WHITE & CASE

The European Court affirms that public safety comes first: financial considerations cannot justify the placing on the market of unlicensed medicines

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Abstract

On 29 March 2012, the European Court of Justice (CJEU) issued a ruling in a case brought by the European Commission against Poland declaring unlawful the supply of unlicensed medicines on financial grounds as a cost containment measure.[2] The article looks into this judgment and assesses its significance in view of the increasing tendency of national healthcare authorities to look for new ways to reduce their costs. We give an overview of the regulatory framework for the authorisation of medicinal products and explain the limited possible derogations. The article then examines the main points of the ruling which declared that Poland has failed to fulfill its obligations under Article 6 of Directive 2001/83/EC on the Community code relating to medicinal products[3] by adopting and maintaining in force Article 4 of its 2001 Law on Medicinal Products.[4] The analysis will look at the Court's interpretation of the scope of Article 5(1) of the Directive and the role of financial considerations thereunder. We explain why the judgment is consistent with established case law, which stresses the need to financial considerations from trumping the regulatory framework, with its focus on public health.[5] Finally, the article notes the relevance of this judgment to the current controversy about some UK authorities' decisions to encourage off-label use of Avastin for cost saving reasons. Clearly the judgment casts strong doubt on the legality of such UK authorities' decisions.

Facts of the case

The European Commission brought an action against Poland for failing to respect EU law. Following the Opinion of the Advocate General given on September 29, 2011, the CJEU upheld the Commission's position in its 29 March 2012 ruling in Case C-185/10 that the Republic of Poland failed to fulfill its obligations under Art. 61 of Directive 2001/83 by keeping in force Art. 4 of the Polish Pharmaceutical Law of 6 September 2001, as amended by the act of 30 March 2007. The Court declared that Polish law permitting unauthorised medicinal products, having the same active substances, dosage, and form as authorised medicinal products already marketed, to be imported from abroad, if these products are priced lower than that of the authorised equivalent products, was not allowed under the Directive. The CJEU declared that the economic criterion based upon "competitive price" to permit importation of an unauthorised medicinal product was not compatible with EU law.

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2 http://curia.europa.eu/juris/liste.jsf?language=en&num=C-185/10

3 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 (Consolided version: 05/10/2009).

4 Article 4 of the Usatawa 'Prawo farmaceutyczne' (Law on Medicinal Products) of 6 September 2001 as amended by the Law of 30 March 2007 (Dz.U No 75 heading 492)

5 See our previous article on this topic, published in Pharmaceutial Law Insight, Vol 6, No 1, December 2009, available at: http://www.whitecase.com/article_12012009/

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EU law provides for a small number of exceptions to the requirement for a marketing authorization. This case looks at the exception for off-label prescribing to an individual under the concept of special needs.

Legal framework

As a general rule, in order to place a medicinal product on the market, the manufacturer is required to obtain a marketing authorisation from the relevant EU competent authority. The marketing authorisation framework based on the single market principle seeks to protect public health and patient safety through an independent benefit/risk assessment. Article 6 of Directive 2001/83/EC on the Community Code relating to medicinal products for human use reads as follows: *"No medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State in accordance with this Directive or unless an authorization has been granted in accordance with Regulation (EC) 726/2004 […]."*

For reasons of patient safety, EU law only provides for very limited exceptions to this rule. In particular, an exception is contained in Article 5(1) of the Directive, which states that a "*Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.*"

This provision makes it possible for a doctor to prescribe an unauthorized medicinal product or to prescribe an authorized product off-label, i.e. to treat a condition for which the medicine is not authorized. This exception implements the generally recognised principle of therapeutic freedom for prescribing physicians. It is an exception to the general rule and as such is strictly limited to individual, discretionary decisions of physicians where the doctor takes personal responsibility for prescribing the medicine to the patient after having individually examined him or her and thereafter follows closely how that patient reacts to the medicine. Hence, this exception does not encompass general policies by the national healthcare administration, social insurance bodies and similar entities which do not prescribe medicines, which do not take personal responsibility for the prescribing decision and which do not ever examine the individual patient.

The Decision of the Court

In the reasoning to its judgment, the CJEU stated that the main aim of Art. 6 of Directive 2001/83 is to eliminate barriers to trade in medicinal products between the EU member states and to protect public health. As in a previous case brought by the Commission against Poland (C-385/08), the Court stressed that no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that State in accordance with the Directive or Regulation 726/2004.[6] According to the ruling, the Polish domestic law "*does not merely impose stricter conditions, but creates an exception to the prohibition on placing on the market in circumstances not provided for in Article 5(1) of Directive 2001/83.*" However, the Article 5(1) exception is not concerned with the organisation of the healthcare system or its financial stability. Rather, the Court noted that Article 5(1) is a derogation to Article 6 of that Directive, which requires that medicines are authorised before being put on the market. So Article 5(1) must be interpreted narrowly and is only applicable in exceptional cases where it is appropriate to meet special medical needs.

The Court emphasised that the "*concept of 'special needs', referred to in Article 5(1) of the Directive, applies only to individual situations justified by medical considerations and presupposes that the medicinal product is necessary to meet the needs of the patient.*"[7] Therefore, CJEU ruled that Article 5(1) could not be properly relied upon to justify an exemption from the requirement for a marketing authorisation for reasons of a financial nature. More exactly, financial considerations, including the competitive pricing of a foreign product in relation to its national counterpart, are incompatible with Article 6 of the Directive and cannot justify the placing on the market in a Member State of an imported unauthorised medicinal product.

In particular, the CJEU ruled that "financial considerations cannot, in themselves, lead to recognition of the existence of such special needs capable of justifying the application of the derogation provided for in the directive". The patient safety objectives that underlie the EC system of compulsory marketing authorisations are intended to guarantee must take precedence over any budgetary considerations. As the Court states, "the requirement that medicinal products are supplied in response to a 'bona fide unsolicited order' means that the medicinal product must have been prescribed by the doctor as a result of an actual examination of his patients and on the basis of purely therapeutic considerations."[8]

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6 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF

7 Paragraph 34 of the Judgment

8 Paragraph 35 of the Judgment

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For the reasons given above, the CJEU ruled that the Republic of Poland had failed to fulfil its EU law obligations to require the imported products to be properly authorised. According to the ruling, national authorities should refrain from adopting administrative measures encouraging unathorised (or off-label) use of medicines on the ground that the authorised medicines are more expensive. In other words, the price of the authorised medicine to treat a given disease is not a criterion that authorities can take into account when permitting the prescription of unauthorised medicines. Such measures would broaden the scope of what is and should remain a limited exception to the general principle restricting the use of medicines to authorised indications. In sum, under European law, Article 5(1) remains a very limited exception to the general principle of compulsory prior market authorisation.

Conclusions

In this ruling, the Court reiterated previous case law[9] by stating that public health must take predominance over financial or economic considerations. This is not a surprising given the language of Article 152(1) EC, "a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities." At the same time, the Court recognises that EU law does not restrict the power of the Member States to organise their social security systems and to adopt provisions intended to govern the consumption of pharmaceutical products in order to promote the financial stability of their healthcare insurance schemes.

The Court emphasizes that the relevant legislative derogations must be interpreted strictly and stated that the derogation under Article 5(1), allowing the possibility of doctors to prescribe non-approved medicinal products, must remain exceptional in order to preserve the crucial role of the marketing authorization procedure to protect patients' health. By this, it also clarifies the scope of Article 5(1) special needs exemption in respect of unauthorised medicinal products stating that the provision is not concerned with the organisation of the health-care system or its financial stability, but is a specific derogation, which must be interpreted strictly, and is only applicable in exceptional cases where it is appropriate to meet special medical needs.

Therefore, Art. 5(1) of Directive 2001/83 cannot be relied on to justify a broad derogation from the requirement for a marketing authorisation for financial reasons. Where an equivalent authorised medicinal product is available on the market, there exist no special needs for an unauthorised product.

Some healthcare authorities in Europe have recently started to encourage the use of certain medicines outside their approved indication ("off-label use") on the ground that the authorised medicine would be more expensive. For instance, some Finnish and UK authorities have supported the use of Avastin (Bevacizumab) to treat age-related macular degeneration ("AMD"), a disease that affects vision in the centre of the visual field so that reading, recognising faces or driving become difficult or impossible. The use of Avastin, despite the absence of any marketing authorisation for the treatment of AMD, was justified on the ground that Avastin is much cheaper than Lucentis (Ranibizumab), the authorised medicine to treat AMD.[10] By contrast, the Swedish Medical Products Agency came out strongly against such a practice, based on traditional regulatory criteria intended to ensure patient safety. For example, it noted that while its knowledge of the safety profile of Avastin compared to Lucentis was inadequate, there was an increased risk for ocular inflammation and potentially also for certain systemic adverse events.[11]

In an era of budget cuts, where national healthcare authorities are looking for ways to reduce their expenses, the ruling constitutes a much-needed confirmation that public health considerations cannot be put into question for financial considerations especially. The Court's ruling provides welcome clarity and gives a strong indication as to the likely outcome of the Avastin debate. The ruling effectively prohibits authorities from engaging in budget-driven practices which circumvent the regulatory system and its most basic requirement, namely that to ensure patient safety a medicine should have a marketing authorization before being placed on the market and being used for a specific indication. The ruling also confirms that patient safety must not be put at risk via by off-label use that is not the choice of (and responsibility of) a doctor but imposed at a central level by authorities for financial reasons.

9 Case C-180/96R, *UK v Commission (BSE)*, at paragraphs 91-93 and Case T-13/99 at paragraph 456

10 For background, see http://www.bbc.co.uk/news/health-17817945

11 See http://www.lakemedelsverket.se/english/All-news/NYHETER-2012/Position-of-the-Medical-Products-Agency-Regarding-/

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