Reports of Cases

OPINION OF ADVOCATE GENERAL
JÄÄSKINEN
delivered on 29 September 2011 [1]

Case C-185/10

European Commission
v

Republic of Poland

(Failure of a Member State to fulfil obligations — Directive 2001/83/EC — Article 6 — Marketing authorisation — Article 5 — Exclusion from provisions of directive for medicinal products ordered for special needs of individual patient — National legislation allowing importation and placing on the market of equivalent medicinal products based on an economic criterion without prior marketing authorisation — Medicinal products from other Member States and from third countries)

1. Under the present infringement action the Court is obliged to consider for the first time the scope and meaning of Article 5(1) of Directive 2001/83/EC. [2] If the requirements of that provision are fulfilled, the marketing authorisation normally required under Article 6 of that directive can be dispensed with.

2. In Poland, Article 4(3a) of the *Prawo farmaceutyczne* of 6 September 2001 as modified on 30 March 2007 ('Medicinal Products Law') [3] allows, under certain circumstances, for the importation and placing on the national market of competitively priced medicinal products containing the same active substances, the same dosage and the same form (which I will refer to as 'equivalent medicinal products') as those authorised on the Polish market (which I will refer to as 'authorised medicinal products'), without the need to obtain Polish marketing authorisation for them. Such importation can take place from other Member States as well as from third countries.

3. The Commission considers that Article 5(1) of Directive 2001/83 does not allow exclusion from the marketing authorisation contained in Article 6(1) of that directive on the basis of economic criteria. It therefore asks the Court to declare that by adopting and maintaining in force the provisions of Article 4 of the Medicinal Products Law which allow for the importation and placing on the market without marketing authorisation of competitively priced equivalent medicinal products, it has failed to fulfil its obligations under Article 6 of Directive 2001/83. [4]

1 — Original language: English.

2 — 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 modified by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 ('Directive 2004/27') (OJ 2004 L 136, p. 34) and Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 ('Regulation No 1901/2006') (OJ 2006 L 378, p. 1).

3 — Published in the *Dziennik Ustaw* (Polish Journal of Laws) No 75 item 492 of 30 March 2007.

4 — The present infringement action concerns the adoption and maintaining in force of the Medicinal Products Law. In relation to the adoption of the law the relevant provisions relate to Directive 2001/83 as modified by Directive 2004/27. In relation to the maintaining in force of the Medicinal Products Law it relates to Directive 2001/83 as modified by Regulation No 1901/2006.

I – Legal framework

A – *EU law*

4. Article 168 TFEU, contained in Title XIV which is entitled 'Public Health', states in the relevant part:

'7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.'

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

'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.'

6. Article 5(1) of Directive 2001/83 states:

'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.'

7. Article 6(1) of Directive 2001/83 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, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use.'

8. Article 126a(1) of Directive 2001/83 states:

'In the absence of a marketing authorisation or of a pending application for a medicinal product authorised in another Member State in accordance with this Directive, a Member State may for justified public health reasons authorise the placing on the market of the said medicinal product.'

B – *National law*

9. Article 4 of the Medicinal Products Law states in the relevant parts:

'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.

7. The minister with responsibility for health-related matters shall define, by way of regulation:

(1) (repealed);

(2) details relating to the method and form of importation from outside Poland of medicinal products as referred to in paragraph 1, with particular regard to:

   (a) the nature of the requirement;

   (b) the manner in which that minister confirms the circumstances referred to in paragraph 3;

   (c) the manner in which the President of the National Health Fund confirms the circumstances referred to in Article 36(4) of the Law of 27 August 2004 on health-care benefits financed out of public funds (*Dziennik Ustaw* No 210, section 2135, as subsequently amended);

   (d) the manner in which the register of imported medicinal products is maintained by wholesalers, pharmacists and hospitals; and

   (e) the scope of the information provided by a pharmaceutical wholesaler to the minister with responsibility for health-related matters.'

II – Pre-litigation procedure

10. On 6 June 2008 the Commission sent Poland a letter of formal notice considering that Article 4 of the Polish Medicinal Products Law was contrary to Article 6 of Directive 2001/83 since it allowed the placing on the market of certain medicinal products without the granting of prior marketing authorisation.

11. By letter dated 30 July 2008, the Republic of Poland replied that Article 4 of the national law was in conformity with EU law.

12. Not satisfied with Poland's reply, the Commission sent a reasoned opinion on 26 June 2009, where it maintained its position concerning Poland's violation of Article 6 of Directive 2001/83.

13. By letter dated 26 August 2009 Poland affirmed that Article 5 of Directive 2001/83 justified Article 4 of the Medicinal Products Law, and that Article 8a of the Medicinal Products Law had correctly transposed Article 126a of that directive. It therefore said that the Commission's complaints were unfounded.

14. Not satisfied with Poland's responses, the Commission brought the present action under Article 258 TFEU on 14 April 2010.

III – Analysis

A – *The ambit of the case*

15. The present case centres on whether the economic criterion in Article 4(3a) of the Medicinal Products Law, read in conjunction with Article 4(3)(2) and Article 4(1) of that law, can be justified under Article 5(1) of Directive 2001/83. Article 4(3a) of the Medicinal Products Law makes an exception to the rule in Article 4(3)(2) of that law, which excludes the importation of an equivalent medicinal product from the rule contained in Article 4(1) if an authorised medicinal product with the same qualities already exists on the national market.

16. Poland criticises the Commission for focussing on those provisions without having regard to the wider context, namely the other provisions of Article 4 of the Medicinal Products Law as well as the regulation of the health minister of 18 April 2005 concerning imports from other countries of medicinal products which do not possess a marketing authorisation and which are indispensable for the survival or health of the patient ('Regulation of the Health Minister of 2005'). [5]

17. It is important to note that this case does not concern parallel imports of medicinal products from the other Member States. In the European Union parallel imports of medicinal products already having a marketing authorisation in the Member State of importation are allowed under the provisions relating to the free movement of goods. [6] The present case, in contrast, concerns the importation of medicinal products without a valid marketing authorisation in Poland.

5 — Published in Dz. U. z 2005 r., Nr 70, poz. 636, pozn. zm. This regulation was adopted on the basis of Article 4(7) of the Pharmaceutical Law.

6 — See, for example, Case C-201/94 *Smith & Nephew and Primecrown* [1996] ECR I-5819; Case C-94/98 *Rhône-Poulenc Rorer and May & Baker* [1999] ECR I-8789; Case C-172/00 *Ferring* [2002] ECR I-6891.

B – *The general rule contained in Article 6 of Directive 2001/83*

18. Article 6 of Directive 2001/83 requires that all medicinal products placed on the market of a Member State obtain marketing authorisation from the competent authorities of that Member State. As the Court held in *Antroposana*, this is a compulsory requirement which is necessary in order to fulfil the objectives of Directive 2001/83. [7]

19. The aim of Directive 2001/83 is to safeguard public health as well as to ensure that trade is not affected in the market for medicinal products. [8] In my view, the harmonised marketing authorisation procedure is a precondition for access to the market for medicinal products in the European Union, and is the cornerstone of that directive. It enables cost-efficient and non-discriminatory market access, while ensuring that the requirements of safeguarding public health are achieved through meticulous and uniform scrutiny of the pharmaceutical and medicinal properties of the product in question.

20. More precisely, the aim of the marketing authorisation requirement in Article 6(1) of Directive 2001/83 is to guarantee that the potential risks of products are outweighed by their therapeutic efficacy, which is assessed on the basis of particulars and documents accompanying an application for marketing authorisation. [9] Furthermore, it is a means of controlling effectively the placement of products onto the market so as to protect public health. [10] In addition, approximating the standards and protocols across all Member States allows decisions to be made on the basis of uniform tests and by reference to uniform criteria, which will help to avoid differences in evaluation and hence remove disparities that hinder trade in the EU. [11]

21. This is why all medicinal products sold in the EU must obtain a marketing authorisation either by the Member State on whose market they are put, or by the EU according to the centralised procedure contained in Regulation No 726/2004/EC for those medicinal products contained in the annex of that regulation. [12]

22. Directive 2001/83 provides for the mutual recognition of marketing authorisations granted in other Member States thereby ensuring that marketing authorisation can be applied for in several Member States without subjecting the medicinal product to multiple authorisation procedures. [13]

23. There are two exceptions to this general rule. A Member State may derogate from Article 6 provided that the special needs requirement is fulfilled (Article 5 of Directive 2001/83), or if it is necessary for public health reasons (Article 126a of Directive 2001/83). As exceptions, these provisions must be interpreted strictly.

24. In the present case the parties have come to agree that Article 126a of Directive 2001/83 is not relevant, because the contents of that provision were transposed in Article 8a of the Medicinal Products Law, and not in Article 4 of that law. The only question that arises, therefore, is whether Article 4(3a) of the Medicinal Products Law, which allows the placing on the market of medicinal products which have not been granted a marketing authorisation if their price is competitive in comparison to the price of the medicinal products with a marketing authorisation in Poland, is justified by Article 5(1) of Directive 2001/83.

7 — Case C-84/06 *Antroposana and Others* [2007] ECR I-7609, paragraph 36.

8 — Recitals 2 to 4.

9 — Recital 7.

10 — Recital 8.

11 — Recitals 4, 5 and 11.

12 — 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).

13 — Title III, Chapter 4 of Directive 2001/83 and recital 12.

C – *The exception contained in Article 5(1) of Directive 2001/83*

25. The Court has previously considered Article 5(1) of Directive 2001/83 in *Ludwigs-Apoteke*.[14] However, it did not give detailed consideration to that provision since it was required to interpret the advertising provisions contained in Article 86(2) of Directive 2001/83. It therefore simply stated that the German legislation in that case was implementing Article 5(1) of Directive 2001/83 in so far as it made possible the placing on the market of a limited quantity of non-approved medicinal products in the context of an individual order justified by special needs.[15]

26. It is thus necessary to analyse the wording and purpose of Article 5(1) of Directive 2001/83 in greater detail in order to ascertain whether the specific provision of Article 4(3a) of the Medicinal Products Law that the Commission takes issue with conforms to its requirements.

27. In my opinion, taking into account the general aim of Directive 2001/83 as set out in paragraphs 19 and 20 above, the purpose of Article 5(1) of Directive 2001/83 is to provide a mechanism allowing for flexibility to the general system provided for in that directive, and particularly in its Article 6. That flexibility allows Member States to cope efficiently with individual circumstances or certain emergency situations, where time is of the essence.

28. The wording of Article 5(1) of Directive 2001/83 states that in response to a bona fide unsolicited order formulated in accordance with the specification of an authorised health-care professional, the requirements of that directive may be excluded if the medicinal products are required to fulfil special needs, and are for the use of an individual patient.

29. It should first be observed that the text of Article 5(1) of Directive 2001/83 is somewhat cryptic as far as the requirement that the medicinal products referred to in that provision have to be 'formulated in accordance with the specifications of an authorised health-care professional'. It seems clear that, as Poland observed, this condition does not refer to medicinal products prepared in pharmacies on the basis of an individual prescription as Directive 2001/83 only applies to medicinal products either prepared industrially or manufactured by a method involving an industrial process. Indeed, any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula) or in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula) is excluded from the scope of Directive 2001/83.[16]

30. The 'unsolicited order' requirement refers, in my opinion, to a situation where the doctor treating the patient makes the order as a result of an objective assessment of the patient concerned, and on the basis of purely therapeutic considerations. This requirement ensures that public health is preserved when applying the Article 5(1) of Directive 2001/83 exception. This is reinforced by the requirement of good faith of the person making the order as well as the patient, so that the application of Directive 2001/83 is not unduly circumvented.

31. The general aims of Directive 2001/83 explain why products placed on the market in accordance with Article 5(1) of Directive 2001/83 must be limited to truly exceptional situations.[17] That provision ensures this by explicitly limiting its application to orders for individual patients, made 'to fulfil special needs'.

14 — C-143/06 [2007] ECR I-9623, paragraphs 21 to 23.

15 — *Ludwigs-Apotheke*, ibid., paragraph 22.

16 — See Article 2(1) and Article 3, subparagraphs 1 and 2, of Directive 2001/83.

17 — See also *Ludwigs-Apotheke*, cited in footnote 14, paragraph 33.

32. The reference to 'special needs' entails that the medicinal product in question is required for a specific and identified need. The '*need*' should be related to a particular identified individual. '*Special*' refers to situations arising from circumstances that are out of the ordinary. For example, a patient might suffer from a rare disease requiring treatment with medicinal products not authorised on the national market.

33. Does Article 5(1) of Directive 2001/83 require the special need to be health-related as the Commission submits? In my view an affirmative answer follows from the aim of public health protection, which the directive aims to preserve.

34. In addition to being related to specific needs of a patient, the medicinal products that can be excluded from the provisions of Directive 2001/83 pursuant to Article 5(1) must fulfil the requirement of necessity which is, in my view, implicitly included in that provision. In view of the purpose of Article 5(1) of Directive 2001/83 of providing certain flexibility for the Member States in the application of the directive in strictly defined individual cases, as well as the limitations set out in the wording of that provision, I do not think that the provision intends to allow Member States a discretionary power to disapply the provisions of the directive in cases where it is not necessary. 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. Therefore the option to exclude the application of the provisions of Directive 2001/83 can only be applied if that is necessary with regard of the specific needs of the patient.

35. It follows from the criterion of necessity that equivalent medicinal products without marketing authorisation may be put on the market (i) only in appropriate quantities and, (ii) if there is no authorised product already available on the market.

D – *The compatibility of Article 4(3a) of the Medicinal Products Law with Article 5(1) of Directive 2001/83*

36. The *first* question that arises is whether Article 4(1) of the Medicinal Products Law fulfils the special needs requirements. The Commission seems to admit that it does.

37. Article 4(1) of the Medicinal Products Law expressly states that the medicinal product may be placed on the market if it is necessary to safeguard the life or health of a patient. This indicates that it will only be placed on the market in special cases of necessity.

38. In relation to the requirement that orders relate to a particular individual, Poland submits that the law is concerned with individual orders because of certain requirements that have to be complied with under the Regulation of the Health Minister of 2005. Those provisions state that the request for importation must include the full name, age, address, PESEL number (the Polish residence identification number), as well as national social security details. In exceptional cases, when the personal details of the patient are not known, a request can be made 'for immediate needs', but that information about the patient must be provided to the health minister at a later stage and up to a maximum of 30 days following the treatment.

39. The substance of those provisions not having been challenged by the Commission, it seems to me that such a provision is sufficient to demonstrate that the legislation in question concerns specific individuals and is not of a general nature.

40. Therefore, Article 4(1) of the Medicinal Products Law appears to fulfil the special needs requirement. The next question then arises as to whether the reference in Article 4(3a) of the Medicinal Products Law to Article 4(1) of that law is sufficient to fulfil the 'special needs' requirement.

41. In my opinion it is. Poland correctly states that Article 4(3a) of the Medicinal Products Law takes the criteria in Article 4(1) of that law, and adds the additional criterion of price to the formula.

42. It is true, as the Commission points out, that Article 4(3a) excludes importation of equivalent medicines that correspond to a special need of the patient but have a higher price, that is, a price that is not 'competitive'. However, this does not mean that the special needs criterion is not fulfilled since Article 5(1) of Directive 2001/83 merely permits and does not *oblige* the Member States to derogate from the other provisions of that directive. Therefore, it is not against Directive 2001/83 if the national provision does not exhaust all the leeway allowed by Article 5(1), which is the case pursuant to Article 4(3a) of the Medicinal Products Law concerning importation of equivalent medicinal products that are more expensive than the corresponding authorised medicinal products.

43. *Second*, in relation to appropriate quantities, only such quantities as are required to fulfil the needs of the individual patient may be put on the market. The Commission argues that the national legislation allows for the mass importation and placing on the market of the medicinal products in question since they are imported through pharmacies, wholesalers and hospitals. Poland replies that that is the only way, practically speaking, that the medicinal products required under Article 4(1) of the Medicinal Products Law can be imported in a controlled way. This does not mean that the medicinal products are subject to mass importations.

44. According to Article 4(5) of the Medicinal Products Law, the pharmacies, wholesalers and hospitals that put the relevant medicinal products on the market should keep a register of all medicinal products imported pursuant to Article 4(1) of that law, and inform the competent health minister of the imported medicinal products 10 days after each trimester at the latest under Article 4(6) of that law.

45. At first glance this appears a reasonable way to ensure that the medicinal products are imported and placed on the market in the right quantities, since there is a control by the competent health minister of all medicinal products that are imported and placed on the market for the needs identified in Article 4(1) of the Medicinal Products Law. Furthermore, this control is coupled with the fact that the health minister is informed of the individuals for whom the medicinal products are being imported and placed on the market pursuant to the requirements set out in the Regulation of the Health Minister of 2005.

46. Therefore, the criterion of appropriate quantities seems to be fulfilled in the present case in respect of Article 4(3a) of the Medicinal Products Law.

47. However, the parties disagree on two aspects in relation to quantities. The first disagreement concerns the actual amount of medicinal products imported and placed on the market pursuant to Article 4 of the Medicinal Products Law and the second one whether the national legislation should set a fixed level of imports in order to avoid mass importation.

48. These issues depend on the interpretation of Article 4(4) of the Medicinal Products Law. That provision states that medicinal products covered by Article 4(1) of the Medicinal Products Law which raise concerns due to the safety of their use or the quantities of importation, cannot be placed on the market without an authorisation.

49. Article 4(4) of the Medicinal Products Law is not within the scope of the present infringement action. The issue of whether the setting of importation quantities is adequate under the Polish legislation should therefore not distract the Court. Moreover, the infringement action does not concern the issue of quantities in which medicinal products without a marketing authorisation are actually imported.

50. The real question is whether Article 4(3a) of the Medicinal Products Law permits the importation of unreasonable quantities of medicinal products. The answer to that question must, in my view, be in the negative because of the express reference to Article 4(1) of that law.

51. *Thirdly*, in relation to the availability on the national market of equivalent medicinal products, Article 4(3a) of the Medicinal Products Law, in derogation from Article 4(3)(2) of that law, allows for the importation and placing on the market of medicinal products corresponding to equivalent medicinal products which have already received marketing authorisation on the national market, as long as they are competitively priced.

52. The Commission submits that under the terms of Article 5(1) of Directive 2001/83, only medicinal products not already available on the national market can be imported and placed on the market. The Commission seems to refer to unavailability in the literal sense of physical unavailability. Therefore, it uses examples of temporary shortages of medicinal products on the national market, and of the unavailability of a particular dosage which is required to treat the individual patient in the particular case in question.

53. To my mind that interpretation of Article 5(1) of Directive 2001/83 seems correct. If the medicinal product is already physically available on the market then there is no need to import it from elsewhere in order to treat an individual patient. In other words, importation is not necessary to fulfil a special need as required by Article 5(1) of Directive 2001/83.

54. It is true that the unavailability criterion stemming from the necessity to fulfil a special need does not refer to whether the medicinal product in question has obtained a marketing authorisation on the national market. Hence, in my opinion, a Member State may provide that a medicinal product equivalent to one that has already received a marketing authorisation on the national market may be imported if that latter product is for some reason physically not available on the national market, which should be an exceptional situation.

55. However, the Polish legislation does not follow this logic. Article 4(3)(2) of the Medicinal Products Law excludes, in principle, the importation of equivalent medicinal products without a marketing authorisation if there is already a corresponding authorised medicinal product in Poland. Article 4(3a) makes an exception to this rule, not on the basis of actual unavailability of the authorised medicinal product but on the basis of the cheaper price of the equivalent product. Article 4(3a) of the Medicinal Products Law is worded widely, meaning that it would allow both the importation of medicinal products without a marketing authorisation that are physically available on the national market and those which are not. As such, it seems to me that that provision is contrary to the unavailability requirement stemming from Article 5(1) of Directive 2001/83.

56. *Fourthly*, the final argument to consider is the one advanced by Poland in relation to financial considerations. In that respect Poland maintains that there are situations where it is necessary, in order to save the patient's life or health, to import and place on the market a cheaper equivalent alternative to the medicinal product with a marketing authorisation on the Polish market because of limited financial means available. In such a situation the importation and placing on the market of the cheaper medicinal product would be required by the special needs of the patient, in accordance with Article 5(1) of Directive 2001/83.

57. It is true that, as Poland submits, the Union is to respect the responsibilities of the Member States for the definition of their health policy and the organisation and delivery of health services and medical care.[18] These responsibilities include the management of health services and medical care, as well as the allocation of resources assigned to them. Furthermore, according to the Court's case-law, Member States are also allowed to regulate the consumption of medical products by adopting provisions in order to promote the financial stability of their health-care insurance schemes.[19]

18 — Article 168 TFEU.

19 — Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *Menarini* [2009] ECR I-2495, paragraph 19 and cases cited there.

58. However, Article 5(1) of Directive 2001/83 is not a provision concerned with the organisation of the health care system or its financial equilibrium. It is a specific derogatory provision applicable to individual cases where specific needs arise. It cannot therefore, in my opinion, be interpreted in a way which allows the importation and placing on the market of cheaper equivalent medicinal products because patients (or, the health insurance system) cannot afford the available authorised medicinal products.

59. To allow cheaper medicinal products to be imported under Article 5(1) only for that reason would stretch that provision further than it was intended to apply. Instead, Member States should address the problem of unaffordable prices of medicinal products which have been granted marketing authorisations by using their competences pursuant to Article 4(3) of Directive 2001/83. That provision states that nothing in Directive 2001/83 shall affect the powers of the Member States' authorities 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. Such powers may be exercised pursuant to Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems. [20]

60. Therefore, in my view, Article 4(3a) of the Medicinal Products Law cannot be justified with reference to Article 5(1) of Directive 2001/83.

IV – Conclusion

61. In light of the above I consider that the Court should:

— declare that Poland has failed to fulfil its obligations under Article 6 of Directive 2001/83/EC on the Community code relating to medicinal products for human use, as modified by Directive 2004/27/EC and Regulation (EC) No 1901/2006, by adopting and maintaining in force Article 4(3a) of the Medicinal Products Law which, read in conjunction with Article 4(3)(2) and Article 4(1) thereof, allows the placing on the market of medicinal products without a marketing authorisation if the price of these products is competitive in comparison with the price of the medicinal products which have a marketing authorisation with the same active substance or substances, the same dosage and the same form;

— order Poland to pay the costs.

20 — OJ 1989 L 40, p. 8.