Allowing the import of unlicensed medicines on financial grounds breaches EU law

The Court of Justice of the EU has told Poland it is breaching EU law by allowing the supply of unlicensed medicines on economic grounds. ***Lincoln Tsang*** examines the legal judgment.

In a judgment handed down on 29 March, the Court of Justice of the EU clarified that allowing the supply of unlicensed medicines on economic grounds is illegal in the EU[1-3].

The decision, which relates to the *European Commission v the Republic of Poland 2012*, ruled that Polish legislation allowing the placing on the market of unauthorised medicinal products imported from outside the EU that are cheaper copies of products already authorised in Poland is contrary to EU law.

The judgment is welcome news for research-based pharmaceutical companies. On the one hand, the CJEU recognised 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. Importantly, however, it also ruled that "exemptions from the requirement for a marketing authorisation for reasons of a financial nature cannot be justified".

The Polish government had argued that the importation of unauthorised medicinal products from countries other than EU member states could be justified because such products were indispensable for the survival or health of the patient as contemplated by EU pharmaceutical law. The judgment sends a clear message to Poland and other EU member states that the practice is not allowed.

If Poland does not comply with the judgment without delay, the commission may bring a further action seeking financial penalties[4].

Background

EU pharmaceutical law requires as a general rule a marketing authorisation to be obtained for a medicinal product before it can be legally placed on the market[5]. The marketing authorisation system seeks to protect public health and patient safety through an independent assessment of the safety, quality and efficacy underpinning the benefit-risk assessment. However, in certain defined circumstances, EU member states may dispense with the marketing authorisation requirement (but there is no obligation to do so) under their domestic laws to permit an unauthorised medicinal product to be supplied. It can do so if it is intended to fulfil special needs of a patient under the care of an authorised healthcare professional (Article 5(1) special need exemption or named patient supply), or if it is necessary for public health reasons (Article 126a public health exemption). The case law of the CJEU establishes that these exemptions from the general rule to place a product on the market should be interpreted narrowly[6].

Under the Treaty for the Functioning of the EU, the EU is required to respect the responsibilities of the member states for defining and managing their national healthcare policy such as the organisation and delivery of health services and medical care. Such responsibilities include the management of health services and medical care and the allocation of the resources.

In order to contain and reduce healthcare costs, it appears to be the practice of Poland through its domestic law to permit unauthorised medicinal products to be imported from abroad, but not from another EU member state. These imported unauthorised products would have the same active substances, the same dosage and form as the authorised medicinal products already marketed in Poland. They could be imported into Poland for general medical use if they are competitively priced, ie they are cheaper than the authorised equivalent products[7].

On 6 June 2008[8], the commission notified Poland in writing as part of the so-called pre-infraction procedure (ie pre-litigation) that the Polish domestic law in question was incompatible with EU pharmaceutical law because the Polish law allowed the placing on the market of certain medicinal products without the granting of prior marketing authorisation. By letter of 30 July 2008, Poland replied that its domestic law was in conformity with EU law. The commission was not satisfied with the response and sent a reasoned opinion on 26 June 2009 in which it maintained its position concerning Poland's infringement of EU law, and specifically the requirement for a marketing authorisation to place a medicinal product on the market. In its reply to the commission, Poland affirmed that its domestic law properly transposed the exemption scheme provided under EU pharmaceutical law on public health grounds.

Not satisfied with Poland's responses, the commission brought an infringement procedure under Article 258 TFEU on 13 April 2010[9,10], requesting the CJEU to declare the offending Polish domestic law as contrary to EU pharmaceutical law, and that Poland had failed its EU law obligation to implement EU pharmaceutical law properly. Specifically, the commission asked the CJEU to declare that the economic criterion based upon "competitive price" to permit importation of an unauthorised medicinal product could not be properly said to be compatible with the exception to the requirement for a marketing authorisation envisaged by EU pharmaceutical law.

The commission contended that the Polish law provision concerned medicinal products with the same active substance, same dosage form as the products already authorised to be placed on the national market. Therefore it is not possible to consider them to be unavailable on the national market. Most critically, the commission alleged that the Polish domestic law did not authorise the importation of unauthorised products in a limited quantity to cover only individual needs according to the wording of the exemption, but authorised importation on a larger scale of products which are competitively priced in relation to authorised products already on the market.

The Polish government during the legal proceedings in the CJEU criticised the commission for focusing on those provisions without having regard to the wider context. Specifically, the Polish government said that importation of unauthorised medicinal products from countries other than EU member states could be justified because they are indispensable for the survival or health of the patient as contemplated by EU pharmaceutical law.

Advocate General Jääskinen's opinion was issued on 29 September 2011[11] and the CJEU judgment was published on 29 March 2012. The CJEU essentially followed the opinion of the advocate general and both disagreed with the Polish government's position. Their reasoning is set out below.

Analysis

This case essentially centres on whether the economic criterion set out in the offending Polish domestic law can be justified under the specific exemption scheme based on special needs under EU pharmaceutical law. This case is not concerned about parallel importation of an authorised product from another EU member state. As the advocate general put it, in the EU, parallel imports of products already having a marketing authorisation in the

member state of importation are allowed under the provisions relating to the free movement of goods principle as explained in the established case law. In contrast, this case is about the importation of products without a valid marketing authorisation in Poland.

The CJEU agreed with the advocate general's opinion that the harmonised marketing authorisation procedure enables cost-efficient and non-discriminatory market access of medicinal products whilst ensuring that the requirements of safeguarding public health are achieved.

Consistent with the established CJEU case law[12], all medicinal products placed on the market in a member state must be granted a marketing authorisation from a competent authority in order to fulfil the public health objectives of EU pharmaceutical law. Both the advocate general and the CJEU indicated that the Article 5(1) special need exemption entails that the product in question is required for a specific and identified need. The need should be related to a particular identified individual. The plain and natural meaning of the word "special" suggests that the circumstances in which the unauthorised product could be legitimately supplied should be out of the ordinary, consistent with the case law in order to preserve the practical effect of the marketing authorisation procedure[13].

As to the question of whether the special need contained in Article 5(1) should be health-related as suggested by the commission, the advocate general and the CJEU were of the view that the special need must be health related as it follows from the aim of public health protection, which EU pharmaceutical law seeks to preserve. Moreover, the Article 5(1) special need exemption could not be properly said to provide member states a discretionary power to disapply the general requirement to obtain a marketing authorisation in cases where there is no proper basis on grounds relating to special needs or public health. Otherwise, it would be in conflict with the aim of protecting public health.

The concept of "special needs" under Article 5(1) applies only to individual situations on medical grounds. It therefore presupposes that the medicinal product is necessary to meet the needs of the individual patient. In this regard, the CJEU considers that administration of an unauthorised product could be justified in the light of the state of health of the individual patients if there is no authorised equivalent product on the national market or which is unavailable on that market. In the commission's submission to the CJEU, unavailability should be considered in the literal sense of physical unavailability. By way of examples, the commission considered temporary shortages of products on the national market, and of the unavailability of a particular dosage which is required to treat an individual patient as justifiable situations. Essentially, as the advocate general and the CJEU indicated, supply of such unauthorised products would ordinarily be in a small quantity intended to treat specific patients, and should not be treated properly as legitimate replacement of the authorised products for routine clinical use.

Therefore, the CJEU considered at paragraph 37 of its judgment that where there are medicinal products with the same active substances, the same dosage and the same form as those that are already authorised and available on the national market, there could not be a proper basis on grounds relating to special needs to prescribe the unauthorised products. The CJEU went on to say that financial considerations could not in themselves lead to recognition of such special needs capable of justifying the application of applying the Article 5(1) exemption.

The CJEU also considered the Polish government's contention that the Polish domestic law was stricter than the Article 5(1) special need exemption. It disagreed with the Polish government's submission and explained at paragraphs 41 and 45 that the Polish domestic law imposed supplementary conditions stricter than those required by Article 5(1) on grounds not relating to actual unavailability of the authorised medicinal product on the national territory, but on the competitively lower price of the equivalent unauthorised product. As the CJEU put it, 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)".

The CJEU recognised 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. However, the Article 5(1) exemption is not concerned with the organisation of the healthcare system or its financial stability. Rather, the CJEU noted that it is a specific derogatory provision, which must be interpreted strictly applicable in exceptional cases where it is appropriate to meet special medical needs. Therefore, the 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.

For the reasons given above, Poland was found to have failed to fulfil its EU law obligations to require the imported products to be properly authorised.

Conclusions

The CJEU has clarified the scope of the Article 5(1) special needs exemption in respect of unauthorised medicinal products. Where an equivalent authorised medicinal product is physically available on the market, there exist no special needs for an unauthorised product. According to the CJEU judgment, the two products would be considered as equivalent if they contain the same active ingredient, the same dosage, and have the same form.

It may be suggested that the same reasoning as indicated in this case ought to be applied in an off-label use of an authorised medicinal product. Similar to the situation of prescription of an unauthorised medicinal product, EU pharmaceutical law does not preclude the prescription of an authorised product for an unauthorised indication ("off-label" prescription) at the discretion of the doctor and at his own responsibility. Such prescription has always occurred in circumstances where no authorised product is available to treat the condition suffered by the particular patient. But it has been reported elsewhere that off-label prescription may also take place where the product authorised for a specific indication is more expensive than a similar product which has not been so authorised, in order to contain healthcare costs.

References

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6. *Case C-64/05 Sweden v European Commission, http://bit.ly/HGOi52*
7. *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)*
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11. *See Reference 8*
12. *Case C-84/06 Antroposana and Others, http://bit.ly/HwkAN7*
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