Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

29 March 2012*

((Failure of a Member State to fulfil obligations — Directive 2001/83/EC — Articles 5 and 6 — Proprietary medicinal products — Medicinal products for human use — Marketing authorisation — Legislation of a Member State exempting medicinal products similar to but cheaper than authorised products from marketing authorisation))

In Case C-185/10,

ACTION under Article 258 TFEU for failure to fulfil obligations, brought on 13 April 2010,

European Commission, represented by M. Šimerdová and K. Herrmann, acting as Agents, with an address for service in Luxembourg,

applicant,

v

Republic of Poland, represented by M. Szpunar, acting as Agent,

defendant,

THE COURT (Third Chamber),

composed of K. Lenaerts, President of the Chamber, E. Juhász, G. Arestis, T. von Danwitz and D. Šváby (Rapporteur), Judges,

Advocate General: N. Jääskinen,

Registrar: K. Malacek, Administrator,

after hearing the Opinion of the Advocate General at the sitting on 29 September 2011,

gives the following

Judgment

1 By its application, the European Commission asks the Court to declare that, by adopting and maintaining in force Article 4 of the Law on Medicinal Products (Prawo farmaceutyczne) of 6 September 2001, as amended by the Law of 30 March 2007 (Dz. U. No 75, heading 492) ('the Law on Medicinal Products'), inasmuch as that statutory provision dispenses with the requirement for a marketing authorisation for medicinal products from abroad which have the same active substances,

* Language of the case: Polish.

the same dosage and the same form as those having obtained a marketing authorisation in Poland, 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, the Republic of Poland has failed to fulfil its obligations under Article 6 of 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 the European Parliament and of the Council of 13 November 2007 (OJ 2007 L 324, p. 121) ('Directive 2001/83').

Legal context

European Union ('EU') law

2 Article 2(1) of Directive 2001/83 states:

'1. This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.'

3 Article 5(1) of that directive provides:

'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.'

4 The first subparagraph of Article 6(1) of that directive states:

'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 Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004 [of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1)], read in conjunction with [Regulation No 1394/2007].'

National law

5 Article 4 of the Law on Medicinal Products states as follows:

'1. Subject to the reservation in paragraphs 3 and 4, medicinal products imported from outside Poland may be placed on the market without the need to obtain authorisation for them if their use is necessary for the purpose of saving the life or safeguarding the health of a patient, on condition that the medicinal product in question is allowed to be marketed in the country from which it was imported and holds an up-to-date marketing authorisation.

2. The basis for the importation of a medicinal product, as referred to in paragraph 1, is the requirement of the hospital or external doctor treating the patient, as confirmed by a consultant in the medical sector concerned.

3. The following medicinal products may not be placed on the market within the terms of paragraph 1:

(1) those in respect of which the minister with responsibility for health-related matters has issued a decision refusing to grant authorisation, refusing to extend the duration of validity of an authorisation, or revoking authorisation; and

(2) those containing the same active substance or substances, the same dosage and having the same form as medicinal products which have obtained authorisation, subject to the reservation in paragraph 3a.

3a. The rule in paragraph 3(2) shall not apply to medicinal products, as referred to in paragraph 1, the price of which is competitive in relation to the price of the medicinal product which has obtained authorisation within the terms of Article 3(1) or (2), on condition that the requirement has been expressed by a health insurance doctor and has been confirmed by a consultant in the medical sector concerned, and that the minister with responsibility for health-related matters has expressed, by way of a decision, his agreement to the importation of those products.

4. Medicinal products, as referred to in paragraph 1, which, having regard to the safety of their application or the scale of importation, must be granted marketing authorisation pursuant to Article 3(1), may also not be placed on the market.

5. Pharmacies, wholesalers and hospitals engaging in the commercial sale of medicinal products, as referred to in paragraph 1, shall maintain a register of those products.

6. On the basis of that register, a pharmaceutical wholesaler shall forward to the minister with responsibility for health-related matters, no later than 10 days after the end of each quarter, a summary list of imported medicinal products.'

Pre-litigation procedure

6 Since it considered that Article 4 of the Law on Medicinal Products was contrary to Article 6 of Directive 2001/83, in that it allowed certain medicinal products to be placed on the Polish market without prior marketing authorisation having been granted, the Commission sent the Republic of Poland a letter of formal notice on 6 June 2008.

7 That Member State responded to the letter of formal notice by letter dated 30 July 2008 in which it disputed that any EU law had been infringed.

8 Since it was not satisfied with the reasons given by the Republic of Poland, the Commission issued a reasoned opinion on 26 June 2009 in which it called upon that Member State to adopt the measures necessary to comply with the reasoned opinion within two months of its receipt.

9 By letter dated 26 August 2009, the Republic of Poland responded to the reasoned opinion and stated that the Commission's complaints were unfounded since compliance of Article 4 of the Law on Medicinal Products with EU law could be substantiated on the basis of Article 5 of Directive 2001/83.

10 As it was not persuaded by the Republic of Poland's response, the Commission decided to bring the present action.

The action

Arguments of the parties

11 The Commission claims that Article 4(1), Article 4(3)(2) and Article 4(3a) of the Law on Medicinal Products, read together, infringe Article 6 of Directive 2001/83 in that they allow the placing on the Polish market, without national authorisation, of medicinal products imported from outside Poland which are almost identical to those already authorised on that market, provided that the price of those foreign medicinal products is 'competitive' in relation to the price of the medicinal products which have obtained national authorisation.

12 The Commission considers that Directive 2001/83 does not provide for the possibility of placing medicinal products on the market having regard to their 'competitive' price, when they have not, also, obtained the authorisation referred to in Article 6 of that directive, issued by the national authorities or in accordance with the centralised procedure provided for in Regulation No 726/2004.

13 According to the Commission, Article 5(1) of Directive 2001/83 makes it possible to derogate, for a particular medicinal product, from the requirement to have a national marketing authorisation where the medicinal product is supplied on account of a specific individual order and, not being on the national market, has to be imported, but it does not, in contrast, justify a derogation based on financial reasons.

14 The Commission adds that the possibility offered by the Polish legislation is not limited to the importation of medicinal products necessary in the course of treating specific problems which affect certain patients in particular, but concerns, in particular, medicinal products used for treating persons who cannot leave their place of care, so that the derogation at issue is capable of relating to patients of an entire hospital sector or to wholesale marketing. It points out, furthermore, that Article 4(3a) of the Law on Medicinal Products does not refer to the medical opinion in an individual case, but only to 'the requirement … expressed by a health insurance doctor'. That provision therefore authorises not the importation of solely a limited quantity of a medicinal product such as to cover only individual needs, but importation on a larger scale of medicinal products the price of which is 'competitive' in relation to that of medicinal products available on the national market.

15 The Commission points out that its complaint concerns not all of the provisions of Article 4 of the Law on Medicinal Products, but only the 'lifting', based on the existence of a 'competitive' price, of the prohibition provided for in Article 4(3)(2) of that law. Article 4(3a) of that law allows the placing on the Polish market, without authorisation issued by the national authorities, of both foreign equivalent medicinal products which are less expensive, that is to say generic medicinal products, and identical medicinal products marketed in other countries at lower prices than those on the Polish market. In that case it is only the criterion of the lowest price which allows the prohibition set out in Article 4(3)(2) of the Law on Medicinal Products to be lifted.

16 The Republic of Poland contests the merits of the allegation of failure to fulfil obligations. It contends that Article 4 of that law, which allows, under well-defined conditions, some medicinal products to be imported in the context of the procedure of 'targeted importation', complies with the derogation provided for in Article 5(1) of Directive 2001/83.

17 In focussing on the competitive nature of the price, the Commission overlooks the conditions which arise from an overall analysis of Article 4 of the Law on Medicinal Products. The application of the exception in that article is contingent on the following conditions:

— that the use of the medicinal product is necessary for the purpose of saving the life or safeguarding the health of a patient (paragraph 1);

— that the medicinal product the importation of which is envisaged is marketed in the foreign country and, for that purpose, has a current marketing authorisation (paragraph 1);

— that the basis for the importation of the medicinal product is the requirement of the hospital or the doctor treating the patient (paragraph 2);

— that that requirement is confirmed by a consultant in the medical sector concerned (paragraph 2);

— that pharmacies, wholesalers and hospitals engaging in the commercial sale of those medicinal products maintain a register for that purpose (paragraph 5);

— that the requirements governing safety of the application of the medicinal products are satisfied (paragraph 4 a contrario);

— that the normal procedure to authorise placing on the market provided for in the Law on Medicinal Products, that is to say a marketing authorisation, need not be applied having regard to the limited nature of the importation (paragraph 4 a contrario);

— that, as regards the medicinal product which is intended to be imported, the Minister of Health has not refused marketing authorisation, refused to extend the duration of its validity or revoked authorisation (paragraph 3(1)).

18 The Republic of Poland contends that its national legislation provides for supplementary conditions, stricter than those set by Article 5(1) of Directive 2001/83, for the importation of medicinal products containing the same active substance or substances and the same dosage and having the same form as medicinal products which have obtained marketing authorisation. Accordingly, Article 4 of the Law on Medicinal Products excludes, in principle, the possibility of importing such medicinal products, unless their price is competitive in relation to the price of the medicinal product which has obtained a marketing authorisation and on condition, first, that the requirement expressed by a health insurance doctor has been confirmed by a consultant in the medical sector concerned, and, second, that the minister with responsibility for health-related matters has expressly decided to authorise the importation.

19 The Republic of Poland maintains that Article 5(1) of Directive 2001/83 does not lay down a condition of unavailability of a medicinal product on the national market in the sense of the lack of an 'equivalent' registered medicinal product.

20 The derogation provided for in Article 4(1) of the Law on Medicinal Products from the requirement that a marketing authorisation be obtained is based not on the lower price of the medicinal product abroad, but on the need to import a medicinal product where it is necessary for the purpose of saving the life or safeguarding the health of a patient. That objective satisfies the condition of fulfilling special needs set out in Article 5(1) of Directive 2001/83.

21 As regards the Commission's assertion that Article 4 of that law allows the importation into Poland of medicinal products on a larger scale, potentially leading to the entry onto the national market of a large number of pharmaceutical products from third countries, the Republic of Poland points out that, according to Article 4(4) of that law, 'medicinal products, which, having regard to the safety of their application or the scale of importation, must be granted marketing authorisation pursuant to Article 3(1), may also not be placed on the market'.

22 The Republic of Poland states that the regulation of the Minister for Health of 18 April 2005 concerning importation of medicinal products not having a marketing authorisation and which are necessary for saving the life or safeguarding the health of the patient provides that the request for importation of a medicinal product must, in all cases, include the forename, surname and age of the

patient, his address, his PESEL number (the Polish residence identification number) and information concerning the national social security fund. That request must also state the name of the medicinal product, its pharmaceutical form and its dosage, the quantity of the medicinal product which is intended to be imported and indications concerning the duration of treatment for an individual patient. It is only in exceptional cases, when it is not possible to determine the details for the patient at the time of his admission to hospital, that that information may be replaced by the formula 'for immediate needs'. However, in that case, the hospital is required to provide to the Minister for Health within 30 days of the end of the treatment a statement setting out details of the patients who benefited from that treatment as well as the dosages administered.

23 It follows from Article 4(3a) of the Law on Medicinal Products that the requirement is always established by the doctor treating an individual patient, whether or not that doctor is attached to a hospital. Besides, the doctor providing treatment must sign the request and attest that he is aware of having ordered a medicinal product which is not authorised to be marketed in Poland and that he is responsible for the use of that medicinal product.

24 The Republic of Poland maintains that a decision to import a medicinal product in the context of health insurance can be dictated by financial considerations, namely by the need to ensure the financial stability of the national health insurance system. It points out in that regard that, according to Article 168(7) TFEU, EU law does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, measures intended to govern the consumption of pharmaceutical products in order to promote the financial stability of their health-care insurance schemes. Similarly, it notes that Article 4(3) of Directive 2001/83 provides that the directive's provisions are not to affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.

25 Finally, the Republic of Poland claims, first, that Article 4(3a) of the Law on Medicinal Products is used in rare and exceptional cases and, second, that the basic criterion for authorising the importation of a medicinal product is the safety of the patient and the concern of guaranteeing him a real possibility of obtaining the treatment which is necessary for his survival or health; the competitive nature of the price of that treatment in relation to that of equivalent medicinal products registered in Poland constitutes only a supplementary condition. In a situation where a number of patients have only limited financial means, the importation of an equivalent but less expensive medicinal product is the only possibility of treating those persons, even of saving their life, and this certainly satisfies the condition concerning the need to 'fulfil special needs' provided for in Directive 2001/83.

Findings of the Court

26 It must be noted at the outset that Article 6(1) of Directive 2001/83 provides 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 that directive or unless an authorisation has been issued in accordance with the centralised procedure provided for in Regulation No 726/2004 for medicinal products referred to in the annex to that regulation.

27 This requirement is intended to fulfil the objectives which Directive 2001/83 seeks to attain, namely, first, the elimination of hindrances to trade in medicinal products between the Member States and, second, the protection of public health (see Case C-84/06 *Antroposana and Others* [2007] ECR I-7609, paragraph 36). As the Advocate General stated in points 19 to 21 of his Opinion, the harmonised marketing authorisation procedure enables cost-efficient and non-discriminatory market access, while ensuring that the requirements of safeguarding public health are achieved.

28 Directive 2001/83 provides, however, for derogations from that general rule laid down in Article 6(1). It is common ground that only the derogation referred to in Article 5(1) of that directive is relevant to the present case.

29 Under Article 5(1) of the directive, a Member State may exclude from the directive's scope, in order to fulfil special needs, 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.

30 As is apparent from the wording of that provision, implementation of the derogation for which it provides is conditional on fulfilment of a set of cumulative conditions.

31 In order to interpret that provision, it must be taken into account that, generally, provisions which are in the nature of exceptions to a principle must, according to settled case-law, be interpreted strictly (see in particular, to this effect, Case C-3/09 *Erotic Center* [2010] ECR I-2361, paragraph 15 and the case-law cited).

32 More specifically, as regards the derogation referred to in Article 5(1) of Directive 2001/83, the Court has already pointed out that the possibility of importing non-approved medicinal products, provided for under national legislation implementing the power laid down in that provision, must remain exceptional in order to preserve the practical effect of the marketing authorisation procedure (see, to this effect, Case C-143/06 *Ludwigs-Apotheke* [2007] ECR I-9623, paragraphs 33 and 35).

33 As the Advocate General stated in point 34 of his Opinion, the power, which arises from Article 5(1) of Directive 2001/83, to exclude the application of the directive's provisions can be exercised only if that is 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.

34 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.

35 Also, 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.

36 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 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.

37 Where 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.

38 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 Article 5(1) of that directive.

39 In the present case, although the parties do not agree, in a number of respects, on the interpretation of the Law on Medicinal Products, it is not however disputed that Article 4(1), Article 4(3)(2) and Article 4(3a) of that law, read together, allow medicinal products from abroad, including third countries, which contain the same substances and the same dosage and have the same form as medicinal products already authorised in Poland to be placed on the Polish market without a marketing authorisation when their price is competitive in relation to the prices of authorised medicinal products.

40 It must be found that, to that extent, the Law on Medicinal Products does not satisfy the conditions of Article 5(1) of Directive 2001/83 as described above.

41 Although Article 4(3)(2) of that law excludes the importation, without a marketing authorisation, of medicinal products which contain the same active substance or substances and the same dosage and have the same form as medicinal products having obtained such authorisation in Poland, Article 4(3a), however, introduces an exception to that rule, 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. The interpretation of Article 4 of the Law on Medicinal Products as a whole, as put forward by the Republic of Poland, cannot cast doubt on this finding, since it does not call into question the existence of that exception.

42 Those provisions thus allow the importation and the placing on the national market, without a marketing authorisation, of medicinal products which are not necessary to meet special medical needs.

43 It follows that the exception provided for in Article 4(3a) of the Law on Medicinal Products does not satisfy the conditions required in order to benefit from the derogation provided for in Article 5(1) of Directive 2001/83.

44 None of the other arguments put forward by the Republic of Poland is capable of calling that finding into question.

45 The argument of that Member State that the provisions of that law, and in particular Article 4(3a), impose supplementary conditions, stricter than those required by Article 5(1) of Directive 2001/83, rests on a misreading of the latter provision, for it does not allow the placing on the market, without a marketing authorisation, of medicinal products where equivalent authorised medicinal products are available on the national market, as is apparent from paragraphs 40 and 41 of this judgment. However, Article 4(3a) of the Law on Medicinal Products allows such placing on the market where certain other conditions are satisfied. Accordingly, contrary to what the Republic of Poland maintains, that provision 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.

46 It is also necessary to reject the argument of the Republic 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.

47 It must be noted in that respect, first, that although EU 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, the Member States must, however, comply with EU law in exercising that power (Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *A. Menarini Industrie Farmaceutiche Riunite and Others* [2009] ECR I-2495, paragraphs 19 and 20).

48 It must be pointed out, next, that Article 5(1) of Directive 2001/83 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.

49 Finally, 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, as is apparent from Article 4(3) of that directive.

50 Article 5(1) of the directive cannot therefore be relied on to justify a derogation from the requirement for a marketing authorisation for reasons of a financial nature.

51 It follows from the foregoing that the action is well founded.

52 Consequently, it must be held that, by adopting and maintaining in force Article 4 of the Law on Medicinal Products, inasmuch as that statutory provision 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 Poland, 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, the Republic of Poland has failed to fulfil its obligations under Article 6 of Directive 2001/83.

Costs

53 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the Republic of Poland has been unsuccessful in its submissions, the latter must be ordered to pay the costs.

On those grounds, the Court (Third Chamber) hereby:

1. **Declares that, by adopting and maintaining in force Article 4 of the Law on Medicinal Products (Prawo farmaceutyczne) of 6 September 2001, as amended by the Law of 30 March 2007, inasmuch as that statutory provision 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 Poland, 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, the Republic of Poland has failed to fulfil its obligations under Article 6 of 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, as amended by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007;**

2. **Orders the Republic of Poland to pay the costs.**

[Signatures]