Case C-178/20

Request for a preliminary ruling

Date lodged:

7 April 2020

Referring court:

Fővárosi Közigazgatási és Munkaügyi Bíróság **(**Budapest Administrative and Labour Court, Hungary)

Date of the decision to refer:

10 March 2020

Applicant:

Pharma Expressz Szolgáltató és Kereskedelmi Kft

Defendant:

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (National Institute of Pharmacy and Nutrition)

Fővárosi Közigazgatási és Munkaügyi Bíróság (Budapest Administrative and Labour Court, Hungary)

06.K.31 290/2019/24.

In the administrative proceedings concerning the trade in medicinal products brought by **Pharma Expressz Szolgáltató és Kereskedelmi Korlátolt Felelősségű Társaság** ([…] Budapest […]), applicant, […] against **Országos Gyógyszerészeti és Élelmiszer-egészségügyi Intézet** (National Institute of Pharmacy and Nutrition […] Budapest […]), defendant, the Fővárosi Közigazgatási és Munkaügyi Bíróság (Budapest Administrative and Labour Court, Hungary) has given the following

Decision

This court hereby commences the procedure for a reference to the Court of Justice of the European Union for a preliminary ruling concerning the interpretation of 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

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products for human use (OJ 2001 L 311, p. 67; 'Directive 2001/83') and Article 36 of the Treaty on the Functioning of the European Union ('TFEU').

This court refers the following questions to the Court of Justice of the European Union:

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?**

[…] [procedural aspects of national law]

Grounds

This court requests from the Court of Justice of the European Union an interpretation of Articles 70 to 73 of Directive 2001/83 and Article 36 TFEU in a case relating to the import of medicinal products from another Member State.

I. Relevant legislative provisions

EU law

Articles 70 to 73 of Directive 2001/83.

Article 36 TFEU.

Hungarian law

Law XCV of 2005 on medicinal products for human use and amending other laws governing the market in medicinal products (az emberi alkalmazásra kerülő gyógyszerekről és egyéb, a gyógyszerpiacot szabályozó törvények módosításáról szóló 2005. évi XCV. törvény; 'Law on medicinal products')

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Paragraph 25(2): 'Medicinal products that do not have a marketing authorisation in a State which is a party to 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 professional association's opinion concerning the safety and effectiveness of the therapeutic procedure.'

Ministry of Health and Social and Family Affairs Regulation 44/2004 of 28 April on prescribing and dispensing medicinal products for human use (az emberi felhasználásra kerülő gyógyszerek rendeléséről és kiadásáról szóló 44/2004. (IV. 28.) ESzCsM rendelet; 'Regulation 44/2004'), in force until 13 February 2018.

Paragraph 3(5): '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 ("State party to an EEA treaty"), only if, before prescribing those medicinal products, they lodge a notification with the Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (National Institute of Pharmacy and Nutrition, Hungary) and they obtain a declaration from that Institute.'

Paragraph 12/A: '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 issued by the National Institute of Pharmacy and Nutrition or a copy of the authorisation.'

Government Regulation 448/2017 of 27 December on authorisation of the prescription and individual use of medicinal products for human use (az emberi felhasználásra kerülő gyógyszerek egyedi rendelésének és felhasználásának engedélyezéséről szóló 448/2017. (XII. 27.) Korm. rendelet; 'new Government Regulation'), in force since 1 January 2018.

Paragraph 5(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 another Member State of the European Economic Area

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(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 ("State party to an EEA treaty"), only if, before prescribing those medicinal products, they lodge a notification with the Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (National Institute of Pharmacy and Nutrition, Hungary) 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 an EEA treaty 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

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 Paragraph 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 Regulation 44/2004. The National Institute of Pharmacy and Nutrition 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 National Institute of Pharmacy and Nutrition 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 National Institute of Pharmacy and Nutrition 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 continues to maintain that it is 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.'

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II. Subject matter of the dispute and relevant facts

1. The National Institute of Pharmacy and Nutrition, the defendant in the present case, in its capacity as the authority with competence for overseeing the distribution of medicinal products, found, following an investigation of retail sales by the applicant of medicinal products, that the applicant had, on a number of occasions, imported from another EEA Member State a medicinal product not on the market in Hungary and that that product was registered in that other EEA Member State as a medicinal product not subject to medical prescription. On those occasions, the patient ordered the medicinal product directly from the pharmacy without a prescription. Then the applicant, acting in its own name, obtained and stocked the medicinal product from the other Member State and finally, acting in its own name, the applicant sold and supplied the medicinal product directly to the patient who had ordered it.

2. Under national law, a medicinal product imported from another Member State which does not have a national marketing authorisation can be used for medical purposes if it has been notified to the State pharmaceutical administrative body. Medical practitioners may prescribe that medicinal product if they give prior notice to the pharmaceutical authority and obtain a declaration from that authority.

   The content of the declaration from the authority covers the following matters:

   – whether the medicinal product has a marketing authorisation in another Member State;

   – the active substances and indications of the medicinal product;

   – whether the medicinal product has been withdrawn from the market or its distribution has been suspended;

   – whether there is an interest relating to patient care to which particular regard must be had.

   The previous national legislation, which must be applied to this case, did not provide that the medicinal product could be ordered or dispensed on the basis of the content of the declaration from the authority. In accordance with the provisions now in force, the wording of which is essentially the same, in the absence of any interest relating to patient care to which particular regard must be had, the medical practitioner is required to make the patient aware of that fact, although that does not preclude the medicinal product from being ordered. It follows that the mere fact that there is a declaration, whatever its wording, is sufficient to comply with the legislative requirement. On the other hand, in the case of medicinal products imported from a third country which is not party to an EEA treaty, the national legislation requires authorisation from the pharmaceutical authority.

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3. The defendant concluded that the national rule referred to must apply to medicinal products imported from any other Member State, regardless of whether or not the medicinal product in question has been registered in the other Member State as a medicinal product the acquisition of which is subject to medical prescription.

4. At the patient's request, the applicant ordered, from another Member State, medicinal products not subject to medical prescription, without requiring a medical prescription or a declaration from the National Institute of Pharmacy and Nutrition to order and dispense those products. In view of this, by decision of 7 March 2019, the defendant authority, together with other measures, prohibited the applicant from continuing to carry out that unlawful conduct on the grounds that it breached the provisions on the dispensation of individually acquired medicinal products. The legal basis for the offence was the infringement of Paragraph 12/A of the Regulation, since, in the absence of a declaration from the pharmaceutical authority, the applicant was supplying medicinal products obtained in another Member State which did not have a national marketing authorisation.

Essential aspects of the parties' submissions

5. The **applicant** brought an action against the decision before this court and sought, inter alia, a declaration that it had not committed any offence in the context of the individual acquisition of medicinal products. The applicant submits, in particular, that the legal interpretation adopted by the defendant and the application of a provision of restrictive national legislation to the individual acquisition of medicinal products registered in another Member State as medicinal products not subject to medical prescription constitute a prohibited quantitative restriction on imports contrary to Article 34 TFEU. That type of quantitative restriction cannot be justified in the interests [of the objective] of [protecting] the health and [life] of humans laid down in Article 36 TFEU. The declaration from the pharmaceutical authority does not serve to protect the health of humans because it does not provide additional information regarding the matters it should include, referred to above. The medicinal product can be dispensed even if the declaration is unfavourable because the legislation does not contain any requirements regarding its content. Nor does the legislation provide for a penalty if medicinal products are dispensed in spite of an unfavourable declaration. Furthermore, practical experience shows that it can take several weeks or even several months to obtain a declaration, which can jeopardise the patient's health rather than serving to protect it.

6. The applicant submits that a restriction of that kind is also disproportionate. First, because, in the case of medicinal products that have a national marketing authorisation, the legislation does not provide that a declaration must be obtained. Second, in the case of medicines which can be freely acquired without prescription in another Member State, the condition regarding a medical prescription and a declaration from the authority is an unnecessary and disproportionate requirement, because that other Member State has authorised the

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placing of the medicinal product concerned on the market in accordance with criteria which are compatible with the harmonised provisions and principles of the European Union and has classified the medicinal product in the category of medicines which can be acquired without a prescription. Therefore, making acquisition of the medicine within the country subject to a medical prescription is a disproportionate restriction which does not really contribute to protecting the patient's health. In certain Member States, such as, for example, Germany and Austria, patients can order directly, in pharmacies, medicines not subject to medical prescription which are on the market in another Member State, because the classification of medicinal products carried out by the other Member State is accepted. Member States classify medicines in accordance with uniform criteria which comply with the applicable directive. Accordingly, a medicinal product classified as a medicinal product not subject to medical prescription in another Member State must also be treated as a medicinal product not subject to medical prescription in Hungary.

7. The **defendant** contends that the national legislation constitutes a quantitative restriction aimed at protecting the health and life of humans, which can be justified under Article 36 TFEU. The defendant points out that the provision of medicines falls within the sphere of competence of the Member States and that it is for the Member States to decide what level of protection of public health they are seeking to ensure. The defendant states that, when examining the principle of proportionality, it is necessary to take into consideration the fact that the health and life of humans rank foremost among the assets protected by the TFEU. The Member States may adopt measures which reduce the risks to public health and [the risks which threaten] the safe and high-quality supply of medicinal products to society.

8. The national legislation does not preclude the import of foreign medicinal products. The National Institute of Pharmacy and Nutrition ensures that the population has access to safe medicines, in the exercise of its State function, 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 it can be used in relation to the indications given by the medical practitioner. If the medical practitioner has the declaration, he or she may issue a prescription to the patient and this ensures that, if the opinion is negative, no prescription will be issued, which guarantees the protection of patients' health.

9. The classification of medicinal products as subject to or not subject to medical prescription takes place in the context of the marketing authorisation procedure. Therefore, as long as a medicinal product does not have a marketing authorisation in Hungarian territory, it is not possible to decide whether it can be dispensed with or without a medical prescription. In that regard, it should be noted that, during the investigation, the defendant did not even examine which category the medicinal products imported from abroad were classified under in the Member State.

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III. Reasoning on which the reference for a preliminary ruling is based

Question 1

10. The placing of medicinal products on the market in the territory of the European Union is an area harmonised by Directive 2001/83. The EU legislation also provides that each Member State, in the exercise of its own powers, is to handle the procedure to authorise the placing of medicinal products on the market, using a procedure compatible with the provisions of the Directive. Recognition of a marketing authorisation is not automatic and is instead subject to the procedure laid down in in Title IV of the Directive.

11. Title VI of the Directive concerns the classification of medicinal products, for which the Member States have competence provided that they respect the uniform principles set out in Articles 70 to 75. In accordance with Article 73 of the Directive, the competent authorities of the Member States are to draw up a list of the medicinal products which are subject, on their territory, to medical prescription.

12. The resolution of the present proceedings requires an interpretation of whether the fact that the Directive lays down uniform principles for the classification of medicinal products imposes on a Member State an obligation to accept unconditionally the classification — that is, whether or not the medicinal product is subject to medical prescription — carried out by another Member State of a medicine placed on the market in that other Member State, and to treat that medicine in the same way as medicinal products which have a national marketing authorisation.

Question 2

13. In the interests of security of the supply of medicinal products to the population and the protection of public health, the national legislation makes the import from another EEA State of medicinal products which do not have a national marketing authorisation subject to the existence of a medical prescription and the obtaining of a declaration from the pharmaceutical authority. The legislation does not distinguish in any way between medicinal products which are subject to medical prescription and those which are not and this suggests that it is also applicable to medicinal products which can be acquired without medical prescription in another Member State.

14. The referring court has reached the conclusion, in the light of the case-law of the Court of Justice of the European Union, that the national legislation set out above constitutes a measure restricting the free movement of goods.

15. The resolution of the dispute requires an interpretation of Article 36 TFEU in order to determine whether the restrictive measure in question can be justified by

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the protection of the health and life of humans, including where the medicinal product can be dispensed without a medical prescription in another Member State.

16. The restriction introduces two additional requirements to those laid down in respect of medicinal products which have a national marketing authorisation and which can be dispensed without a medical prescription: 1) a declaration from the pharmaceutical authority and 2) the existence of a medical prescription. The medical practitioner requests the declaration from the authority in advance and, therefore, the involvement of a medical practitioner is also necessary for that purpose.

17. The reply that the Court of Justice gives to question 1 is also relevant for the purposes of determining 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 in accordance with the provisions of Directive 2001/83, the fact that use of that medicinal product is allowed only in the context of medical treatment is justified in the interests of the protection of the health of humans. If the classification of a medicinal product carried out by another Member State must be recognised, there are not necessarily any grounds for making its use conditional on a medical recommendation since the medicine may be dispensed to patients in that other Member State without the involvement of a medical practitioner. On the other hand, if the Court finds that a Member State is not obliged to accept a classification carried out by another Member State, it is not clear which category a medicinal product that has not been placed on the market should fit into, meaning that, in such a case, the involvement of a medical practitioner and the obtaining of an opinion are necessary to protect the patient's health.

18. The declaration from the pharmaceutical authority must be examined in conjunction with the medical prescription and also separately from that prescription in order to assess whether it constitutes a restriction on the movement of goods. The declaration contains information that is important from the perspective of public health and the patient. The matter of whether or not the medicinal product has a foreign marketing authorisation, the indications relating to the medicine and its active substances constitute the minimum information that can be required in order to be able to determine whether a medicinal product is safe. The Hungarian pharmaceutical authority obtains from the equivalent authority of the other Member State [particulars which comprise] the subject matter of objective information in the declaration. The patient, the medical practitioner and the pharmacy may not consult that information directly. The declaration must also contain the authority's opinion concerning whether there is an interest relating to patient care to which particular regard must be had. That is a professional medical question which may reflect a subjective view.

19. Unlike the situation with regard to the previous legislation, the legislation in force since 2018 lays down specific provisions governing the procedure to be followed on the basis of the content of the declaration. In accordance with the legislation in

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force, if the authority does not consider that there is an interest relating to patient care to which particular regard must be had, the medical practitioner must make the patient aware of that fact. The medical practitioner may, with knowledge of the content of the declaration, prescribe the medicine to the patient.

20. The referring court takes the view that the declaration from the authority 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 medicine is ordered. Obtaining that information in advance can also be justified if it is accepted that the medicine may be dispensed without a prescription and on the basis of a direct order from the patient.

21. In addition, for health protection purposes, the length of time which it takes to obtain the declaration is also important. On that point, the referring court does not have any conclusive information. The legislation currently in force lays down a time limit of eight days for the authority to issue its declaration. The previous legislation did not lay down a specific time limit. The defendant referred to an instance in which the declaration took approximately three months.

[…] [procedural aspects of national law]

Budapest, 10 March 2020.

[…] [signatures]

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