Reports of Cases

OPINION OF ADVOCATE GENERAL
SZPUNAR
delivered on 20 May 2021 [1]

Case C-178/20

Pharma Expressz Szolgáltató és Kereskedelmi Kft
v
Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet

(Request for a preliminary ruling
from the Fővárosi Törvényszék (formerly the Fővárosi Közigazgatási és Munkaügyi Bíróság)
(Budapest High Court, formerly Budapest Administrative and Labour Court, Hungary))

(Reference for a preliminary ruling – Free movement of goods – Medicinal products for human use – Medicinal products not authorised in one Member State but authorised in another – National legislation making the sale, in pharmacies, of such medicinal products imported from other Member States subject to formalities)

I. Introduction

1. The system of EU rules governing the medicinal products for human use sector comprises a number of legislative texts, [2] including Directive 2001/83/EC, [3] which consolidates in a single text several previous directives, [4] and Regulation (EC) No 726/2004. [5] That system is based on the principle that no medicinal product may be placed on the market unless a marketing authorisation has been issued by the competent authorities. [6]

2. That system provides for several routes for authorisation of medicinal products. Marketing authorisations may be issued by the European Union via a centralised procedure, in accordance with the provisions of Regulation No 726/2004, or by the competent national authorities of a Member State, via a procedure under Directive 2001/83 ('national marketing authorisation'). As a rule, national marketing authorisations are valid only for the Member State concerned.

1 Original language: French.

2 For a more detailed description of EU pharmaceutical law, see Martens, M., Carbonelle, N., 'The EU Regulatory Framework for Medicinal Products for Human Use', in Figueroa, P., Guerrero, A. (eds), *EU Law of Competition and Trade in the Pharmaceutical Sector*, Edward Elgar Publishing, Cheltenham – Northampton, 2019, p. 519 et seq.

3 Directive 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 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 (OJ 2011 L 174, p. 74) ('Directive 2001/83').

4 See recital 1 of Directive 2001/83.

5 Regulation 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).

6 See Article 6(1) of Directive 2001/83.

3. Moreover, according to Directive 92/26/EEC,[7] when a marketing authorisation is granted, medicinal products are to be classified either as medicinal products subject to medical prescription or medicinal products not subject to medical prescription, in accordance with the criteria laid down in that directive. The provisions of that directive were also codified in Directive 2001/83.

4. It is in the context of that legislative framework that the referring court seeks to ascertain, in the first place, whether a medicinal product which has a national marketing authorisation in one Member State and has been classified, in that Member State, as a medicinal product not subject to medical prescription, may legally be supplied in another Member State in which that medicinal product does not have a national marketing authorisation and has not been classified. In the second place, it asks whether the conditions laid down in Hungarian law as regards dispensing such medicinal products are justified in the light of Article 36 TFEU, in so far as they constitute a quantitative restriction on imports.

II. Legal framework

A. European Union law

5. Article 5(1) of Directive 2001/83 is worded as follows:

'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.'

6. Under Article 6(1), first subparagraph, of that directive:

'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 No 726/2004], read in conjunction with [Regulation (EC) No 1901/2006] [8] and Regulation (EC) No 1394/2007. [9]'

7. Article 70 of that directive provides:

'1. When a marketing authorisation is granted, the competent authorities shall specify the classification of the medicinal product into:

– a medicinal product subject to medical prescription,

– a medicinal product not subject to medical prescription.

[7] Council Directive of 31 March 1992 concerning the classification for the supply of medicinal products for human use (OJ 1992 L 113, p. 5).

[8] Regulation of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation No 726/2004 (OJ 2006 L 378, p. 1).

[9] Regulation of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83 and Regulation No 726/2004 (OJ 2007 L 324, p. 121).

To this end, the criteria laid down in Article 71(1) shall apply.

2. The competent authorities may fix sub-categories for medicinal products which are available on medical prescription only. …'

8. Article 71(1) of the same directive provides:

'Medicinal products shall be subject to medical prescription where they:

– are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision, or

– are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or

– contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation, or

– are normally prescribed by a doctor to be administered parenterally.'

9. Under Article 72 of Directive 2001/83:

'Medicinal products not subject to prescription shall be those which do not meet the criteria listed in Article 71.'

10. Article 73 of that directive is worded as follows:

'The competent authorities shall draw up a list of the medicinal products subject, on their territory, to medical prescription, specifying, if necessary, the category of classification. They shall update this list annually.'

B. Hungarian law

11. Article 25(2) of the az emberi alkalmazásra kerülő gyógyszerekről és egyéb, a gyógyszerpiacot szabályozó törvények módosításáról szóló 2005. évi XCV. törvény (Law No XCV of 2005 on medicinal products for human use and amending other laws governing the market in medicinal products) ('the Law on medicinal products') provides:

'Medicinal products that do not have a marketing authorisation in a State which is a party to the Agreement [on the European Economic Area[10] ("the EEA Agreement")] but do have a marketing authorisation in another country may be used for medical purposes in special cases where their use is justified in the pursuit of an interest relating to patient care to which particular regard must be had and where the State pharmaceutical administrative body has authorised their use in accordance with the specific conditions laid down in a special provision. Medicinal products that have a marketing authorisation in a State which is a party to the EEA Agreement may be used for medical purposes if they have been notified to the State pharmaceutical administrative body in accordance with a special provision. The assessment of an interest relating to patient care to which particular regard must be had shall be carried out, where necessary, in the light of the

[10] OJ 1994 L 1, p. 3.

professional association's opinion concerning the safety and effectiveness of the therapeutic procedure.'

12. Paragraph 3(5) of the emberi felhasználásra kerülő gyógyszerek rendeléséről és kiadásáról szóló 44/2004 (IV. 28.) (Decree No 44 of the Ministry of Health and Social and Family Affairs of 28 April 2004 on prescribing and dispensing medicinal products for human use) ('Ministerial Decree No 44'),[11] which was applicable until 13 February 2018, provided:

'In accordance with Paragraph 25(2) of the Law on medicinal products, medical practitioners may prescribe medicinal products which are not authorised to be placed on the market in Hungary but which are authorised to be placed on the market in another Member State of the [European Economic Area (EEA)], or in a State which has the same legal status as that held by Member States of the EEA pursuant to an international treaty concluded with the European Community or the EEA …, only if, before prescribing those medicinal products, they lodge a notification with the [Institute] and they obtain a declaration from that Institute …'

13. Under Paragraph 12/A of that decree:

'In the context of the direct supply of medicinal products to the public, pharmacists may supply medicinal products prescribed in accordance with Paragraph 3(5) and Paragraph 4(1) only after lodging a copy of the declaration or the authorisation issued by the Institute.'

14. Parasgraph 5 of the emberi felhasználásra kerülő gyógyszerek egyedi rendelésének és felhasználásának engedélyezéséről szóló 448/2017. (XII. 27.) (Government Decree No 448 of 27 December 2017 on authorisation of the prescription and individual use of medicinal products for human use), applicable with effect from 1 January 2018,[12] is worded as follows:

'1. In accordance with Paragraph 25(2) of the Law on medicinal products, medical practitioners may prescribe medicinal products which are not authorised to be placed on the market in Hungary but which are authorised to be placed on the market in a [State party to the EEA Agreement], only if, before prescribing those medicinal products, they lodge a notification with the Institute and they obtain a declaration from that Institute concerning the following matters:

(a) whether the medicinal product which the medical practitioner wishes to prescribe has a marketing authorisation in a Member State of the EEA or in a State party to the EEA Agreement identified by the medical practitioner, in relation to the indications given by that practitioner,

(b) whether the competent authority has withdrawn the marketing authorisation for the medicinal product which the medical practitioner wishes to prescribe or suspended its distribution, and

[11] I would emphasise that, in its written observations, the Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (National Institute of Pharmacy and Nutrition, Hungary; 'the Institute') notes that, in its request for a preliminary ruling, the referring court only partially reproduces Article 3(5) of Ministerial Decree No 44, which contains provisions that correspond, in essence, to those of Article 5 of Government Decree No 448 (see point 14 of this Opinion). Like the provisions of the government decree, those of the ministerial decree also set out, individually, the matters concerning the content of the declaration. The legal framework set out in the written observations of the Hungarian Government supports that finding.

[12] It is not clear from the request for a preliminary ruling which provisions were applicable in respect of the period between 1 January 2018 (the date from which that decree was applicable) and 13 February 2018 (the date on which Ministerial Decree No 44 was applicable).

(c) whether, in the medical practitioner's opinion and based on information provided by the medical practitioner, there is an interest relating to patient care to which particular regard must be had, as defined in Article 1(23) of the Law on medicinal products.

2. Medical practitioners shall request that the declaration referred to in subparagraph 1 be issued on the data sheet included in Annexes 3 to 5 of Ministerial Decree No 44. The Institute shall notify the medical practitioner who is prescribing the medicinal product of its opinion on the matters set out in subparagraph 1 within eight working days of receipt of the data sheet.

3. Where the Institute issues a declaration according to which the conditions set out in subparagraph 1 are satisfied, the medical practitioner shall give the patient – in the case of a prescription-only medicine – a copy of the declaration from that Institute together with the prescription.

4. Where the Institute issues a declaration according to which, in its opinion, there is no interest relating to patient care to which particular regard must be had, as defined in Paragraph 1(23) of the Law on medicinal products, the medical practitioner shall give the patient – if the practitioner maintains that it remains necessary to prescribe the medicinal product and it is a prescription-only medicine – a copy of the declaration from that Institute together with the prescription and shall provide the patient with information concerning the contents of the declaration and its possible consequences.'

III. Facts in the main proceedings

15. As the competent authority for overseeing the marketing of medicinal products, the Institute found that the undertaking Pharma Expressz Szolgáltató és Kereskedelmi Kft. ('Pharma Expressz') had, on a number of occasions, imported from another EEA Member State a medicinal product which did not have a marketing authorisation in Hungary, but was authorised in that other EEA Member State as a medicinal product not subject to medical prescription. In that context, at the request of its customers and acting in its own name, Pharma Expressz obtained and stocked the medicinal product from that other Member State and then sold and supplied it directly to its customers.

16. By decision of 7 March 2019, the Institute ordered Pharma Expressz to refrain from such conduct on the ground that it constituted an infringement of Article 12/A of Ministerial Decree No 44, since Pharma Expressz was supplying medicinal products which were obtained in another Member State and did not have a national marketing authorisation 'without requesting a declaration from the pharmaceutical authority'.

17. Pharma Expressz brought an action against that decision before the Fővárosi Törvényszék (formerly the Fővárosi Közigazgatási és Munkaügyi Bíróság) (Budapest High Court, formerly Budapest Administrative and Labour Court, Hungary), seeking, inter alia, a finding that it had not committed any infringement in connection with the individual acquisition of medicinal products.

18. Pharma Expressz claimed that the Institute's interpretation of Hungarian law constituted a quantitative restriction on imports contrary to Article 34 TFEU. According to Pharma Expressz, that restriction cannot be justified by the objective of protecting the health and life of humans laid down in Article 36 TFEU. The declaration from the Institute, which is necessary for the

import of medicinal products, does not serve to protect the health of humans, and experience shows that obtaining that declaration can take several weeks or even months, which could jeopardise the patient's health rather than protect it.

19. Moreover, Pharma Expressz asserted that the requirement to obtain such a declaration is a disproportionate one since, inter alia, the Member State which authorised the medicinal product in question had classified it as a medicinal product not subject to medical prescription, in accordance with criteria which are compatible with the harmonised provisions and principles of the European Union. It claims that, in some Member States, individuals may purchase in pharmacies medicinal products which are on the market in another Member State without a prescription, because those Member States accept the classification of medicinal products carried out by that other Member State.

20. The Institute acknowledged, first of all, that the Hungarian legislation imposes a quantitative restriction, but that restriction is justified under Article 36 TFEU. It is for the Member States to determine the level of protection which they wish to afford to public health as regards the supply of medicinal products.

21. Secondly, as regards the proportionality of the restriction at issue, the Institute stated that it is necessary to take into consideration the fact that the protection of the health and life of humans is a priority objective of the TFEU. The national legislation does not preclude the import of medicinal products. The Institute ensures that the population has access to safe medicines by gathering information from equivalent authorities of the Member States concerning the use of foreign medicinal products for medical purposes, concerning whether a marketing authorisation exists and concerning whether such medicinal products can be used in relation to the indications given by the medical practitioner. The medical practitioner may issue a prescription to the patient if a declaration has been obtained, and this ensures that, if the opinion is negative, the medicinal product in question cannot be ordered, which therefore guarantees the protection of patients' health.

22. Lastly, the Institute stated that the classification of medicinal products into two categories (as subject to or not subject to medical prescription) takes place in the context of the marketing authorisation procedure. Where a medicinal product does not have a marketing authorisation in Hungary, it is not possible to determine whether it can be supplied with or without a medical prescription. Therefore, the Institute did not examine which category the medicinal products at issue were classified under in the Member State of origin.

23. In the light of the Court's case-law, the referring court considers that the Hungarian legislation at issue in the main proceedings constitutes a measure restricting the free movement of goods, and that it is therefore necessary to interpret Article 36 TFEU in order to determine whether that measure can be justified by the protection of the health and life of humans.

24. It notes that that measure introduces two additional requirements to those laid down in respect of medicinal products which have a national marketing authorisation and which can be supplied without medical prescription, namely a declaration from the Institute and a medical prescription.

25. It questions whether or not, in the case of a medicinal product which has been classified in another Member State as a medicinal product not subject to medical prescription, the fact that use of that product is allowed only in the context of medical treatment is justified.

26. The referring court states that the declaration from the Institute contains, first, information that is important from the perspective of public health and the patient, which is obtained from the equivalent authorities of other Member States, and may not be consulted directly, in the absence of such a declaration, by the patient, the medical practitioner or the pharmacy, and secondly an opinion as to whether the medicinal product in question pursues an interest relating to patient care, which requires professional medical expertise.

27. It states that the national legislation in force since January 2018 lays down specific provisions governing the procedure to be followed on the basis of the content of that declaration.

28. It considers that the declaration contains relevant information from the point of view of the safety of medicinal products which must be brought to the attention of the patient before the medicinal product in question is ordered.

29. Lastly, it notes that, for health protection purposes, it is important to know how long it takes to obtain the declaration from the Institute, but that it does not have any information in that regard, since the legislation provides for a time limit of eight days for the Institute to issue its declaration, while Pharma Expressz refers to a case in which the declaration took approximately three months.

IV. The procedure before the Court and the questions referred for a preliminary ruling

30. In those circumstances, by decision of 10 March 2020, received at the Court on 7 April 2020, the Fővárosi Törvényszék (formerly the Fővárosi Közigazgatási és Munkaügyi Bíróság) (Budapest High Court, formerly Budapest Administrative and Labour Court) suspended the proceedings and referred the following questions to the Court:

‘(1) Does an obligation flow from Articles 70 to 73 of Directive 2001/83 to regard a medicinal product which can be dispensed without medical prescription in one Member State as a medicinal product which can also be dispensed without medical prescription in another Member State, including where, in that other Member State, the medicinal product in question does not have a marketing authorisation and has not been classified?

(2) Is a quantitative restriction which makes the possibility of ordering and dispensing to a patient a medicinal product which does not have a marketing authorisation in one Member State but does have such an authorisation in another [Member State of the EEA] conditional on the existence of a medical prescription and a declaration from the pharmaceutical authority, including where the medicinal product is registered in the other Member State as a medicinal product not subject to medical prescription, justified in the interests of protection of the health and life of humans, as referred to in Article 36 TFEU?’

31. Written observations were lodged by the parties to the main proceedings, the Hungarian, Czech, Greek and Polish Governments and the European Commission. The parties to the main proceedings, the Hungarian and Greek Governments and the Commission were represented at the hearing held on 25 February 2021.

V. Analysis

A. Preliminary remarks on the questions referred for a preliminary ruling

32. Before proceeding to examine the questions referred for a preliminary ruling, it is necessary to note the difference in terminology in the formulation of those questions. While the first question mentions a medicinal product which can be supplied without medical prescription in *another Member State*, the second question concerns a medicinal product which has a marketing authorisation in *another Member State of the EEA*.

33. It seems clear, however, that those two questions refer to circumstances which arise in the same context. The decision of 7 March 2019 refers to the conduct of Pharma Expressz with regard to the medicinal product at issue in the main proceedings. [13]

34. The request for a preliminary ruling does not specify where Pharma Expressz obtained the medicinal product concerned. The referring court mentions only Austria and Germany when setting out the arguments of Pharma Expressz according to which, in those two Member States, individuals can order directly, in pharmacies, medicinal products which are on the market in another Member State without prescription.

35. The Institute stated in its written observations and at the hearing that Pharma Expressz imported medicinal products from Austria and Germany. Based on the formulation of the second question, which refers to one EEA Member State, it is not possible to rule out that the medicinal products come from the Member States mentioned by the Institute. At the hearing, in response to a question from the Court, the parties stated that the formulation of that question had been influenced by the wording of the provisions of Hungarian law, since those provisions refer to medicinal products which have a marketing authorisation in a State party to the EEA Agreement.

36. Moreover, the second question, as formulated by the referring court, concerns only the interpretation of Article 36 TFEU. In that context, I would observe that the articles of the EEA Agreement relating to the free movement of goods, namely Articles 11 and 13, are worded in terms almost identical to those used in Articles 34 and 36 TFEU and, as is clear from the settled case-law of the Court, that those provisions must be interpreted uniformly. [14] Following that reasoning, in the judgment in *Ludwigs-Apotheke*, [15] the Court therefore held that, in order to give a useful answer to the national court, it was necessary to examine together whether a prohibition on advertising medicinal products which were not approved in Germany, but could nevertheless be imported in response to individual orders from other Member States or States parties to the EEA Agreement, is compatible with EU law, in the light of Articles 28 EC and 30 EC and

[13] Based on a reading of the request for a preliminary ruling, it cannot be ruled out that Pharma Expressz may have adopted the same course of conduct as regards a number of medicinal products from one or more Member States. According to the decision of 7 March 2019, the unlawful conduct of Pharma Expressz consists of supplying *medicinal products* obtained in another Member State. However, even in that case, the two questions concern the same conduct arising in similar circumstances. That fact does not, therefore, affect the reasoning followed in answering the two questions referred for a preliminary ruling.

[14] See judgment of 11 September 2014, *Essent Belgium* (C-204/12 to C-208/12, EU:C:2014:2192, paragraph 72). See, for the sake of completeness, although a Member State party to the EEA Agreement is mentioned only in the context of the second question, as regards the applicability of Directive 2001/83 to such Member States, *The rules governing medicinal products in the European Union. Volume 2A – Procedures for marketing authorisation. Chapter 1 – Marketing authorisation*, July 2019, https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/vol2a_chap1_en.pdf, pp. 4 and 5.

[15] Judgment of 8 November 2007 (C-143/06, EU:C:2007:656; 'the judgment in *Ludwigs-Apotheke*'; paragraph 24).

Articles 11 and 13 of the EEA Agreement. The dispute in the case which gave rise to that judgment concerned the advertising of medicinal products from either a Member State of the European Union or a non-Member State which is a signatory to the EEA Agreement. [16]

37. As regards the present request for a preliminary ruling, in the absence of any clear information to support the assumption that the medicinal products concerned come from a non-EU Member State party to the EEA Agreement, and taking into account the fact that, in its second question, the national court refers only to Articles 34 and 36 TFEU, I shall start from the premiss that Pharma Expressz obtained medicinal products in a Member State of the European Union.

B. The first question referred for a preliminary ruling

1. Reformulation of the first question referred for a preliminary ruling

38. By its first question, as formulated in the request for a preliminary ruling, the referring court seeks to ascertain whether Articles 70 to 73 of Directive 2001/83 must be interpreted as meaning that it is necessary to regard a medicinal product which can be supplied without medical prescription in one Member State as a medicinal product which can also be supplied without medical prescription in another Member State, even where the medicinal product in question does not have a marketing authorisation and has not been classified in that second Member State.

39. As is clear from the grounds of the request for a preliminary ruling, based on the premiss that Articles 70 to 73 of Directive 2001/83 lay down uniform principles for the classification of medicinal products, the referring court is uncertain whether a Member State is under an obligation to accept 'unconditionally' the classification carried out by another Member State of medicinal products placed on the market in that other Member State.

40. The formulation of the first question concerns only the classification of a medicinal product in a Member State in which it has a marketing authorisation as a medicinal product which can be supplied without medical prescription. The conduct of Pharma Expressz involved such a medicinal product.

41. However, at least as regards the issue underlying that question, the national court expressly refers both to medicinal products subject to medical prescription and to medicinal products not subject to medical prescription and, without making a distinction between the two, [17] asks whether the classification of a medicinal product carried out in one Member State is binding for all other Member States.

[16] Judgment in *Ludwigs-Apotheke*, paragraph 12.

[17] The distinction between these two categories of medicinal products may be relevant in certain contexts. In the first place, where the application of certain provisions of Directive 2001/83 is concerned. See, to that effect, judgment of 11 June 2020, *ratiopharm* (C-786/18, EU:C:2020:459, paragraph 41). However, those provisions are not referred to in the questions referred for a preliminary ruling. In the second place, in the context of the second question, by which the referring court raises the question whether the conditions for ordering and dispensing medicinal products laid down in Hungarian law are justified. See, by analogy, judgment of 11 December 2003, *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 111 et seq.). Lastly, in the third place, in view of the nature of the other national measures the justification for which is being assessed. See, to that effect, my Opinion in *Deutsche Parkinson Vereinigung* (C-148/15, EU:C:2016:394, points 43, 53, 56 and 79).

42. That being so, I consider that it will not be possible to provide a useful answer to the referring court merely by interpreting Articles 70 to 73 of Directive 2001/83 in isolation. That court is required to settle a dispute in which one of the parties has brought an action against a decision by which the Institute held that that party had infringed national provisions by supplying medicinal products which were obtained in another Member State and did not have a marketing authorisation, and 'without requesting a declaration from the pharmaceutical authority'.

43. For the reasons which I shall set out below, those provisions must therefore be read and interpreted in combination with Article 5(1) and Article 6(1) of that directive in order to provide a useful answer.

44. I propose therefore that the Court reformulate the first question so that the referring court asks whether Article 5(1), Article 6(1) and Articles 70 to 73 of Directive 2001/83 should be interpreted as meaning that it is necessary to regard a medicinal product which can be supplied without medical prescription in one Member State as a medicinal product which can also be supplied without medical prescription in another Member State in which that medicinal product does not have a marketing authorisation and has not been classified.

2. The relationship between classification and authorisation

45. Articles 70 to 73 appear in Title VI of Directive 2001/83, the title of which – 'Classification of medicinal products' – perfectly reflects the subject matter of those articles. In the system established by that directive, medicinal products are to be classified in the context of a marketing authorisation procedure. As is clear from Article 70(1) of that directive, the competent authorities are to specify the classification of a medicinal product 'when a marketing authorisation is granted'.

46. In that regard, Title III of Directive 2001/83, as is clear from its heading, concerns the placing on the market of medicinal products. Under Article 6(1) of that directive, which appears under that title, and as is apparent from the consistent interpretation of that provision, no medicinal product may be placed on the market for the first time in a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with that directive, or an authorisation has been granted under a centralised procedure by the European Union, which is not the case here, since the medicinal product involved in the conduct of Pharma Expressz did not obtain such an authorisation. [18] In that context, placing a medicinal product on the market is equivalent to marketing it. [19] As the Court has held, Article 6(1) of that directive should be understood to mean that the Member States must, generally, entirely prohibit the marketing of medicinal products which do not have a marketing authorisation. [20]

47. If the classification of a medicinal product in one Member State were considered binding for all Member States, so that, whether or not it is subject to medical prescription, the medicinal product concerned is available on the market in all Member States, that would result in a situation where compliance with that classification presupposes the automatic granting – or automatic recognition – of a marketing authorisation granted by the national competent authorities of the Member State of origin.

[18] See, to that effect, judgment of 3 July 2019, *Delfarma* (C-387/18, EU:C:2019:556, paragraph 18).

[19] See, to that effect, judgment of 20 September 2007, *Antroposana and Others* (C-84/06, EU:C:2007:535, paragraph 35 and the case-law cited).

[20] Judgment in *Ludwigs-Apotheke*, paragraph 19.

48. It is true that recital 12 of Directive 2001/83 states, inter alia, that a marketing authorisation granted by a competent authority in one Member State ought to be recognised by the competent authorities of the other Member States, unless there are serious grounds for supposing that the authorisation of the medicinal product concerned may present a risk to public health.

49. However, the mutual recognition to which that recital refers is not automatic, since a national marketing authorisation does not, in itself, produce transnational effects.[21] Directive 2001/83 provides for a mutual recognition procedure, conducted in accordance with the provisions of Chapter 4 of that directive, entitled 'Mutual recognition and decentralised procedure'.

50. More specifically, as regards the mutual recognition procedure, Article 28(2) of Directive 2001/83 states that 'where the medicinal product has already received a marketing authorisation at the time of application, the concerned Member States shall recognise the marketing authorisation granted by the reference Member State. To this end, the marketing authorisation holder shall request the reference Member State either to prepare an assessment report on the medicinal product or, if necessary, to update any existing assessment report … [Then, the documents prepared by the reference Member State] shall be sent to the concerned Member States …'. Lastly, the wording of Article 28(4) of Directive 2001/83 suggests that those documents are to be approved only by the Member States concerned and, subsequently, a marketing authorisation granted by another Member State is to be recognised by the Member States concerned. Lastly, it is clear from Article 29 of that directive that those Member States may object to such recognition on the grounds of a potential serious risk to public health.[22] The procedure conducted in accordance with Article 29 et seq. of that directive is initiated in order for the Member States to reach an agreement.[23]

51. There is nothing to suggest that the marketing authorisation for the medicinal product involved in the conduct of Pharma Expressz has been recognised in Hungary, in accordance with the mutual recognition procedure. In the light of Article 6(1) of Directive 2001/83, that medicinal product could not, therefore, be placed on the market in Hungary, regardless of its classification in another Member State in which it has a national marketing authorisation, because that classification is not binding for all Member States.

[21] See, to that effect, Roth, W.H., 'Mutual recognition', in Koutrakos, P., Snell, J. (eds), *Research Handbook on the Law of the EU's Internal Market*, Edward Elgar Publishing, Cheltenham – Northampton, 2017, p. 442, which states that 'given the sensitive implications of medicinal product standards, this authorisation has not (yet) been attributed trans-national effect. Instead, the marketing of a medicinal product in another Member State is dependent on a wholly new authorisation procedure in this Member State. Mutual cooperation among the authorities of the Member States is meant to alleviate the burden that goes with this multi-authorisation procedure in the Member States'.

[22] See judgment of 16 October 2008, *Synthon* (C-452/06, EU:C:2008:565, paragraph 28).

[23] For a more detailed account of the mutual recognition procedure and its characteristics, see Škrnjug, I., Uzeirbegović, S., Romčević, M.L., Tomić, S., Meyer, H., Conrad, C., 'Mutual recognition in the European system: A blueprint for increasing access to medicines?', *Regulatory Toxicology and Pharmacology*, 2019, vol. 106, pp. 272-274.

52. That said, EU law does provide for certain exceptions to the principle laid down in Article 6(1) of Directive 2001/83.[24] The exception set out in Article 5(1) of the directive, which concerns the individual ordering of unauthorised medicinal products, bears some similarity to the circumstances of the main proceedings.[25]

53. Moreover, as regards the question asked by the Court, only Pharma Expressz appeared to dispute, at the hearing, that the provisions of Hungarian law reproduced in points 12 to 14 of this Opinion can be regarded as transposing Article 5(1) of Directive 2001/83. It is those provisions of Hungarian law, in the version applicable until 13 February 2018, which, according to the Institute's decision challenged in the main proceedings, were infringed by Pharma Expressz when it supplied medicinal products that were obtained in another Member State and did not have a marketing authorisation, without requesting a declaration from the pharmaceutical authority. Another issue raised by the referring court in its second question is whether those provisions, which impose conditions for 'ordering and dispensing to a patient a medicinal product', are compatible with Article 36 TFEU.

54. However, in its written observations, Pharma Expressz puts forward a series of arguments asserting that Article 6(1) of Directive 2001/83 is not applicable, which would make any derogation provided for in Article 5(1) of that directive superfluous. I shall therefore examine the arguments by which Pharma Expressz asserts, first, that an individual may acquire medicinal products not authorised in Hungary by other means and, secondly, that it sells medicinal products in its pharmacy in the course of its business and that the sale of medicinal products to end consumers has not been completely harmonised.

3. The argument that there are several means of acquisition

55. According to Pharma Expressz, notwithstanding the fact that a medicinal product is not authorised in Hungary, an individual may obtain that product in another Member State where it has a marketing authorisation, either in person, using a courier service or via the internet. Under Hungarian law, those means of acquisition are not subject to any conditions, nor are they prohibited, even though Article 14 of Directive 97/7/EC[26] permits Member States to make such provisions. Furthermore, the objective set out in recital 30 of Directive 2001/83, according to which it must be possible for a person established in one Member State to receive from another Member State a reasonable quantity of medicinal products intended for his or her personal use, must be recognised as being of crucial importance.

[24] In addition to Article 5(1) of Directive 2001/83, analysed in this Opinion, Article 5(2) of that directive provides that 'Member States may temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm'. Under Article 126a of that directive, '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'. Regulation No 726/2004 also contains a provision which allows the use of medicinal products even if they do not have a marketing authorisation. It is apparent from Article 83(1) of that regulation that, by way of exemption from Article 6 of Directive 2001/83/EC, when compassionate use is envisaged, Member States may make available a medicinal product for human use which may or must be granted a marketing authorisation. Only medicinal products which already have a marketing authorisation issued by the European Union (see point 2 of this Opinion), or are undergoing clinical trials, may be considered for 'compassionate use'.

[25] In a similar vein, the Polish Government and the Commission maintain that Articles 70 to 73 of Directive 2001/83 are not relevant for the purposes of answering the first question, and focus, in their written observations, on Article 5(1) of that directive. At the hearing, the other parties also maintained that Article 5(1) was the provision that was relevant to the main proceedings.

[26] Directive of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts (OJ 1997 L 144, p. 19). According to Article 14 of that directive, 'Member States may introduce or maintain, in the area covered by this Directive, more stringent provisions compatible with the Treaty, to ensure a higher level of consumer protection. Such provisions shall, where appropriate, include a ban, in the general interest, on the marketing of certain goods or services, particularly medicinal products, within their territory by means of distance contracts, with due regard for the Treaty'.

56. By those observations, Pharma Expressz appears to assert that, if it is possible for an individual to obtain medicinal products not authorised in Hungary by various means, Pharma Expressz itself should also be entitled to buy and stock such medicinal products in order to sell and supply them directly to individual customers. It is therefore necessary to examine whether an individual can actually buy an unauthorised medicinal product by the above means and, if so, whether that fact is capable of influencing the analysis of the applicability of Article 6(1) of Directive 2001/83 to Pharma Expressz.

(a) Buying a medicinal product in person

57. As regards the possibility of buying a medicinal product in person in another Member State, it is certainly true that recital 30 of Directive 2001/83 states that 'persons moving around within the [European Union] have the right to carry a reasonable quantity of medicinal products lawfully obtained for their personal use'.

58. However, the conduct referred to in the situation described in that recital – a situation which is, in practice, difficult for the Member State to which that person returns to control – does not concern the placing on the market of a medicinal product in that Member State, since the medicinal product not authorised in that Member State is not marketed in its territory.[27] That situation is not the same as that which forms the subject matter of the contested decision in the main proceedings, which concerns the conduct of Pharma Expressz and, as such, cannot be relied upon to call into question the applicability of Article 6(1) of Directive 2001/83 to that conduct.

(b) Buying a medicinal product by means of a courier service

59. The Court has on several occasions clarified various aspects of the treatment of medicinal products which are not authorised in a Member State of destination and may be acquired using a courier service. It is possible to see the evolution of harmonisation in the field of medicinal products for human use from an analysis of the case-law arising from the judgments concerned.

60. In the judgment in *Ortscheit*,[28] delivered while Directive 65/65 was in force, the Court interpreted Articles 30 and 36 of the EEC Treaty (subsequently Articles 28 and 30 EC, and now Articles 34 and 36 TFEU) in order to clarify whether a national provision prohibiting the advertising of medicinal products which were not authorised in Germany was compatible with those articles. Such medicinal products could, however, in accordance with a derogating provision, be imported from another Member State in which they had a marketing authorisation, provided that they had been ordered by a pharmacy, in limited quantities, and with a medical prescription.

[27] See, to that effect, judgment of 7 March 1989, *Schumacher* (215/87, EU:C:1989:111, paragraph 15). Despite the fact that Article 3 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ English Special Edition, Series I, Volume 1965-1966, p. 20) provided that 'no proprietary medicinal product may be placed on the market in a Member State unless an authorisation has been issued by the competent authority of that Member State', the Court did not hold that the prohibition on the importation of medicinal products by an individual for his or her personal needs constituted the implementation of that provision. The Court ruled, in that context, that the harmonisation brought about by that directive had not been fully achieved since, for example, a medicinal product could be authorised in one Member State, but not in one or more others, with or without prescription. Under Article 6(1) of Directive 2001/83, such a situation may still arise.

[28] Judgment of 10 November 1994 (C-320/93, EU:C:1994:379).

61. In that judgment, the Court stated that Member States are entitled to prohibit entirely the marketing in their territory of medicinal products which have not been authorised by the competent national authorities.[29] It appears that such a prohibition constituted the implementation of Directive 65/65 and, as such, was not examined in the light of the provisions of the Treaty.

62. However, given that the request for a preliminary ruling in that case arose from a dispute concerning the prohibition on advertising unauthorised medicinal products, the Court did not have the opportunity to rule on whether the compatibility with EU law of the derogating national provision mentioned in point 60 of this Opinion should have been examined in the light of Directive 65/65 or of Articles 30 and 36 of the EEC Treaty.

63. Next, as regards personal imports, not effected by personal transport, of medicinal products unauthorised in the Member State of destination, the Court held, in *Commission* v *France*,[30] adopting the Commission's reasoning, that such imports could be subject to authorisation.[31] However, in that judgment, the Court ruled that applying the same authorisation procedure for those imports as for medicinal products imported for commercial use was disproportionate and that, therefore, the French Republic had failed to fulfil its obligations under Article 28 EC. It may be understood from a reading of that judgment that where a Member State decides to derogate from the prohibition on marketing unauthorised products in its territory, it must stay within the limits set by the Treaty.

64. Lastly, more recently, in the judgment in *Ludwigs-Apotheke*,[32] the Court interpreted the provisions of Directive 2001/83 relating to the advertising of medicinal products which are not authorised in the Member State of destination. It is true that the factual background of the case which gave rise to that judgment differed from that of the case which gave rise to the judgment in *Ortscheit*,[33] but both cases concerned the same prohibition on advertising unauthorised medicinal products. However, it seems that the case which gave rise to the judgment in *Ludwigs-Apotheke* concerned a different derogating provision, allowing the import of unauthorised medicinal products. The Court stated that that provision allowed pharmacists to obtain, in another Member State, small quantities of medicinal products not authorised in the Member State of destination in response to individual orders,[34] with no reference to a prescription from a medical practitioner.[35]

65. In that context, the Court stated, in the first place, that, even if the power to make such a derogation was not expressly granted by Directive 2001/83, that derogation was not necessarily contrary to that directive, provided that it was applied so as not to undermine the general obligation to obtain a marketing authorisation. According to the Court, 'under recital 30 in the preamble to the directive, it must be possible for a person established in one Member State to have a reasonable quantity of medicinal products intended for his personal use sent to him from

29 Judgment of 10 November 1994, *Ortscheit* (C-320/93, EU:C:1994:379, paragraph 18).

30 Judgment of 26 May 2005 (C-212/03, EU:C:2005:313).

31 See, to that effect, George, C., 'The Internet and Pharmaceutical Drugs in the Era of Interoperable eHealth Systems across the European Union', in George, C., Whitehouse, D., Duquenoy, P. (eds), *eHealth: Legal, Ethical and Governance Challenges*, Springer, Heidelberg, 2013, p. 156.

32 Paragraph 24 of that judgment.

33 Judgment of 10 November 1994 (C-320/93, EU:C:1994:379).

34 Judgment in *Ludwigs-Apotheke*, paragraphs 9 and 20.

35 See, for comparison, point 60 of this Opinion.

another Member State. From that point of view, Article 5(1) of Directive 2001/83 provides that a Member State may, [in accordance with the conditions set out in that provision, exclude from the provisions of that directive unauthorised medicinal products]'. [36]

66. In the second place, while acknowledging that it was not possible to confirm that it had been the intention of the national legislature to implement Article 5(1) of Directive 2001/83 by that derogating provision, the Court held that 'inasmuch as [that provision] aims to make it possible to place on the market a limited quantity of non-approved medicinal products in the context of an individual order justified by special needs, that provision may be regarded as actually implementing Article 5(1) of Directive 2001/83'. [37]

67. In the third place, the Court held that the medicinal products covered by the derogating national provision were therefore excluded from the scope of Directive 2001/83 and, accordingly, that the provisions of Title VIII of that directive, on advertising, were not applicable to them. According to the Court, the national provision prohibiting advertising should therefore have been examined in the light of Articles 28 and 30 EC (now Articles 34 and 36 TFEU). [38] However, the Court has not clarified whether the derogating provision, implementing Article 5(1) of Directive 2001/83, should also have been examined in the light of those provisions of the Treaty.

68. Although the Court appears to have reached a controversial conclusion in that judgment, by implicitly confirming that the derogating national provision at issue fell within the scope of recital 30 of Directive 2001/83 and that that provision constituted a correct transposition of Article 5(1) of that directive, [39] it is nevertheless clear from that judgment that individual orders for a limited quantity of medicinal products which have not been authorised in the Member State of destination are, in principle, also subject to Article 6(1) of Directive 2001/83 and, as such, are prohibited. Such orders are allowed only if one of the exceptions laid down in EU law applies, in particular that provided for in Article 5(1) of Directive 2001/83.

69. Those considerations apply to the conduct of Pharma Expressz in so far as, at the request of individual customers, it placed individual orders for a medicinal product which is not authorised in Hungary and which it then sold and supplied directly to those individuals.

(c) Buying a medicinal product online

70. In the judgment in *Deutscher Apothekerverband*, [40] the Court was required to interpret Articles 28 EC and 30 EC (now Articles 34 and 36 TFEU) to clarify the issue of the compatibility with those articles of, inter alia, a provision whereby medicinal products for human use the sale of which is restricted to pharmacies may not be imported commercially by way of mail order through authorised pharmacies in other Member States on the basis of individual orders placed by end consumers over the internet.

[36] Judgment in *Ludwigs-Apotheke*, paragraph 21.

[37] Judgment in *Ludwigs-Apotheke*, paragraph 22.

[38] Judgment in *Ludwigs-Apotheke*, paragraph 23.

[39] In his Opinion in *Commission* v *Poland* (C-185/10, EU:C:2011:622, point 25), Advocate General Jääskinen stated that, in the judgment in *Ludwigs-Apotheke*, the Court had been required to interpret the advertising provisions contained in Article 86(2) of Directive 2001/83 and had not therefore given detailed consideration to Article 5(1) of that directive. The Court therefore simply stated that the German legislation at issue in the case which gave rise to that judgment 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, and was therefore implementing Article 5(1) of that directive.

[40] Judgment of 11 December 2003 (C-322/01, EU:C:2003:664, paragraph 53).

71. In answering that question, the Court, first of all, distinguished between medicinal products which were authorised in the Member State of destination, and those which were not. [41]

72. Secondly, the Court held that a national provision prohibiting the commercial import of medicinal products which have not been authorised in the Member State of destination, whereby that Member State discharges its obligations under Article 3 of Directive 65/65 (replaced by Article 6(1) of Directive 2001/83), cannot be classified as 'a measure having equivalent effect to a quantitative restriction on imports' under Article 28 EC. Therefore, as regards medicinal products which were subject to, but had not obtained, authorisation, there was no need to consider whether the national provisions at issue in the main proceedings in that case were precluded by Articles 28 EC to 30 EC. [42] On the other hand, as regards medicinal products which were authorised in the Member State of destination, the Court examined the prohibition in question in the light of the provisions of the Treaty, taking the view that it fell within the scope of Directive 97/7 and was implemented on the basis of Article 14 of that directive. [43]

73. Since that judgment, the relevant legal framework has been substantially amended. First, Directive 97/7 has been repealed and replaced by Directive 2011/83/EU. [44] Although the latter directive takes a different approach to harmonisation and does not contain a provision equivalent to Article 14 of Directive 97/7, recital 11 of Directive 2011/83 states that the provisions of that directive should be without prejudice to EU provisions relating to specific sectors, such as medicinal products for human use. Secondly, although that case concerned the commercial import of medicinal products on the basis of individual orders placed by end consumers over the internet, the Court did not analyse the questions referred for a preliminary ruling in the light of Directive 2000/31/EC. [45] The request for a preliminary ruling was dated 10 August 2001, and the date for transposition of Directive 2000/31 was set at 17 January 2002. [46]

74. An online sales service relating to medicinal products may constitute an information society service, within the meaning of Article 2(a) of Directive 2000/31, and, therefore, may be within the scope of that directive as regards the requirements applicable to that service, which come within the 'coordinated field', within the meaning of Article 2(h) of that directive. [47] However, the national rules relating to the requirements applicable to goods as such and those relating to the conditions under which goods sold via the internet may be supplied within the territory of a Member State are not covered by the 'coordinated field' and fall outside the scope of that directive. [48]

75. Similarly, under Article 85c(2) of Directive 2001/83, Member States may impose conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services.

41 Judgment of 11 December 2003, *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 46).

42 Judgment of 11 December 2003, *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraphs 52 to 54).

43 Judgment of 11 December 2003, *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 63).

44 Directive of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC (OJ 2011 L 304, p. 64).

45 Directive of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ 2000 L 178, p. 1).

46 See Article 22 of Directive 2000/31.

47 Judgment of 1 October 2020, *A (Advertising and sale of medicinal products online)* (C-649/18, EU:C:2020:764, paragraph 33).

48 See, to that effect, judgment of 2 December 2010, *Ker-Optika* (C-108/09, EU:C:2010:725, paragraphs 29 and 30).

76. Conversely, Article 85c(1)(c) of Directive 2001/83 provides that the Member States are to ensure that medicinal products are offered for sale at a distance to the public by means of information society services provided, inter alia, that those products comply with the national legislation of the Member State of destination, in accordance with Article 6(1) of that directive. Medicinal products offered for sale by means of such services must therefore have a valid marketing authorisation in the Member State of destination. [49]

77. Thus, unlike Article 85c(2) of that directive, Article 85c(1)(c) does not concern the power of the Member States to impose conditions for the retail supply of medicinal products bought online. That provision lays down a requirement which is consistent with the principle established by Article 6(1) of Directive 2001/83.

78. In the light of the foregoing, it must be held, contrary to the assertions of Pharma Expressz, that EU law does not allow individuals to obtain via the internet medicinal products which are not authorised in a Member State of destination.

4. The argument that the conditions for dispensing medicinal products to the public are not harmonised

79. Pharma Expressz submits that it buys goods on the internal market and then sells them directly to patients at its pharmacy. Thus, it is not placing medicinal products on the market, but merely reselling products which are already available on the market, so that Article 6(1) of Directive 2001/83 is therefore irrelevant in the present case.

80. In that regard, Pharma Expressz asserts that the sale of medicinal products to end consumers has not been completely harmonised. That assertion appears to be supported by the assertions, made in different contexts, of the Institute, the Hungarian Government and the Commission, according to which the judgment in *VIPA* [50] shows that 'the national legislation relating to the conditions applicable to the supply of medicinal products does not fall within a harmonised area of EU law'.

81. Admittedly, it is clear from recital 21 of Directive 2011/62, which amended Directive 2001/83 and is still in force, that 'specific conditions for retail supply of medicinal products to the public have not been harmonised at Union level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the [TFEU]'.

82. As is clear from the judgment in *Apothekerkammer des Saarlandes and Others*, [51] to which recitals 22 and 23 of Directive 2011/62 refer, and from the judgment in *VIPA*, [52] such non-harmonised conditions for the supply of medicinal products to the public concern, inter alia, persons authorised to market medicinal products and the conditions applicable to the supply, by pharmacies, of medicinal products subject to medical prescription when they are ordered by healthcare professionals for use in their healthcare activity.

[49] See Kleyn, M., van Wyk, L., *International Pharmaceutical Law and Practice*, Matthew Bender, New York, 2020, paragraph 22.09, and George, C., op. cit., p. 156.

[50] Judgment of 18 September 2019 (C-222/18, EU:C:2019:751, paragraph 56).

[51] Judgment of 19 May 2009 (C-171/07 and C-172/07, EU:C:2009:316).

[52] Judgment of 18 September 2019 (C-222/18, EU:C:2019:751, paragraph 56).

83. Nevertheless, first of all, Directive 2001/83 established a complete regulatory framework for registration and market authorisation procedures in respect of medicinal products for human use.[53] Consequently, save in the case of exceptions provided for by EU law, a medicinal product may be imported into another Member State only upon acquisition of a marketing authorisation issued in accordance with the provisions of that directive.[54]

84. Secondly, in the judgment in *Deutscher Apothekerverband*,[55] the Court recalled that the sale of medicinal products to end consumers has not been subject to full Community harmonisation.[56] However, that did not prevent the Court from ruling that a national provision prohibiting the commercial import of medicinal products not authorised in the Member State of destination cannot be classified as 'a measure having equivalent effect' to a quantitative restriction on imports. By contrast, that provision constituted the implementation of Article 6(1) of Directive 2001/83. A contrary interpretation would mean that Article 28 EC could be used to circumvent that provision.

85. Lastly, as is clear from point 68 of this Opinion, in the light of the judgment in *Ludwigs-Apotheke*,[57] the above considerations are also applicable as regards orders placed by pharmacists, in response to individual orders, for a limited quantity of medicinal products which have not been authorised in the Member State of destination. Such orders are compliant with Directive 2001/83 only if one of the exceptions under Article 6(1) of that directive applies.

86. Therefore, the arguments put forward by Pharma Expressz, based on the existence of other means of acquiring unauthorised medicinal products[58] and on the absence of harmonisation of the conditions for dispensing medicinal products to the public,[59] for the purposes of asserting that Article 6(1) of Directive 2001/83 is not applicable in this case, must be rejected.

5. Conclusion in respect of the first question referred

87. It follows from the above analysis that the first question should be answered in the negative.

88. The answer to that question, as reformulated, should be that Articles 70 to 73 of Directive 2001/83 must be interpreted as meaning that there is no obligation, under those provisions, to regard a medicinal product which can be supplied without medical prescription in one Member State as a medicinal product which can also be supplied without medical prescription in another Member State, including where the medicinal product in question does not have a marketing authorisation and has not been classified in that other Member State. Article 6(1) of that directive must be interpreted as meaning that, save in the case of exceptions provided for by EU law, such as the one provided for in Article 5(1) of that directive, that provision not only does not require the other Member State automatically to recognise that product's marketing authorisation or classification, but requires the other Member State to prohibit the marketing of that product.

[53] See judgment of 20 September 2007, *Antroposana and Others* (C-84/06, EU:C:2007:535, paragraphs 41 and 42).

[54] See judgment of 9 June 2005, *HLH Warenvertrieb and Orthica* (C-211/03, C-299/03 and C-316/03 to C-318/03, EU:C:2005:370, paragraph 60).

[55] Judgment of 11 December 2003 (C-322/01, EU:C:2003:664, paragraphs 52 to 54).

[56] Judgment of 11 December 2003, *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664, paragraph 102).

[57] Paragraph 24 of that judgment.

[58] See points 58, 69 and 78 of this Opinion.

[59] See point 85 of this Opinion.

C. The second question referred for a preliminary ruling

89. By its second question, and starting from the premiss that the conditions for ordering and supplying to a patient an unauthorised medicinal product, such as those provided for in a national provision whereby a Member State has implemented Article 5(1) of Directive 2001/83, namely the conditions that the medicinal product has been prescribed by a medical practitioner and that a declaration from the pharmaceutical authority has been obtained, constitute a quantitative restriction on imports or a measure having equivalent effect, within the meaning of Article 34 TFEU, the referring court asks whether that restriction or that measure is justified in the interests of the protection of the health and life of humans referred to in Article 36 TFEU.

90. It is true that the second question referred for a preliminary ruling, as formulated by the referring court, presupposes that the conditions laid down by the Hungarian legislation constitute a quantitative restriction on imports within the meaning of Article 34 TFEU. However, in view of my suggested reformulation of the first question and the answer I propose, I consider it necessary to verify the accuracy of this premiss and to reformulate the second question in order also to be able to examine whether such conditions for ordering and supplying to a patient an unauthorised medicinal product constitute a restriction within the meaning of Article 34 TFEU.

1. Is the implementation of the derogation provided for in Article 5(1) of Directive 2001/83 a restriction within the meaning of Article 34 TFEU?

91. Obviously, national legislation by which a Member State implements the prohibition provided for in Article 6(1) of Directive 2001/83 does not constitute a restriction under Article 34 TFEU, since such a prohibition has been harmonised at the level of EU law by that directive. [60]

92. There remains some uncertainty: is it possible that national legislation implementing the derogation provided for in Article 5(1) of Directive 2001/83 does not constitute such a restriction either and, therefore, does not require examination in the light of Articles 34 and 36 TFEU? That uncertainty arises from the fact that that provision of Directive 2001/83 allows a Member State to exclude a medicinal product from the application of that directive's provisions, [61] which may suggest that such a situation no longer falls within an area harmonised by EU law. This is the case as regards the provisions harmonising specific measures, in particular relating to advertising for medicinal products for human use, the application of which is excluded because of the use of that derogation. [62] As those provisions cease to apply to the medicinal product concerned, a Member State may make that medicinal product subject only to requirements which are consistent with the obligations under the TFEU, in particular the principle of the free movement of goods laid down in Articles 34 and 36 TFEU.

[60] See point 72 of this Opinion. See also Sadeleer, N., 'Restrictions of the Sale of Pharmaceutical and Medical Devices such as Contact Lenses over the Internet and the Free Movement of Goods', *European Journal of Health Law*, 2012, vol. 19, pp. 5 and 11.

[61] In the judgment of 29 March 2012, *Commission* v *Poland* (C-185/10, EU:C:2012:181, paragraph 33), the Court held that Article 5(1) of Directive 2001/83 provides the power 'to exclude the application of [that directive's] provisions' so that, as is apparent from the judgment in *Ludwigs-Apotheke*, 'the medicinal products covered by [the national provision by which a Member State, when transposing the directive, implemented that power] are excluded from the scope of [that directive]' (paragraph 23 of that judgment).

[62] See point 67 of this Opinion.

93. The margin of discretion that a Member State has when implementing Article 5(1) of Directive 2001/83 is limited by the fact that, first, the conditions laid down by that provision are cumulative [63] and, secondly, that those conditions must be interpreted strictly in order to preserve the practical effect of the marketing authorisation procedure and to achieve the aim of protecting public health. [64] When implementing that provision, a Member State may not, therefore, introduce more liberal conditions [65] which could give rise to the possibility of derogating from Article 6(1) of Directive 2001/83 in cases going beyond what is permitted by that directive.

94. Therefore, the question whether a Member State has correctly exercised that discretion in imposing the conditions in which it is possible to exclude the application of Article 6(1) of Directive 2001/83 must be examined in the light of Article 5(1) of that directive.

95. The provisions of Directive 2001/83 must, of course, be interpreted in the light of the TFEU, and that interpretation must comply with the principle of proportionality. Articles 34 and 36 TFEU cannot, however, be relied on to circumvent the national authorisation system in cases going beyond what is permitted by the conditions set out in Article 5(1) of that directive. If it were to be held that a Member State of destination may impose such conditions only within the limits determined by the provisions of the TFEU, this would mean that that Member State would be required systematically to justify, in the light of Article 36 TFEU, the refusal to supply an unauthorised medical product. In practice, a Member State of destination may thus find it impossible to prevent the marketing and/or supply of certain unauthorised medicinal products in its territory. In each case, it would have to provide not only justifications relating to protection of health but also an analysis of the appropriateness and proportionality of the measure, and also specific evidence substantiating its arguments. [66]

96. However, only national legislation which correctly transposes a directive does not constitute a measure having equivalent effect within the meaning of Article 34 TFEU. [67] In such circumstances, there is no need to examine the correct implementation of Article 5(1) of Directive 2001/83 in the light of Article 36 TFEU.

97. I shall therefore make some additional observations to allow the Court to ascertain whether the conditions for ordering and dispensing medicinal products provided for in the Hungarian legislation constitute a correct transposition of the conditions set out in Article 5(1) of Directive 2001/83.

2. The conditions laid down in the Hungarian legislation

98. As is clear from the request for a preliminary ruling, Hungarian law lays down two conditions as regards ordering and supplying to a patient an unauthorised medicinal product: there must be a medical prescription and a declaration from the Institute.

63 See, to that effect, judgment of 29 March 2012, *Commission* v *Poland* (C-185/10, EU:C:2012:181, paragraph 30).

64 See judgment of 29 March 2012, *Commission* v *Poland* (C-185/10, EU:C:2012:181, paragraphs 31 to 33).

65 See, to that effect, judgment of 29 March 2012, *Commission* v *Poland* (C-185/10, EU:C:2012:181, paragraphs 42, 43 and 45).

66 See, to that effect, judgment of 19 October 2016, *Deutsche Parkinson Vereinigung* (C-148/15, EU:C:2016:776, paragraph 35).

67 See, to that effect, judgment of 5 April 2001, *Bellamy and English Shop Wholesale* (C-123/00, EU:C:2001:214, paragraph 21).

(a) The existence of a medical prescription

99. The referring court explains that the first requirement under the Hungarian legislation is the existence of a medical prescription. In so far as it is the medical practitioner who requests the declaration from the authority in advance, the involvement of a medical practitioner is necessary.

100. Given that Article 5(1) of Directive 2001/83 concerns medicinal products 'formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility',[68] that provision also requires the involvement of a medical practitioner.

101. As regards the concept of an 'authorised health-care professional', it is clear from a reading of Article 102 of Directive 2001/83 that that concept covers not only medical practitioners, but also pharmacists. However, Article 5(1) of that directive refers to authorised professionals who, moreover, may assume direct personal responsibility for the treatment of patients with unauthorised medicinal products.[69]

102. Thus, concurring with the written observations submitted by the Polish Government, I consider that Article 5(1) of Directive 2001/83 applies where a medicinal product necessary to save a patient's life or health is imported from another Member State in response to an order (in the form of a prescription, request or application) placed by a healthcare professional who assumes responsibility for administering that medicinal product. The Hungarian legislation does not therefore differ from that provision.

(b) Obtaining a declaration from the Institute

103. The second requirement laid down by the Hungarian legislation is that a declaration from the Institute must be obtained.

104. According to the explanations provided by the referring court, that declaration contains information on whether the medicinal product concerned has a valid marketing authorisation as well as the Institute's opinion as to whether there is an interest relating to patient care to which particular regard must be had.

105. As regards that opinion, the referring court explains that the previous national legislation which is applicable to this case did not provide that the medicinal product could be ordered or supplied on the basis of the content of the declaration. According to the new legislation, the mere fact that there is a declaration, whatever its content, is sufficient to comply with the requirement laid down in the national legislation. It should be found that the same was true of

[68] In the interests of completeness, I would like to recall, as was observed by Advocate General Jääskinen in his Opinion in *Commission* v *Poland* (C-185/10, EU:C:2011:622, point 29), that that requirement does not concern medicinal products prepared in pharmacies on the basis of a medical prescription for an individual patient, since Directive 2001/83 applies only to medicinal products prepared industrially or manufactured by a method involving an industrial process.

[69] The Court recently recalled, in its judgment of 23 January 2018, *F. Hoffmann-La Roche and Others* (C-179/16, EU:C:2018:25, paragraph 57), that the derogation provided for in Article 5(1) of Directive 2001/83 can only concern situations in which *the doctor considers that the state of health of his or her individual patients requires that a medicinal product be administered*. In that vein, in the judgment of 11 April 2013, *Novartis Pharma* (C-535/11, EU:C:2013:226, paragraph 46), the Court stated that that provision is applicable in exceptional cases, where it is appropriate to meet special medical needs, *in circumstances in which a doctor, following an actual examination of his or her patients and on the basis of purely therapeutic considerations, prescribes a medicinal product* which does not have a valid marketing authorisation.

the previous national legislation applicable in this case. That finding is not called into question by Pharma Expressz, which considers that the requirement to obtain a declaration from the Institute is merely a formality.

106. Article 5(1) of Directive 2001/83 does not expressly lay down any conditions as regards obtaining a document in addition to that drawn up by a medical practitioner.

107. However, first of all, in so far as it contains information on the existence of a marketing authorisation, a declaration such as that required by the Hungarian legislation serves only to ascertain whether the derogation provided for in that article of Directive 2001/83 is applicable. Only medicinal products authorised in another Member State may be covered by that derogation.

108. Secondly, in so far as such a declaration contains an opinion as to whether there is an interest relating to patient care to which particular regard must be had, I would point out that that derogation may be used only where necessary to meet special medical needs. Taking into account the essential aims of Directive 2001/83, in particular the aim of protecting public health, a Member State may, in my view, decide to be competent to ascertain, on a case-by-case basis, whether there are special medical needs to be met, in order to ensure that the conditions laid down in Article 5(1) of that directive are satisfied. I do not rule out the possibility that a Member State may even decide to be competent to refuse to implement that derogation where there are no special needs to be met.

109. Therefore, taking into account the non-binding nature of the declaration required by the Hungarian legislation, a question arises as to whether that legislation is too liberal, in so far as it may result in the authorisation of an exception to the marketing prohibition in circumstances not provided for in Article 5(1) of Directive 2001/83.

110. It appears that the Hungarian legislature started from the premiss that it is the medical practitioner who, as an authorised healthcare professional, is best placed to ensure that the conditions laid down in the national legislation are satisfied. Conversely, the declaration provides the medical practitioner with an easy way to access information on the marketing authorisation of a medicinal product, and offers that practitioner an additional opinion as regards administering that product. Furthermore, at least according to the new Hungarian legislation, in so far as the declaration is likely to be made available to the patient by the medical practitioner, the person directly concerned is able to make an informed decision regarding the proposed treatment on the basis of that declaration.

111. Lastly, as regards the time limit for obtaining a declaration,[70] a Member State must ensure that that time limit is not unreasonable in relation to the time required to take the necessary steps in order to establish the content of the declaration, which could render nugatory the derogation provided for in Article 5(1) of Directive 2001/83. The Hungarian legislation applicable in the present case did not expressly set a time limit and the referring court admits that it has no information in that regard. However, the information provided by the Institute at the hearing does not support a conclusion that the time limit was unreasonable.

112. Accordingly, I consider that the Hungarian legislation does not go beyond the requirements of Article 5(1) of Directive 2001/83 in so far as it lays down the condition relating to the declaration from the Institute.

[70] See points 18 and 29 of this Opinion.

113. I propose, therefore, that the answer to the second question referred for a preliminary ruling should be that national legislation by which a Member State has implemented Article 5(1) of Directive 2001/83 and which makes the possibility of ordering and supplying to a patient a medicinal product which does not have a marketing authorisation in that Member State conditional on the existence of a medical prescription from a medical practitioner and a declaration from the pharmaceutical authority, does not constitute a restriction under Article 34 TFEU.

VI. Conclusion

114. In the light of the foregoing, I propose that the Court should reply as follows to the questions referred for a preliminary ruling by the Fővárosi Törvényszék (formerly the Fővárosi Közigazgatási és Munkaügyi Bíróság) (Budapest High Court, formerly Budapest Administrative and Labour Court, Hungary):

(1) Articles 70 to 73 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 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, must be interpreted as meaning that there is no obligation, under those provisions, to regard a medicinal product which can be supplied without medical prescription in one Member State as a medicinal product which can also be supplied without medical prescription in another Member State in which that medicinal product does not have a marketing authorisation and has not been classified.

    Article 6(1) of that directive must be interpreted as meaning that, save in the case of exceptions provided for by EU law, such as the one provided for in Article 5(1) of that directive, that provision not only does not require the other Member State automatically to recognise that product's marketing authorisation or classification, but requires the other Member State to prohibit the marketing of that product.

(2) National legislation by which a Member State has implemented Article 5(1) of Directive 2001/83, as amended by Directive 2011/62, and which makes the possibility of ordering and supplying to a patient a medicinal product which does not have a marketing authorisation in that Member State conditional on the existence of a medical prescription from a medical practitioner and a declaration from the pharmaceutical authority, does not constitute a restriction under Article 34 TFEU.