEU. Given that

[15] *Ibid.*, para. 124.
[16] Case C-108/09 *Ker-Optika,* para. 64.

positive harmonization determines more precisely the room for manoeuvre left to the Member States than a changeable adjudicatory approach, it has been preferred to negative harmonization. In such a case, the free discretion of national authorities will be limited as harmonization deepens. The advantage of such harmonization is undeniable for producers and distributors since it allows the setting, on the scale of the internal market, of product standards which then govern the marketing of products and their free circulation within that market.

Before embarking on the discussion of positive and negative harmonization, we shall first give careful consideration to the rationale of the national measures regulating or prohibiting the sale through Internet of some products. We shall then analyse simultaneously the issues of positive and negative harmonization in the light of the *Deutscher Apothekerverband* and *Ker-Optika* judgments.

3.2. *Rationale of National Measures Regulating the On-Line Sale of Pharmaceuticals and Medical Devices such as Contact Lenses*

The very particular nature of medicinal products distinguish them substantially from other goods.[17] Given that pharmaceutical activity is characterised by an asymmetrical distribution of information, the patient must be able to have complete confidence in the advice given by the professional selling the pharmaceuticals.[18] Indeed, the therapeutic effects of these products have the consequence 'that, if medicinal products are consumed unnecessarily or incorrectly, they may cause serious harm to health, without the patient being in a position to realise that when they are administered'. [19]

Due to the risks run by patients (overconsumption or incorrect use of medicinal products), Member States 'may make persons entrusted with the retail supply of medicinal products subject to strict requirements, including as regards the way in which the products are marketed and the pursuit of profit'.[20] By way of illustration, the sale of pharmaceuticals is generally reserved for qualified professionals such as pharmacists. As a result, non-pharmacists can be excluded from running pharmacies on public-health grounds.[21] Furthermore, the purchase of certain pharmaceuticals or medical devices is conditional upon presentation of a doctor's prescription.

Against this background, some national legislation provide for an outright prohibition on mail order sales of medicinal products, the sale of which is restricted to pharmacies or to specialised operators. Broadly speaking, the main purpose of the prohibition is to ensure that the patient receives individual information and

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17) Case C-369/88 *Delattre* [1991] ECR I-1487, para. 54.
18) Opinion AG Bot in Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes e.a.* [2009], para. 51.
19) Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes e.a.* [2009] ECR I-384, para. 32.
20) *Ibid.*, para. 34.
21) *Ibid.*, paras. 28-30.

advice from the pharmacist when the product is purchased, as well as to ensure the safety of medicines. What is more, if medicinal products which have not obtained the authorisation required by the importing Member States can be ordered over the Internet, the system of marketing authorisations for pharmaceutical products will be fatally undermined.[22] Indeed, manufacturers of medicinal products will be able to obtain authorisation in the Member State with the least stringent legislation in this domain, and release the products into circulation in Member States in which they are unable to obtain the authorization. Last but not least, given that mail-order sales of pharmaceutical products are likely to jeopardise the continued existence of traditional pharmacies, an argument put forth to adopt such prohibition is that it forms an integral part of the social security system, the aim of which is to ensure that a reliable and balanced supply of medicines is available to the general public at any time.[23]

In this connection, a single example will suffice. As regards contact lenses, their purchase is generally conditional upon the presentation of a medical prescription from an ophthalmologist, to whom the exclusive right to perform eye examinations can be granted, excluding opticians who are not qualified medical doctors.[24] This medical requirement is generally followed by other services, in particular those performed by the optician. The ability to receive advice from an optician when fitting the contact lenses provides the benefit of being able to adjust them depending on various tests. In addition, opticians can advice customers on the correct use and care of the lenses. These various interventions are intended in particular to reduce the risk of eye inflammations and even lasting impairment of sight.[25] This is the reason why the conditions under which contact lenses may be sold are strictly framed in several Member States.

3.3. *Positive Harmonization of the Sale of Pharmaceuticals and Medical Devices over the Internet*

Article 36 TFEU justifications remain applicable 'as long as full harmonization of national rules has not been achieved',[26] or in other words, as long as the EU

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22) Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, as amended by Council Directive 93/39/EEC of 14 June 1993, makes the placing on the market of medicinal products subject to prior authorisation.

23) Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paras. 47 to 49, and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, paras. 72 to 74; Case C-322/01 *Deutscher Apothekerverband,* above, para. 122.

24) Case C-271/92 *LPO* [1993] ECR I-2899; and Case C-108/96 *Mac Quen* [2001] ECR I-837, paras. 28-30.

25) Case C-108/09 *Ker-Optika*, para. 40; opinion AG Mengozzi in Case C-108/09 *Ker-Optika*, para. 77.

26) See Case 215/87 *Schumacher* [1989] ECR 617, para. 15; Case C-369/88 *Delattre* [1991] ECR I-1487, para. 48; Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, para. 26; Case C-62/90 *Commission* v. *Germany* [1992] ECR I-2575, para. 10; and Case C-320/93 *Ortscheit* [1994] ECR I-5243, para. 14.

lawmaker has not pre-empted the field. Whenever harmonization is deemed to be complete or exhaustive, Member States' measures must be assessed exclusively in the light of the harmonising measure and not of primary law.[27]

In the *Deutscher Apothekerverband*, the prohibition to place unauthorised pharmaceuticals marketed in other Member States on the German market was deemed to be consistent with Article 3 of Directive 65/65/EEC of 26 January 1965 relating to medicinal products. It followed that the national prohibition was falling outside the scope of ambit of Article 34 TFEU.[28] It followed that the prohibition of the on-line sales of pharmaceuticals authorised in Germany had to be assessed in the light of the Treaty provisions on free movement of goods.

Another case in point is *Ker-Optika*. At the outset, it should be noted that in *LPO* the Court stressed that EU law contains no harmonisation rules on the distribution of contact lenses.[29] Nonetheless, seventeen years later, the Court was asked to answer the question as to whether the sale of medical devices such as contact lenses falls within the scope of ambit of Directive 2000/31/EC on electronic commerce, an issue that could not be addressed at the time that the *LPO* judgment was handed down on 25 May 1993.[30] What deserves attention is that the obligations laid down in Directive 2000/31/EC on electronic commerce would have precluded the verification of the consistency of national measures hindering free trade with treaty provisions. Conversely, in case the on-line sale of lenses constituted medical advice, this would have the effect of precluding the application of the Directive on electronic commerce.

At first sight, it is barely possible to classify the marketing of this type of medical devices as an "information society service"[31] within the meaning of the Directive on electronic commerce. What is more, it may be recalled that this Directive simply approximates national regulations, without however harmonizing them.

The Ker-Optika company had argued before the national court that the sale of contact lenses via Internet amounted to an information society service within the meaning of the "Directive on electronic commerce". The company went on to argue that the prohibition imposed on it against the sale of lenses over the Internet breached that Directive on the grounds that Article 4 provided that no prior authorisation or administrative decision having analogous effect is necessary in order to take up or pursue the activity of an information society service provider.

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27) Case C-37/92 *Vanacker and Lesage* [1993] ECR I-4947, para. 9; Case C-324/99 *DaimlerChrysler* [2001] ECR I-9897, para. 32; Case C-99/01 *Linhart and Biffl* [2002] ECR I-9375, para. 18; and Case C-322/01 *Deutscher Apothekerverband*, para. 64. Total harmonization pre-empts national regulators to enact more stringent measures whereas minimum harmonization permits Member States to maintain or to introduce more stringent standards than those prescribed by the EU lawmaker. See M. Dougan, 'Minimum Harmonization an the Internal Market', (2000)37 *CMLRev* 855.

28) Case C-322/01 *Deutscher Apothekerverband*, para. 53.

29) Case C-271/92 *LPO* [1993] ECR I-2899, para.5.

30) OJ [2000] L *178/1.*

31) As regard the scope of this concept, see Article 1(2) and the 18th recital of the directive.

On the other hand, the Hungarian public authority considered that the sale of contact lenses amounted to an activity that could not be carried out at a distance on the grounds that it was equivalent to a medical consultation requiring a physical examination of the patient. This activity fell outside the scope of the said directive.

AG Mengozzi took the view that 'The sale of contact lenses... does not... form part of the field coordinated by the Directive on electronic commerce'.[32]

Since the Directive does not have the object of a general liberalisation of the electronic trade in goods, the CJEU held that Member States were not required to permit, on a general and systematic basis, the Internet sale of any type of goods.[33] Moreover, since it emphasises the concept of "services" and not "goods",[34] the Directive on electronic commerce only covers "certain" legal aspects of information society services.[35]

To make matters more complex, the scope of the Directive on electronic commerce is determined by reference[36] to Directive 98/34 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services.[37] Directive 98/34 defines "information society services" as "any information society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services".[38]

The CJEU applied the following distinction between the sale and the supply of the contact lenses. First of all, the rules concerning the procedures applicable to the supply of lenses fall outside the scope of the Directive[39] since it amounts more to a physical than an electronic operation.[40]

On the other hand, where it is possible to dissociate the act of sale from the medical services, the Court concluded that the rules governing the sale over the Internet fell within the scope of the Directive.[41] However, the judgment leaves open the issue as to how to draw the dividing line between the operations related

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32) Opinion AG Mengozzi, para. 39.
33) Judgment, para. 36.
34) Case C-108/09 *Ker-Optika*, para. 35.
35) Ibid., para. 34.
36) Article 2 (a) Directive on electronic commerce.
37) [1998] OJ L 24/37. Repealing directive 83/189/EEC of 28 March 1983, directive 98/34/CE was amended short after its adoption by directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 ([1998] OJ L 207/18). In laying down a procedure for the provision of information in the field of technical standards and regulation, Directive 98/43/EC is intended to help avoid the creation of new regulatory barriers to trade within EU. In addition, the notification and stand-still procedures increase transparency, since national draft regulations are brought to the attention of the authorities and interested parties before being enacted.
38) Article 1(2) Directive 98/34.
39) Case C-108/09 *Ker-Optika*, paras. 29 à 31.
40) Opinion AG Mengozzi in Case C-108/09 *Ker-Optika*, para. 46.
41) Case C-108/09 *Ker-Optika*, paras. 40 à 42.

to the supply of contact lenses and the act of sale. No easy answer can be given to that question.

3.4. *Negative Harmonization*

Since the Directive on medicinal products and the Directive on electronic commerce were only partially applicable to the measures at issue, the CJEU was also asked by the two national courts to consider the compatibility of the contested regulations with Article 34 TFEU. Without attempting an exhaustive review of the scope of that provision, the following sub-sections explain how it unfolds.

3.4.1. *Material Scope of Application of Article 34 TFEU*

Article 34 TFEU runs as follows: 'Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States'. Needless to say that measures regulating pharmaceuticals and medical devices are likely to fall under the concept of 'measures having equivalent effect' to 'quantitative restrictions' on imports within the meaning of that provision. However, if the wording of this provision is concise, its meaning and therefore its scope have given rise to questions of interpretation. Moreover, treaty provisions on services could also be applicable.

3.4.1.1. General Considerations

Two criteria are used to define the scope of Article 34 TFEU, namely the nature of the 'goods' meant to move freely within the internal market and the nature of the barriers concerning these goods. In the absence of Treaty definitions of 'goods', 'quantitative restrictions' and 'measure having equivalent effect' (MEE), one must refer to the CJEU's case law to determine the scope of these terms.

Nowhere in the Treaty is the concept of "goods" defined. Both Article 34 and Article 35 TFEU use respectively the terms "imports" and "exports" rather than the terms "goods" or "products". Concerning all 'goods taken across a frontier for the purposes of commercial transactions..., whatever the nature of those transactions',[42] the concept of 'goods' is interpreted broadly and can thus cover goods such as pharmaceuticals and medical devices. This broad definition may not be undermined by national classifications.

Obviously, pharmaceuticals are goods falling within the scope of ambit of Article 34 TFEU. Is the situation any different as regards the sale of contact lenses? As the Court held in the *LPO* judgment, the sale of contact lenses is not a commercial activity like any other and cannot be considered independently of the health services that are provided at the time they are sold.[43] In *Ker-Optika,* the Court had thus to address the question as to whether the measure regulating the supply of

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[42] Case C-324/93 *Evans Medical* [1995] ECR I-563, para. 20.

[43] Case C-271/92 *LPO* [1993] ECR I-2899, para. 11.

the contact lenses had to be examined in relation to the freedom to provide services, or in relation to the free movement of goods.[44] It is in this context important to stress that the TFEU provisions on free movement are mutually exclusive of one another.[45] It ought to be remembered that the distinction between goods and services is a fine one: on one hand, both are normally subject to commercial transactions; on the other, goods are tangible whereas services are not.[46] When confronted with the parallel application of the Treaty provisions on the free movement of goods and services, the Court is required to resolve the question as to which rules are applicable to the dispute.

It is settled case law that, where a national measure relates to both the free movement of goods and the free movement of services, the Court will in principle 'examine it in relation to one only of those two fundamental freedoms, if it appears that one of them is entirely secondary in relation to the other and may be considered together with it'.[47]

Taking into consideration that the sale of contact lenses, on the one hand, and any consultations which may take place in connection with it, on the other, are entirely separable activities, AG Mengozzi held that the compatibility of the national regulation at issue with EU law must be examined by reference to the Treaty provisions relating to the free movement of goods.[48] The CJEU concurred with the AG's opinion: according to the *Deutscher Apothekerverband* case law, it examined the prohibition solely with regard to the rules on the free movement of goods.[49]

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[44] It must be noted that with respect to the free movement of services, the Court held that within the context of the correction of purely optical defects, the objective examination of a client's eyesight can be reserved, for reasons relating to the protection of public health, to ophthalmologists, to the exclusion, in particular, of opticians who are not qualified medical doctors. See case C-108/96, *Mac Quen,* above.

[45] For instance, it is settled case law, as regard the free movement of persons, that any restriction on individual economic freedom must be justified whereas the case law on goods does not require the justification of any market rule. The question whether or not to bring the case law on free movement on goods in line with case law on free movement of persons has been dogged by controversy, as much as about the reasoning as about the concrete results. Several authors are taking the view that these freedoms should be harmonized. See C. Barnard, *The Substantive Law of the EU,* 3rd ed. (Oxford: OUP, 2010) 148; Opinion AG Poiares Maduro in Joined Cases C-158/04 and C-159/04 *Alfa Vita* [2006] ECR I-8153. According to other authorities, there are limits to the suggestion to merge these freedoms into a single concept. See A. Rosas, "Life after *Dassonville* and *Cassis*: Evolution but not Revolution", in: M. Poiares Maduro and L. Azoulai (eds.), *The Past and Future of EU Law: The Classics of EU Law Revisited on the 50th Anniversery of the Treaty of Rome* (Oxford: Hart, 2010) 433 and 444; P. Oliver (ed.), *Oliver on Free Movement of Goods in the European Union* (Oxford: Hart, 2010) 11.

[46] Case C-390/99 *Canal Satélite Digital v. Spain* [2002] ECR I-4071. See also generally P. Oliver, "Goods and Services: Two Freedoms Compared", in: M. Dony and A. De Walsche (eds.), *Mélanges en l'honneur de M. Waelbroeck* (Brussels: Bruylant, 1999) 1378; Oliver, *ibid.*, 11 and 32.

[47] See, Case C-275/92 *Schindler* [1994] ECR I-1039, paras. 22, and Case C-20/03 *Burmanjer and Others* [2005] ECR I-4133, para. 35; and Case C-108/09 *Ker-Optika* [2010] nyr, para. 43.

[48] Opinion A.G. Mengozzi in Case C-108/09, paras. 56 and 59.

[49] Case C-108/09 *Ker-Optika,* para. 44.

That being said, Articles 34 TFEU only applies if one can establish the existence of a quantitative restriction or a MEE. Given that it is unlikely to face quantitative restrictions, the definition of a MEE is therefore essential in the CJEU's case law, which, through a broad interpretation of free movement of goods, puts more store in the effect of the measure than in its legal nature.

Since its *Dassonville* judgment of 11 July 1974, the Court has broadly interpreted the concept of measures having equivalent effect to quantitative restrictions. According to the wording of the judgment, 'all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions'.[50] Repeated on countless of occasions, this formula is still regularly cited in judgments. The striking feature of this formula is its sheer breadth.[51]

In its landmark case *Cassis de Dijon*, the Court clarified that MEEs, not limited to measures directly affecting imports, were encompassing measures that are 'applicable without distinction' to foreign and domestic goods, as a foreign producer may find it more difficult to respect these rules than the national producer. According to settled case law, 'in the absence of harmonization of legislation, obstacles to free movement of goods which are the consequence of applying, to goods coming from other Member States where they are lawfully manufactured and marketed, rules that lay down requirements to be met by such goods' constitute MEEs prohibited by Article 34 TFEU.[52] The condition that the goods were 'lawfully manufactured and marketed in another Member State' reflects 'the obligation to comply with the principle of mutual recognition of products'.[53] Mutual recognition can be defined as 'a principle whereby the sale of goods lawfully produced and marketed in one Member State may not be restricted in another Member State without good cause'.[54] It follows that the importer can reckon upon a single regulation by the home state instead of having to overcome the hurdle to cope with both the home state and the domestic regulation.[55]

For a MEE to be prohibited, it need not necessarily apply to imports or exports; it is sufficient that it be applicable to them. Furthermore, the measure need not intervene at the moment of the crossing of borders; its effects may only be felt later, inside the importing country.[56] Finally, to be prohibited, the measure need not render import or export impossible. It is sufficient for these operations to be

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50) Case 8/74 *Dassonville* [1974] ECR I-837.

51) P. Oliver, "Of Trailers and Jet-Skis: is the Case Law on Article 34 TFEU. Carrering in a New Direction" (2010) *Fordham Intl L J* 4; Barnard, *supra* note 45, 92.

52) Case C-120/78 *Cassis de Dijon* [1979] ECR 649.

53) Case C-110/05 *Commission* v. *Italy* [2009] ECR I-519, para. 34 and the case law cited; Case C-108/09 *Ker-Optika* [2010], para. 48, noted by N. de Sadeleer (2011) 2 *EJCL* 435-444.

54) Case C-120/78 *Cassis de Dijon* [1979] ECR 642, para. 14.

55) Rosas, *supra* note 45, 440.

56) Case 222/82 *The Apple and Pear Development Council* [1983] ECR I-4083.

rendered more difficult, for there to be a MEE.[57] This broad interpretation of this key Treaty provision puts more store in the effect of the measure than in its legal nature.[58]

To sum up, where imported goods such as pharmaceuticals are subject to conditions that are more difficult to satisfy than those applying to domestic products, these conditions are clearly prohibited by Article 34 TFEU. This was indeed the case of both the German and Hungarian measures.

3.4.1.2. Selling Arrangements

In both cases, provided that they could be qualified as selling arrangement and not as product standards, the national measures could escape the scope of ambit of Article 34 TFEU. This calls for a few words of explanation.

The incorporation under former Article 28 EC (new Article 34 TFEU) of national measures which are indistinctly applicable has in any case permitted a considerable extension of the control of obstacles to trade between the Member States. However, this extension has ever since been fraught with controversies.

In the landmark judgment *Keck*,[59] the Court departed partially from earlier case law. *Keck* has come in for considerable criticism precisely on the account that the CJEU gave too much emphasis on factual and legal equality to the detriment of a market access test.[60] Though *Keck* and subsequent case law did not reverse *Dassonville* and *Cassis de Dijon* case law,[61] it narrowed down the scope of Article 34 TFEU in removing 'certain selling arrangements' (sales at a loss, rules on advertising, opening of stores on Sundays, etc.) from the scope of that provision.

As a result, a dividing line must be drawn between two categories of measures. On the one hand, measures laying down requirements to be met by goods concerning for instance the dimensions, weight, form, size, composition, designation, labelling, and presentation of goods are to be considered as MEEs.

On the other hand, measures governing the arrangements for the sale of goods fall outside the scope of ambit of Article 34 TFEU, provided they meet two conditions. Those two conditions are that such measures must apply to all relevant

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57) Case 8/74 *Dassonville* [1974]; and Case C-128/89 *Commission v. Italy* [1990].

58) L. Gromley, *EU Law of Free Movement of Goods and Customs Union* (Oxford: OUP, 2009) 426.

59) Joined cases C-267 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097.

60) F. Picod, "La nouvelle approche de la Cour de justice en matière d'entraves aux échanges", *RTDE* 2 (1998) 169; A. Mattera, "De l'arrêt "Dassonville" à l'arrêt "Keck": l'obscure clarté d'une jurisprudence riche en principes novateurs et en contradictions", *RMUE* (1994) 117; S. Weatherill, "After Keck: some thoughts on how to clarify the clarification", *CMLRev* 33 (1996) 885; R. Kovar, "Dassonville, Keck et les autres: de la mesure avant toute chose", *RTDE* 2 (2006) 213; M. Poiares Maduro, "Keck: The End? The Beginning of the End? Or just the End of the Beginning?" (1994) *Irish Journal of European Law* 36; L. Gromley "Two Years after Keck", *Fordham Intl L J* 19 (1996) 866; C. Barnard, "Fitting the remaining pieces into the goods and persons jigsaw?", *ELRev* (2001) 26 35.

61) P. Kapteyn and P. VerLoren van Themaat, *Introduction to the Law of the European Communities*, 3rd ed. (The Hague: Kluwer Law Intl., 1998) 632; M. Poiares Maduro, *We, the Court. The European Court of Justice and the European Economic Constitution* (Oxford: Hart, 1998) 79.

traders operating in national territory and must affect in the same manner, in law and in fact, the marketing of both domestic products and those from other Member States.[62] Generally speaking, the first condition is met on the account that the regulation of sales over Internet applies to all the traders concerned, whether domestic or not.[63] Provided that the second condition — absence of *de facto* discrimination — is also fulfilled, the selling arrangements are not subject to any sort of justification.

Regarding the restrictions on pharmaceuticals, the Court has found in *Hünermund* that a prohibition on pharmacists from advertising quasi-pharmaceutical products outside the pharmacy, which they were authorised to offer for sale, did not affect the ability of traders other than pharmacists to advertise those products.[64]

Recently, most of the selling arrangements reviewed by the Court have been found falling within the scope of ambit of Article 34 TFEU.[65] By way of illustration, the Court held that a prohibition on television advertising deprived a trader of the only effective form of promotion which would have enabled it to penetrate a national market.[66] What is more, the Court has found that in the case of products such as alcoholic beverages, 'the consumption of which is linked to traditional social practices and to local habits and customs, prohibiting all advertising directed at consumers in the form of advertisements in the press, on the radio and on television, the direct mailing of unsolicited material or the placing of posters on the public highway is liable to impede access to the market for products from other Member States more than it impedes access for domestic products, with which consumers are instantly more familiar'.[67] Accordingly, the second condition was not met.

With respect to on-line sales of pharmaceuticals and medical devices and the second *Keck* requirement, the two judgments commented on above are instructive.

In *Deutscher Apothekerverband*, the CJEU held that the prohibition on the on-line sale of pharmaceuticals is more penalising for economic operators not located in the national territory.[68] Given that the prohibition applied to all the traders concerned, whether German or not, the first condition was fully met.[69] However, as regard the second condition, the Court focused its analysis on the fact that the German measure entailed greater hindrances to pharmacies outside Germany

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[62] Joined cases C-267 and C-268/91 *Keck and Mithouard*, para. 15; Case C-292/92 *Hünermund and Others* [1993] ECR I-6787, para. 21; and Case C-412/93 *Lerclerc-Siplec* [1995] ECR I-179, para. 21. See also Case C-110/05 *Commission v. Italy* [2009] ECR I-519, para. 36.

[63] Case C-322/01 *Deutscher Apothekerverband*, para. 69; and Case C-108/09 *Ker-Optika*, para. 53.

[64] Case C-292/92 *Hünermund*, *supra* note 62, para. 19.

[65] E. Spaventa, "Leaving *Keck* behind? The free movement of goods after the rulings in *Commission v. Italy* and *Mickelsson and Roos*", *ELRev* 34 (2009) 920 and 922.

[66] Joined Cases C-34/95 to C-36/95 *De Agostini and TV-shop* [1997] ECR I-3843, para. 43.

[67] Case C-405/98 *Gourmet International Products* [2001] ECR I-1795, paras. 21 and 24.

[68] Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, para. 74.

[69] *Ibid.*, para. 69.

than to those within it. In particular, the Court expressed the view that: 'Although there is little doubt that as a result of the prohibition, pharmacies in Germany cannot use the extra or alternative method of gaining access to the German market consisting of end consumers of medicinal products, they are still able to sell the products in their dispensaries. However, for pharmacies not established in Germany, the Internet provides a more significant way to gain direct access to the German market. A prohibition which has a greater impact on pharmacies established outside German territory could impede access to the market for products from other Member States more than it impedes access for domestic products.'[70] Given that the measure at issue constituted *de facto* discrimination against imports, the national prohibition on the sale by mail order of medicinal products was deemed to be an MEE for the purposes of Article 34 TFEU.

In *Ker-Optika*, the national measure restricting the sale of medical devices over Internet did not lay down measures relating to the technical characteristics of these devices. Accordingly, it was likely to amount to a selling arrangement[71] inasmuch as the two conditions resulting from *Keck*[72] were fulfilled. The Court was thus required to verify whether the two requirements had been met in this case. Although the first requirement was met, since the Hungarian regulation applied to all economic operators,[73] the Court went on to hold that the contested measure did not affect the sale of national lenses in the same way as the sale of foreign lenses. In effect, the measure 'deprives traders from other Member States of a particularly effective means of selling those products and thus significantly impedes access of those traders to the market of the Member State concerned'.[74] Accordingly, the Hungarian measure could not escape the scope of ambit of Article 34 TFEU. In so doing, the Court endorsed a narrow interpretation of the second condition.

These judgments hardly came as a surprise to more circumspect observers; since following *De Agostini*, the CJEU has only grudgingly accepted that selling arrangements do not indirectly discriminate against foreign goods.[75]

3.4.1.3. *Keck* and its Aftermath

As seen with respect to the *Ker-Optika* judgment, the CJEU is not about to abandon the *Keck* case law, as some might have imagined following the judgment in

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70) *Ibid.*, para. 74.

71) Case C-108/09 *Ker-Optika*, para. 45.

72) Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097, paras. 16 et 17.

73) Case C-108/09 *Ker-Optika*, para. 53. Given that the regulation applied to a local economic operator, the answer to that question was obvious.

74) Case C-108/09 *Ker-Optika*, para. 54. AG Mengozzi considered that the second condition flowing from *Keck* was not fulfilled on the account that 'the requirements laid down by Hungarian law for the marketing of contact lenses affect to a greater degree the selling of products from other Member States'. *See Opinion*, para. 64.

75) See Case C-34/95 *De Agostini*, [1997] ECR I-3843; Case C-405/98 *Gourmet International* [2001] ECR I-1795; Case *Deutscher Apothekerverband*, above, para. 75. About these cases, see Oliver, *supra* note 45, 120.

Commission v. Italy (Trailers).[76] This question deserves further analysis. Until the *Trailers* judgment,[77] the Court distinguished as noted above between measures relating to the characteristics of goods and those relating to their selling arrangements. Having been requested to rule on an entirely new category, the manner in which goods are used, the Court backtracked somewhat on this twin-category approach by inserting a third category of a residual nature. In *Trailers*, the Court distinguished between three categories of measures.[78]

The first involves measures which have the goal or effect of treating products originating from other Member States less favourably.[79] In other words, this first category covers all national measures which are directly or indirectly discriminatory. It follows that, whenever they have the effect of discriminating against foreign producers, all measures governing the characteristics of a product, its use as well as selling arrangements fall under this first category. As discussed above, the German and Hungarian measures were deemed to be classified as MEEs on the grounds that they were discriminating implicitly against foreign products.

The second category encompasses measures which, where national laws have not been harmonized, regulate the requirements which these products must satisfy, even if these rules are indistinctly applicable to all products. This corresponds to the category of measures relating to the intrinsic characteristics of the products as defined under *Dassonville*.[80] By way of illustration, that would be the case of national regulations laying down technical standards on the placing on the market of pharmaceuticals. In fact, this second category is difficult to distinguish from the first, in any case as far as the "actual characteristics of the products" are concerned. Indeed, it is difficult to distinguish between a measure tantamount to indirect discrimination and an indistinctly applicable measure. What is more, the second category from this trilogy established an exception to "selling arrangements" within the meaning of the *Keck* jurisprudence,[81] which led certain commentators to conclude that this case law had been superseded.[82]

Finally, 'any other measure which hinders access of products originating in other Member States to the market of a Member State is also covered by that

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76) Case C-110/05 *Commission v. Italia* [2009] ECR I-519, noted by T. Horsley, *CMLRev* 46 (2009) 2001-2019; and A. Rigaux, *Europe*, 4 (2009) 158. See also C. Barnard, "Trailing a New Approach to Free Movement of Goods?", *CLJ* (2009) 288-290.

77) N. de Sadeleer, "L"examen, au regard de l'article 28 CE, des règles nationales régissant les modalités d'utilisation de certains produits", *JDE* (2009) 247-250.

78) Case C-110/05 *Commission v. Italia*, paras. 35 et 37.

79) *Ibid.*, para. 36; and Case C-108/09 *Ker-Optika*, para. 49.

80) Case 8/74 *Dassonville* [1974] ECR I-837.

81) Case C-110/05 *Commission v. Italia, supra* note 76, para. 36.

82) C. Barnard, 'Trailing a new approach to free movement of goods?', *Cambridge Law Journal* (2009) 290; E. Spaventa, 'Leaving Keck behind? The free movement of goods after the ruling in Commission v. Italy and Michelsson and Roos', *ELRev* 34 (2009) 914.

concept'.[83] Vigorous debate ensued as to how to interpret this residual category.[84] We take the view that this third category covers non-discriminatory measures, which are not falling within the scope of the two first categories, that prevent or impede access to the market by imported products. It embraces thus authorization requirements, restrictions on transport as well as the way in which the use of products is regulated.[85] The inclusion of this third limb is indeed a novel feature of the case law (Table 2).[86]

The *Ker-Optika* judgment certainly does not modify this arrangement. Paragraphs 49 and 50 of the judgment refer to the three categories of the measures cited above. Accordingly, the two-pronged approach — on one hand, national measures prescribing the characteristics of goods and, on the other, the selling arrangements — is sidelined. As far as selling arrangements are concerned, the Court appears to consider that they operate as an exception to the *Dassonville* case law, provided that the two requirements established in the *Keck* case are met.[87] The *Ker-Optika* judgment also confirms that certain selling arrangements fall outside the scope of Article 34 TFEU. However, it must be noted that although selling arrangements have not disappeared as such, they are now incorporated into a much broader residual category.

That being said, there will also continue to be squabbles over the approach adopted by the CJEU. On the one hand, rules relating to the sale over the Internet only fall under the scope of Article 34 TFEU if their effect is discriminatory, even if they have a significant effect on access to the national market; on the other hand, a regulation that has no impact on the market will not fall foul of the discrimination test on the grounds that it applies to the product's characteristics.

3.4.2. *Justification*

Though it constitutes 'one of the fundamental principles of the Treaty', the free movement of goods is not absolute.[88] Given that Article 34 TFEU does not enshrine a general freedom to trade or the right to the unhindered pursuit of one's commercial activities,[89] Article 36 TFEU allows Member States to adopt or to maintain quantitative restrictions or MEEs, inasmuch as the latter are justified by

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83) Case C-110/05 *Commission v. Italia*, para. 37; and Case C-142/05 *Mickelsson and Roos (Swedish Watercrafts)* [2009], para. 24, Case C-108/09 *Ker-Optika* , para. 50.

84) Spaventa, *supra* note 82, 921-922; Horsley, *supra* note 76, 2016.

85) Spaventa, *ibid.*, 920.

86) A. Rosas, "Life after *Dassonville* and *Cassis*: Evolution but not Revolution" in M. Poiares Maduro and L. Azoulai (eds.), *The Past and Future of EU Law: The Classics of EU Law Revisited on the 50th Anniversary of the Treaty of Rome* (Oxford: Hart, 2010) 445; Oliver, *supra* note 45, 129-130; Barnard, *supra* note 45, 104-108.

87) Case C-108/09 *Ker-Optika,* para. 51.

88) Case C-51/93 *Schmidberger* [2003] ECR I-5659, para. 78.

89) Case C-292/92 *Hünermund* [1993] ECR I-6787, 6813.

Table 2. Categories of MEEs Following the Judgment in *Commission v. Italy (Trailers)*

Categories of MEEs	Features	Features of MEEs related to pharmaceuticals	Scope of Article 34 TFEU
1st category	Measures discriminating directly or indirectly against foreign producers (measures "the object or effect of which is to treat products coming from other MS less favourably").	All measures governing the characteristics of a product, its use as well as selling arrangements.	Falling within the scope of Article 34 TFEU.
2nd category	Product requirements to be met by goods that have been "lawfully manufactured and marketed " in other MS, even if "those rules apply to all products alike".	Standards related to form, size, dimension, weight, trade description, composition, packaging, labelling and presentation of goods, safety requirements, thresholds of hazardous substances, dangerous properties.	Falling within the scope of Article 34 TFEU.
3rd category	"Any other measure which hinders access of products originating in other Member States."	This residual category covers non-discriminatory measures that are neither product requirements nor selling arrangements. It encompasses prohibitions or restrictions on use of the goods, authorisation requirements, and restrictions on transport.	Falling within the scope of Article 34 TFEU.
Certain selling arrangements		Restrictions on when, where and by whom hazardous goods may be sold or under which conditions.	Falling outside the scope of Article 34 TFEU provided that the measures at issue apply to all relevant traders operating within the national territory and affect in the same manner, in law and in fact, the selling of domestic products and of those from other Member States.

the need to preserve certain interests, exhaustively listed,[90] among which the protection of 'health and life of humans'.

Accordingly, authorities argue that their national measures regulating the sale of medical devices are justified on the basis of Article 36 TFEU on the grounds that they aim to protect *'public health'*, which "rank foremost among the assets and interests protected by the Treaty".[91] What is more, in the absence of common or harmonized rules 'it is for the Member States to decide on the degree of protection which they wish to afford to public health and on the way in which that protection is to be achieved'.[92]

That being said, Article 36 TFEU is interpreted strictly as it allows exceptions to the principle of free movement of goods.[93] Moreover, reasons of general interest regarding health are of a non-economic nature. Expressing general interest, they indicate a supremacy of non-commercial values over free movement of goods. It follows that one may not invoke Article 36 TFEU for economic reasons.

Moreover, Article 36 TFEU justifications cannot be eternally invoked. These justifications remain applicable 'as long as full harmonization of national rules has not been achieved'.[94] In other words, as long as the EU lawmaker has not pre-empted the field, in other words as long as harmonization remains incomplete, Member States may invoke one of the reasons written in Article 36 TFEU.[95] Conversely, whenever the EU lawmaker enact a directive or a regulation pre-empting the matter, the Member States must act in conformity with the obligations laid down by these EU acts. Thus, one should contemplate Article 36 TFEU as a temporary acceptance, pending EU action, of national measures ensuring that they reveal the pre-eminence of certain values over free trade.[96]

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90) Case 46/762 *Bauhuis* [1977] ECR 15.

91) Case 215/87 *Schumacher* [1989] ECR 617, para. 15; Case C-369/88 *Delattre* [1991] ECR I-1487, para. 48; Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, para. 26; Case C-62/90 *Commission* v. *Germany* [1992] ECR I-2575, para. 10; Case C-320/93 *Ortscheit* [1994] ECR I-5243, para. 14; Case C-322/01 *Deutscher Apothekerverband,* para. 103; Case C-141/07 *Commission v. Germany* [2008] ECR I-6935, para. 46; Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes e.a.*, above, para. 19; Case C-108/09 *Ker-Optika*, para. 58.

92) Joined Cases C-1/90 and C-176/90 *Aragonesa* [1991] ECR I-4154, para. 16.

93) Case 46/78 *Bauhuis* [1977] ECR 15; Case 229/83 *Leclerq* [1985] ECR 35; Case 95/81 *Commission v. Italy* ECR I-2204; Case 113/81 *Commission v. Ireland* [1981] ECR I-1625; Case 13/78 *Eggers* [1978] ECR I-1935.

94) See Case 215/87 *Schumacher* [1989] ECR 617, para. 15; Case C-369/88 *Delattre* [1991] ECR I-1487, para. 48; Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, para. 26; Case C-62/90 *Commission* v. *Germany* [1992] ECR I-2575, para. 10; Case C-320/93 *Ortscheit* [1994] ECR I-5243, para. 14. Given that the Treaties have not conferred full and absolute competence on the EU as regard health policy, such competence remains largely shared between the Union and its Member States, as attested by Article 6(a) and 168 TFEU.

95) Total harmonization pre-empts national regulators to enact more stringent measures whereas minimum harmonization permits Member States to maintain or to introduce more stringent standards than those prescribed by the EU lawmaker. See M. Dougan, "Minimum Harmonization an the Internal Market", *CMLRev* 37 (2000) 855.

96) L. Gromley, "The Genesis of the Rule of Reason in the Free Movement of Goods", in A. Schrauwen (ed.), *Rule of Reason* (Groningen: Europa Law, 2005) 24.

Last but not least, given that Member States could be tempted to abuse their right to decide what level of protection they wish to ensure, such a right has been tempered by the principle of proportionality. Thus, the MEEs likely to be justified on the basis of Article 36 TFEU must have a causal link to the objective pursued and be appropriate for achieving it (Table 3).

As a matter of fact, it is settled law that MEE regulating the sale of medicals and medical devices may be justified on the basis of Article 36 TFEU. In this connection, a few examples will suffice. In *Delattre*, the exclusive right to sell medicinal and para-pharmaceutical products to pharmacists was held to be justified on public health grounds, but for the products for which it could be shown that their use would not entail any serious risk.[97] Along the same lines, the national prohibition of advertising for medicinal products which despite the general requirement of authorization are not authorized in a country, but may be imported from another Member State of the EU in response to an individual order, was justified under Article 36 TFEU, inasmuch that they have been lawfully put into circulation in that Member State.[98]

Table 3. Conditions to be Fulfilled to Admit Measures Hindering Inter-State Trade

No complete harmonization at EU level	EU legislation entailing complete harmonization precludes Article 36 TFEU.
Legitimate objective of public interest	The measure must pursue a legitimate objective of public interest, such as health protection.
Non-economic nature of the measures	Expressing general interest, Member States cannot invoke Article 36 TFEU for economic reasons
Respect for the principle of non-discrimination	The measure must not draw distinctions on the basis of the nationality of products or producers.
Necessity and proportionality	The measure must have a causal link to the objective pursued and be appropriate for achieving it.

97) Case C-369/88 *Delattre* [1991] ECR I-1487.
98) Case C-320/93 *Ortscheit* [1994] ECR I-5243.

Confronted with this dilemma in the *Deutscher Apothekerverband*, the CJEU issued a sound and convincing judgment: although Article 36 TFEU may be relied on to justify a national prohibition on the sale by mail order of medicinal products the sale of which is restricted to pharmacies in the Member State concerned in so far as the prohibition covers medicinal products subject to prescription, on the other hand this provision 'cannot be relied on to justify an absolute prohibition on the sale by mail order of medicinal products which are not subject to prescription in the Member State concerned'.[99]

In *Ker-Optika*, since the contested measure could not escape the reach of Article 34 TFEU, the Court was required to verify once again whether the Hungarian prohibition could be justified on the grounds of Article 36 TFEU. The importance that the CJEU granted to measures taken with a view to protecting public health, had led the Court to adopt a more lenient approach in the *Deutscher Apothekerverband* judgment regarding a German regulation in so far as the prohibition covered medicinal products subject to prescription.[100] Could the same apply in this case? The Court had to assess whether the measure at issue was appropriate for securing the attainment of the health objective and did not went beyond what was necessary to attain it.

As stated above, the regulation concerned was appropriate for securing the objective of a high level of protection of health.[101] However, the principle of proportionality also implies a comparison of measures likely to attain the desired result and the selection of the one with the least disadvantages. If it appears that an alternative measure would meet the target while producing lesser barriers to the free movement of goods, the contested measure is no longer necessary. The national measure must therefore be necessary in attaining the objective pursued.

With respect to a possible justification for the MEE under Article 36 TFEU, AG Mengozzi took the view that the measure at issue was inconsistent and as a result disproportionate.[102] Following a somewhat convoluted reasoning, the Court nonetheless held that the prohibition of the sale of lenses over the Internet could be justified under certain conditions by drawing a distinction:

a) on the one hand, between the precautionary medical consultation stage in which medical advice is obtained in advance,
b) and, on the other, the subsequent stages involving the sale of the lenses.

First, the Court accepted that the Member State may require that "when contact lenses are first supplied", the intervention of an optician may be made compulsory in particular in order "to check the positioning of the lenses on the customer's

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[99] Case C-322/01 *Deutscher Apothekerverband*, para. 124.
[100] *Ibid.*, para. 124.
[101] Case C-108/09 *Ker-Optika*, para. 64.
[102] *Ibid.*, para. 79.

eyes" and to make the appropriate advice on the use and the care of the lenses available to the customer.[103] It will be noted that the Court had insisted as a preliminary point on the fact that the checks on positioning carried out after supply amounted in principle to an ophthalmological check of a medical nature that cannot be linked with the selling of the lenses.[104] That being said, the Court has stressed that these compulsory services are usually required when contact lenses are fist supplied.

Although the first stage of a medical nature appears to be indispensable in achieving the precautionary objective pursued, the same does not apply to the mandatory involvement of an optician where the consultation is not inseparably related to the prior intervention of the ophthalmologist.

It follows that the supply of lenses by a specialist undertaking is not equivalent to a medical consultation requiring a physical examination of the patient. In other words, the activity associated with the supply of lenses may be carried out at a distance, depending on the circumstances, upon presentation of a medical prescription.

The Court took particular care to stress that customers may receive advice at a distance before the product is supplied to them "in the same way" from the companies selling the contact lenses over the Internet.[105] Indeed, it may be possible to replace the optician's advice with "interactive features to be found on the supplier's Internet site".[106] This reasoning is completely in line with *Deutscher Apothekerverband*, where the Court stressed that the risks of using incorrectly or abusing the pharmaceuticals 'can be reduced through an increase in the number of on-line interactive features, which the customer must use before being able to proceed to a purchase'.[107]

3.4.3. *Consequences of* Ker-Optika *on the Justification of Restrictions on the Sale of Contact Lenses over Internet*

Is it still possible to the Member State to justify the mandatory involvement of an optician for the first supply of contact lenses under Article 36 TFEU, on the understanding that the trade in replacement lenses is subject to any restrictions?

Other than for the first supply, physical contact with the customer cannot be specified as mandatory. However, it will be necessary for the replacement lenses to be compatible with the models already tried. This will inevitably pose the problem of ensuring that foreign companies adhere to the initial prescriptions of the ophthalmologist, or even the advice provided by the optician at the time they were first supplied. Who will police this control? How will the controls be assured? In this regard, the Court considers that it will be sufficient if the customer informs the

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103) *Ibid.*, paras. 70 and 71.
104) *Ibid.*, para. 39.
105) *Ibid.*, para. 69.
106) *Ibid.*, para. 72.
107) Case C-322/01 *Deutscher Apothekerverband, supra* note 2, para. 114.

on-line seller of the instructions given to him by the ophthalmologist or optician.[108] The Court went on to add that nothing will prevent the Member State from

> requir[ing] the economic operators concerned to make available to the customer 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.[109]

Accordingly, the protection for health is guaranteed at a post-medical stage.

Be that as it may, the *Ker-Optika* judgment is markedly at odds with the *LPO* judgment where the Court took the view that Article 36 TFEU must be interpreted as meaning that national legislation which prohibits the sale of contact lenses and related products in commercial establishments which were not run or managed by persons who fulfil the conditions laid down for practising as opticians was justified on grounds of the protection of public health. In *LPO*, the reservation to opticians of the sale of contact lenses and related products was deemed to be appropriate for the purpose of ensuring the protection of public health. In a single paragraph, the Court held that the French measure did not go beyond what was necessary to achieve its objective.[110] Conversely, in *Ker-Optika*, the Court needed 22 paragraphs to reach the opposite conclusion.

Table 4 summarises, in the light of the findings of the judgment discussed, the margin for manoeuvre of Member States that wish to regulate the sale of lenses over the Internet.

Table 4. Margin for Manoeuvre of Member States that Wish to Regulate the Sale of Lenses over the Internet

Nature of the service	**Margin for manoeuvre of the MS**
Precautionary ophthalmological examination by a doctor.	May be required by the Member State (paragraph 66).
First supply of contact lenses, including the determination of the most appropriate lenses, trial, check of their positioning and initial advice regarding their use.	May be subject to restrictions. The Member State may require the mandatory involvement of an optician (paragraphs 70 and 71).
Advice on the future positioning and the extended use and care of the lenses.	May be provided by means of interactive features on an Internet site (paragraphs 72 and 73), and through the intervention, at a distance, of a qualified optician (para. 73)

108) Case C-108/09 *Ker-Optika*, para. 71.
109) *Ibid.*, para. 73.
110) Para. 16.

3.4.4. *The National Nature of a Dispute*

Article 34 TFEU cannot be set aside by the courts on the sole grounds that all aspects of the dispute are confined to within one single Member State. If the application of such a natural measure favours the sale of goods of national origin to the detriment of imported goods, it must pass muster under Article 34 TFEU.[111] In so doing, the Court admits the compatibility of national legislations requiring the presence of qualified optician in undertakings selling lenses. In *Commission v. Greece*, the Court only accepted implicitly the compatibility of such a requirement with the freedom of establishment.[112] In contrast to *Deutscher Apothekerverband*, the dispute in *Ker-Optika* concerned a situation which by definition did not include any international element liable *ex ante* to engage EU law.[113] Thus, according to the case law mentioned above, the CJEU verified whether the Hungarian prohibition violated Article 34 TFEU since it considered that it was liable to have an effect on the importation of foreign lenses.

4. Conclusion

There are two ways in which to ascertain the compatibility of health measures taken by Member States with the free movement of goods: positive and negative harmonization. Either the measure will be assessed only in the light of EU legislation as in the case of complete harmonization, or it will be observed that the measure goes beyond the scope of existing directives and regulations, and its lawfulness will be assessed directly in the light of Treaty law.

The scope of the Directive on electronic commerce encompasses the selling of medical devices such as contact lenses via Internet. As a result, the directive prohibits the Member States to regulate the on-line sale of such lenses. On the other hand, national rules relating to the "supply" of medical devices, such as contact lenses, are not covered by that directive. As a result, their compatibility with the free movement of goods must be assessed not in the light of the Directive on electronic commerce but in the light of Article 34 TFEU that prohibits any measures having equivalent effect' to 'quantitative restrictions' on imports.

The question arises as to whether the national regulations on on-line sales of pharmaceuticals and medical devices could escape the scope of Article 34 TFEU on the grounds that they are selling arrangements. Regarding the second *Keck*

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111) Joined cases C-1 & 176/90 *Aragonessa de Publicitat Exterior* [1991] ECR I-4179; Case C-47/90 *Delhaize* [1992] ECR I-3669; Case C-184/96 *Commission v. France* [1998] ECR I-6197; Joined cases C-321 — 324/94 *Pistre* [1997] ECR I-2343, paras. 44 and 45.

112) The Court held that a Greek legislation that did not permit a qualified optician as a natural person to operate more than one optician's shop ran counter to the freedom of establishment. See Case C-140/03 *Commission v. Greece* [2005] ECR I-3177, para. 35.

113) Case C-152/78 *Commission v. France* [1980] ECR 2299; Cases C-314 to 316/81 and 83/82 [1982] ECR 4337; Case C-98/86 *Mathot* [1987] ECR 809; Case C-168/86 *Rousseau* [1987] ECR 1000.

condition — absence of *de facto* discrimination —, the Court stressed in both *Deutscher Apothekerverband* and *Ker-Optika* that the regulations on on-line sales of pharmaceuticals and medical devices did not affect the sale of national products in the same way as the sale of foreign goods. In effect, these measures were depriving traders from other Member States of a particularly effective means of selling those products and thus significantly impeded access of those traders to the market of the Member State concerned. Given that they were not qualified as selling arrangements, these national measures were deemed to be measures having equivalent effect' to 'quantitative restrictions' on imports for the purposes of Article 34 TFEU.

However, the prohibition laid down in Article 34 TFEU is not absolute. According to case law, Member States are allowed to enact measures hindering trade insofar as they are justified by one of the public interest ground set out in Article 36 TFEU. In this respect, the protection of health is of paramount importance. As regards the justification of the national measures, in *Deutscher Apothekerverband* and *Ker-Optika*, the Court clearly attempted to strike a balance between the opening up of markets in the area of medicines and contact lenses and the concern that the initial supply of these types of product should be organised by qualified staff, which requires physical contact with the customer. With respect to contact lenses, the judgment draws a dividing line between the phase of medical advice and the first intervention of an optician, which may be required before contact lenses are used, and further services that can be offered by opticians hired by foreign undertakings. One may very well wonder whether, in specifying the rights of the Member States, the adoption of a directive harmonising this type of trade might be a better solution than the contorted reasoning of the Union's Supreme Court. In fact, secondary law is better able to limit the risk of cacophony resulting from the freedom to set the level of protection for health.