Court of Justice of the European Union
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Press and Information

Judgment in Case C-185/10
Commission v Poland

Polish legislation authorising the placing on the market of foreign medicinal products lacking authorisation which are cheaper than, but similar to, those already authorised is contrary to European Union law

Financial considerations cannot justify the placing on the market of such medicinal products

Directive 2001/83 [1] provides that no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued either by the competent authorities of that Member State or by the European Commission. However, by way of exception, in order to fulfil special needs, a Member State may provide that this requirement does not apply to medicinal products which are supplied in response to a bona fide unsolicited order, are formulated in accordance with the specifications of an authorised health-care professional and are for use by an individual patient under his direct personal responsibility.

The Commission brought the present action for failure to fulfil obligations before the Court of Justice as it considers that the Polish legislation is contrary to the directive in that it provides for a derogation from the requirement for marketing authorisation in the case of medicinal products from abroad which have the same active substances, the same dosage and the same form as medicinal products which have obtained marketing authorisation in Poland, on condition, in particular, that the price of those imported medicinal products is competitive in relation to the price of the products which have obtained such an authorisation.

The Court points out, first, that the harmonised marketing authorisation procedure enables cost-efficient and non-discriminatory market access, whilst ensuring that the requirements of safeguarding public health are achieved.

Next, the Court observes that the possibility of importing non-approved medicinal products, provided for under national legislation implementing the derogation laid down in the directive, must remain exceptional and can be exercised only if necessary, taking account of the specific needs of patients.

The concept of 'special needs' applies only to individual situations justified by medical considerations and presupposes that the medicinal product is necessary to meet the needs of the patient. Also, the requirement that medicinal products be 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.

Consequently, the derogation provided for in the directive can only concern situations in which the doctor considers that the state of health of his individual patients requires that a medicinal product be administered for which there is no authorised equivalent on the national market or which is unavailable on that market.

[1] 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), as amended by Regulation (EC) No 1394/2007 of European Parliament of the Council of 13 November 2007 (OJ 2007 L 324, p. 121).

Therefore, where medicinal products composed of the same active substances, of the same dosage and having the same form as those which the doctor providing treatment considers that he must prescribe to treat his patients are already authorised and available on the national market, there cannot in fact be a question of 'special needs' necessitating a derogation from the requirement for a marketing authorisation. Financial considerations cannot, in themselves, lead to recognition of the existence of such special needs capable of justifying the application of the derogation.

The Court states that the Polish legislation at issue introduces an exception to the requirement for a marketing authorisation, based not on the actual unavailability of the medicinal product authorised on national territory, but on the 'competitive' price, that is to say, the lower price, of the equivalent medicinal product. It consequently allows the importation and the placing on the national market, without a marketing authorisation, of medicinal products which are not necessary to meet special needs of a medical nature.

The Court rejects the argument of Poland that the importation and the placing on the national market of a medicinal product cheaper than the equivalent medicinal product which has obtained marketing authorisation may be justified by financial considerations inasmuch as they are necessary both in order to ensure the financial stability of the national social security system and to allow patients who have only limited financial means to have access to the treatment which they need.

The Court notes, in that respect, that although European Union law does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, provisions intended to govern the consumption of pharmaceutical products in order to promote the financial stability of their health-care insurance schemes, they must, however, comply with European Union law in exercising that power.

The exception provided for by the directive is not concerned with the organisation of the health-care system or its financial stability, but is a specific derogating provision, which must be interpreted strictly, applicable in exceptional cases where it is appropriate to meet special medical needs.

The Court states, finally, that the Member States remain competent to set the price of medicinal products and the level of reimbursement by the national heath insurance scheme, on the basis of health, economic and social conditions.

Consequently, the Court held **that Poland has failed to fulfil its obligations under European Union law.**

NOTE: An action for failure to fulfil obligations directed against a Member State which has failed to comply with its obligations under European Union law may be brought by the Commission or by another Member State. If the Court of Justice finds that there has been a failure to fulfil obligations, the Member State concerned must comply with the Court's judgment without delay.
Where the Commission considers that the Member State has not complied with the judgment, it may bring a further action seeking financial penalties. However, if measures transposing a directive have not been notified to the Commission, the Court of Justice can, on a proposal from the Commission, impose penalties at the stage of the initial judgment.

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