Reports of Cases

Case C-185/10

European Commission
v
Republic of Poland

(Failure of a Member State to fulfil obligations — Directive 2001/83/EC — Articles 5 and 6 — Proprietary medicinal products — Medicinal products for human use — Authorisation to market — Legislation of a Member State dispensing with a marketing authorisation for medicinal products which are similar to but have a lower price than authorised products)

Summary of the Judgment

1. *Approximation of laws — Medicinal products for human use — Directive 2001/83 — Importation into a Member State of a product constituting a medicinal product — Necessity of obtaining a marketing authorisation — Derogation in the case of special needs — Scope*

   (European Parliament and Council Directive 2001/83, as amended by Regulation No 1394/2007, Arts 5(1) and 6(1))

2. *Approximation of laws — Medicinal products for human use — Directive 2001/83 — Importation into a Member State of a product constituting a medicinal product — Necessity of obtaining a marketing authorisation — Derogation in the case of special needs — Scope — Exceptional nature — Conditions*

   (European Parliament and Council Directive 2001/83, as amended by Regulation No 1394/2007, Arts 5(1) and 6(1))

1. A Member State that adopts and maintains in force a legal provision that dispenses with the requirement for a marketing authorisation for medicinal products from abroad which have the same active substances, the same dosage and the same form as those having obtained a marketing authorisation in that Member State, on condition that, in particular, the price of those imported medicinal products is competitive in relation to the price of products having obtained such authorisation, fails to fulfil its obligations under Article 6 of Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Regulation No 1394/2007.

When medicinal products having the same active substances, the same dosage and 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', within the meaning of Article 5(1) of Directive 2001/83, necessitating a derogation from the requirement for a marketing authorisation under Article 6(1) of that directive.

Financial considerations cannot, by themselves, lead to recognition of the existence of such special needs capable of justifying the application of the derogation provided for in Article 5(1) of that directive.

(see paras 37, 38, 52)

2. The possibility of importing non-approved medicinal products, provided for under national legislation implementing the derogation laid down in Article 5(1) of Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Directive 1394/2007, must remain exceptional in order to preserve the practical effect of the marketing authorisation procedure.

The option, which arises from Article 5(1) of Directive 2001/83, of excluding the application of the directive's provisions may be exercised only if necessary, taking account of the specific needs of patients. A contrary interpretation would conflict with the aim of protecting public health, which is achieved through the harmonisation of provisions relating to medicinal products, particularly those relating to the marketing authorisation.

The concept of 'special needs', referred to in Article 5(1) of that 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. Likewise, 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.

It is apparent from the conditions as a whole set out in Article 5(1) of Directive 2001/83, read in the light of the fundamental objectives of that directive, and in particular the objective seeking to safeguard public health, that the derogation provided for in that provision can concern only those situations in which the doctor considers that the state of health of his individual patients requires a medicinal product to be administered for which there is no authorised equivalent on the national market or which is unavailable on that market.

(see paras 32-36)