

## **Judgment of the European Court of Justice in Case C-322/01 (Deutscher Apothekerverband eV and 0800 DocMorris NV, Jacques Waterval)**

On 11 December, the European Court of Justice (ECJ) delivered a landmark ruling regarding the sale of medicinal products through the Internet. The Court found that a national prohibition on the sale of medicinal products by mail order is compatible with European Community law where it applies to prescription medicines. However, the Court considered that such a prohibition is contrary to the free movement of goods under Article 28 of the EC Treaty if it applies to non-prescription medicines. We have prepared a short memo on the ECJ decision and a legal analysis of possible implications.

### **Background**

The case dates back to 2000 when the German pharmacists' association, ABDA, filed in a Frankfurt court a complaint against DocMorris, an Internet pharmacy. DocMorris is a limited company established in the Netherlands that sells medicinal products through mail order covering the German territory. DocMorris also carries out a standard pharmaceutical business via traditional dispensary in the Netherlands. Both the traditional pharmacy and its Internet site are covered by a licence issued by the Dutch authorities and are subject to control there. The director of DocMorris is an authorised pharmacist in the Netherlands.

In its complaint ABDA argued that DocMorris' activities were in breach of the German medicines law, which prohibited the sale by mail order of medicinal products which may be sold only in pharmacies. ABDA also claimed that DocMorris' activities were in breach of the German law regulating the advertising of medicinal products. This law prohibits any advertising with the aim of selling by mail order medicinal products which may be supplied only by pharmacies.

The regional civil court in Frankfurt referred questions on cross-border e-pharmacy to the European Court of Justice in August 2001.

### **Main questions referred to the ECJ**

We will focus in our analysis of this judgment on the following questions posed by the German court:

- 1) Whether the principle of the free movement of goods under Articles 28 to 30 of the EC Treaty is infringed by national legislation which prohibits medicinal products for human use the sale of which is restricted to pharmacies in the Member State concerned, to be imported commercially by way of mail order through pharmacies approved in other Member States in response to individual orders placed by consumers over the internet.
- 2) Whether, in the context of a national prohibition on advertising the sale by mail order of medicinal products, a broad interpretation of advertising, whereby a number of features of the internet portal of a pharmacy established in a Member State are classed as prohibited advertising, making cross-border ordering of medicines over the internet appreciably more difficult, is contrary to Articles 28 and 30 of the EC Treaty.

### **Decision of the ECJ**

#### **1) Ban on the sale of medicines by mail order**

In answering the first question the Court makes an initial distinction between medicinal products which are not authorised in Germany and medicinal products which are authorised in Germany.

### **Non-authorised medicinal products**

The Court considers that in relation to medicines not authorised in Germany there is no need to analyse the applicability of Article 28 and 30 as the German law prohibiting the importation of unauthorised medicines is compatible with the Community Code relating to medicinal products for human use.

### **Authorised medicinal products: Applicability of Article 28**

As regards medicinal products which are authorised in Germany, the Courts examines first whether Article 28, which prohibits barriers to the free movement of goods, is applicable to a national prohibition on mail-order sales.

The Court says that despite the possibility of introducing bans on the distance selling of medicines as permitted by the distance selling Directive, the power conferred to the Member States must be exercised with due regard for the Treaty provisions and the measure must be justified by a public interest objective.

The Court also examines the possibility of applying the concept of "selling arrangement" to the German prohibition. Following the doctrine established by Keck and Mithouard<sup>1</sup> the Court analyses if the German measure applies to all relevant traders operating in national territory and affects in the same manner, in law and in fact, the marketing of both domestic products and those from other Member States. The Court concludes that the German prohibition is more of an obstacle to pharmacies outside the German territory. According to the Court, for pharmacies not established in Germany "the internet provides a more significant way to gain direct access to the German market and imposed access to the market for products from other Member States more than it impedes access for domestic products". On this basis, the Court concludes that the German prohibition is a barrier to the free movement of goods under Article 28 of the EC Treaty.

### **Applicability of Article 30: Non-prescription and prescription medicines**

The Court goes on to analyse whether there is any justification for the prohibition on mail-order sales. The Court balances the effects of national rules which have a restrictive effect on the importation of pharmaceutical products and the necessity for the effective protection of health and life of humans. For this, the Court distinguishes between: non-prescription medicines and prescription medicines.

Regarding the non-prescription medicines, the ECJ is of the opinion that a ban is not justified. To reach this conclusion, the Court first states that the virtual pharmacy is properly authorised and subject to supervision by the Netherlands authorities. Second, the provision of advice and information is still possible. Third, the virtual pharmacy is also subject to public service obligations to guarantee the availability of medicinal products. The ECJ recognises therefore the need for certain controls for non-prescription medicines and states that these controls are in place in the Netherlands. In addition the Court recalls that the German law sets only the selling price of medicinal products which require prescription but the prices for non prescription medicines are set freely by German pharmacies. This could indicate that the conclusion could have been different in relation to countries in which the prices of non-prescription medicines are also fixed by the State.

**In conclusion, the ECJ allows the Internet sale of medicines under the following conditions:**

- The medicines must belong to the non-prescription category according to the classification in the country of destination;
- The sale must be done by a traditional pharmacy through an Internet page;
- The medicines must hold a Community authorisation or a national authorisation in the country of destination.

By contrast, the Court recognises first that the supply to the public of prescription medicines needs to be more strictly controlled. According to the Court, such control can be justified first in view of the greater risks which these medicines involve. The risks mentioned by the Court are namely:

- The differences among Member States in classifications;
- The need to be able to check effectively and responsibly the authenticity of doctors' prescriptions and that the medicine is collected by customer himself or somebody who has been entrusted by the customer;
- The possibility of different languages on the prescription.

Second, as a justification for the German prohibition the Court refers to the system of fixed prices which applies to prescription medicines and which forms part of the German health system. In this regard the Court says, "Although aims of a purely economic nature cannot justify restricting the fundamental freedom to provide services, it is not impossible that the risks of seriously undermining the financial balance of the social security system may constitute an overriding general interest reason". In conclusion, the Court finds that Article 30, which provides for derogations to the prohibition of Article 28, can be used to justify the prohibition of the Internet sale of medicines subject to prescription.

**2) Prohibition on advertising**

In relation to the prohibition on advertising the Court follows the same reasoning and concludes that the prohibition on advertising prescription medicines is compatible with Community law while advertising for non prescription medicines is permitted. The Community Code prohibits advertising of prescription medicines but permits as a general rule advertising for medicines intended and designed for use without the intervention of a doctor, but with the advice of a pharmacist if necessary. However, The ECJ has not accepted the ABDA argument that for proper information, the physical presence of a pharmacist is essential.

**PGEU Analysis**

**General considerations**

The present ECJ ruling is of major importance for the pharmacy sector and it could have repercussions on national laws imposing bans on the distance selling of non-prescription medicines.

It is interesting to note that the ECJ has not followed the advice of the Advocate General who in her opinion was much more rigorous in relation to the application of internal market rules to the cross border sale of medicinal products. In her view, a national measure such as the

German prohibition is a barrier to the free movement of goods and it is only justified for medicines that had not been authorised in Germany. She did not make any distinction between prescription and non-prescription medicines.

The present decision of the ECJ sets out a deeper analysis of the justification for the prohibition and concludes that in the case of prescription medicines, the prohibition of mail order sales is justified. It must be emphasised that the ECJ accepts, and in this aspect it agrees with the Advocate General, that the German prohibition constitutes a barrier to the free movement of goods but finds that the barrier in this case is justified for prescription medicines.

The ECJ does not classify the prohibition as a selling arrangement, departing from previous judgments which classified restrictions on advertising, mandatory shop closing hours and the limitation of the sale of certain goods to specific stores as selling arrangements. In our analysis, the reasoning of the ECJ for not accepting the existence of a "selling arrangement" is debatable, especially in view of Case-391/92 (Baby milk) where the ECJ found that the prohibition by Greek legislation of the sale of processed milk for babies in any establishment other than a pharmacy was a selling arrangement and it was not contrary to Article 28.

Despite the consideration of the German prohibition as a barrier, the ECJ recognises the importance of public interest considerations in the pharmacy sector. It is clear that it regards medicines as special products which require special control and involve serious risks (see paragraphs 117 and 118 of the ruling).

Also the ECJ points out that the financial balance of the social security systems or the integrity of the national health systems can constitute an overriding reason of general interest (see paragraphs 120-123). The Court follows here a recent judgment delivered September 2 which recognised the importance of protecting the public interest in relation to the application of internal market rules. In that ruling the Court found that Portuguese legislation which restricts games of chance to casinos is not contrary to Community rules on freedom to provide services as there are overriding reasons of public interests which justify it.

The ECJ, in the present ruling, describes many of the activities of pharmacists as essential for the safe delivery of medicines. In particular the Court says that "The only arguments which are capable of providing adequate reasons for prohibiting the mail-order trade in medicinal products are those relating to the need to provide individual advice to the customer and to ensure his protection when he is supplied with medicines and to the need to check that prescriptions are genuine and to guarantee that medicinal products are widely available and sufficient to meet requirements" (paragraph 106).

It should be noted that with the exception of the need to check the whether the prescriptions are genuine, this paragraph does not make any distinction between prescription and non-prescription medicines. This paragraph can be found at the beginning of the Court analysis before setting out such a distinction.

In our view the public interest aspects underlined by the ECJ and its positive analysis of the activities carried out by pharmacists is very useful for the activities of the PGEU when it comes to stress the special characteristics of the pharmacy profession. This ruling can be used as a supporting argument in the current revision by DG Competition of professional rules and especially in the context of the future Commission proposals on services. The special nature

of medicines, the role that the pharmacist plays in the advice to citizens and the guarantees provided by the pharmacy systems are recognised as essential for the safe dispensing of medicines.

However, it must be stressed that the distinction made by the ECJ between prescription and non-prescription medicines is not in line with the PGEU policy that all medicines are special products, especially considering the current trend of switching from the prescription to the non-prescription category and the lack of clarifying criteria to distinguish between the different categories.

Finally, it must be noted that the ECJ judgment does not deal with the possibility of the sale of non-prescription medicines outside a traditional pharmacy. Furthermore, one of the main arguments of the ECJ in favour of the distance selling of non-prescription medicines is the fact that DocMorris is also a physical pharmacy and as such it is subject to controls and obligations in the Netherlands.

#### Impact of the Judgment on national legislation

The impact of this judgment on national legislation will, of course, vary depending whether exists or not at national level bans on the distance selling of medicines and the scope of such bans.

According to current Community law, Member States can freely decide to introduce a ban for Internet sale of medicines but on the basis of this Judgment the prohibition must be restricted to prescription medicines.

Member States that currently have total prohibitions on the sale of all medicines will have to amend, if they were challenged, the national provisions not allowing the distance selling of non-prescription medicines. However if a national prohibition was challenged there would be still scope to push for a new reference by a national court to the ECJ if the particular circumstances in a country were different from those in place in Germany when the proceedings took place. This could be easily the case as the classification of prescription or non-prescription in the Member States is not uniform and, furthermore, some Member States distinguish between different categories of non-prescription medicines. In some countries the prices of certain prescription medicines are fixed and some non-prescription medicines are reimbursed by the state. In these countries the arguments expressed by the ECJ in the context of prescription medicines on the need for balance of the social security systems could be equally used.

The ECJ does not provide sufficient clarifying criteria as regards the distinction between prescription or non-prescription medicines but this distinction is essential for the correct application of this judgment. The lack of harmonisation on prescription rules and the different price systems together with a variety of reimbursement schemes at national level could lead to legal uncertainty for citizens in the implementation of the present judgment. As mentioned earlier, the distinction between medicines dispensed with or without prescription is delicate. For example in Belgium, certain medicines are subject to compulsory prescription (sleeping, antibiotics, etc) whether they are dispensed with a social security reimbursement or not, while others are on free sale but can be reimbursed by social insurance if prescribed.

A further problem with the implementation of this judgment is the difficulty for the Internet pharmacy, before every sale, to have information on the legislation in force in all Member

States as regards the classification of medicines. In addition, e-pharmacy customers when entering an Internet site will not have enough information to determine whether the site is a legally constituted pharmacy or it is just a web site created for the purposes of selling medicines.

The ECJ judgment has been sent now to the German Court that made the reference. This court will have to decide whether to lift or modify the injunction it originally issued against Doc Morris ordering to stop distributing medicines in Germany. Its decision will have to take into account the fact that, under the German health care reform which came into effect at the beginning of January 2004, mail -order supply of medicines, both prescription and non-prescription are legalised.

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