Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

18 September 2019 *

(Reference for a preliminary ruling – Cross-border healthcare – Directive 2011/24/EU – Articles 3(k) and 11(1) – Prescription – Definition – Recognition of a prescription issued in another Member State by an authorised person – Conditions – Free movement of goods – Prohibition of measures having equivalent effect to quantitative restrictions on exports – Articles 35 and 36 TFEU – Restriction on the dispensing by a pharmacy of prescription-only medicinal products – Order form issued in another Member State – Justification – Protection of human health and human life – Directive 2001/83/EC – Second paragraph of Article 81 – Supply of medicinal products to the public of a Member State)

In Case C-222/18,

REQUEST for a preliminary ruling under Article 267 TFEU from the Fővárosi Közigazgatási és Munkaügyi Bíróság (Administrative and Labour Court, Budapest, Hungary), made by decision of 8 March 2018, received at the Court on 28 March 2018, in the proceedings

VIPA Kereskedelmi és Szolgáltató Kft.

v

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet,

THE COURT (Fifth Chamber),

composed of E. Regan, President of the Chamber, C. Lycourgos, E. Juhász, M. Ilešič and I. Jarukaitis (Rapporteur), Judges,

Advocate General: Y. Bot,

Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 27 February 2019,

after considering the observations submitted on behalf of:

– VIPA Kereskedelmi és Szolgáltató Kft., by Z.P. Horváth, N. Neizer and V. Vajna, ügyvédek,

– the Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet, by B. Pál, ügyvéd,

* Language of the case: Hungarian.

– the Hungarian Government, by M.Z. Fehér, G. Koós, V. Kiss and M. Tátrai, acting as Agents,

– the Spanish Government, by L. Aguilera Ruiz, acting as Agent,

– the Polish Government, by B. Majczyna and M. Malczewska, acting as Agents,

– the European Commission, by L. Armati, A. Szmytkowska, A. Sipos and L. Malferrari, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 12 June 2019,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 3(k) and Article 11(1) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ 2011 L 88, p. 45).

2 The request has been made in proceedings between VIPA Kereskedelmi és Szolgáltató Kft. ('VIPA') and the Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (National Institute of Pharmacy and Nutrition, Hungary) ('the Institute') concerning the Institute's administrative decision penalising VIPA for unlawfully dispensing prescription-only medicinal products.

Legal context

EU law

Directive 2001/83

3 Article 1(17) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by 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'), provides:

'For the purpose of this Directive, the following terms shall bear the following meanings:

…

(17) Wholesale distribution of medicinal products:

All activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in the Member State concerned.'

4 Title VI of that directive, entitled ‘Classification of Medicinal Products’, includes Articles 70 to 75 of the directive. Article 70 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.

…

2. The competent authorities may fix sub-categories for medicinal products which are available on medical prescription only. In that case, they shall refer to the following classification:

(a) medicinal products on medical prescription for renewable or non-renewable delivery;

(b) medicinal products subject to special medical prescription;

(c) medicinal products on “restricted” medical prescription, reserved for use in certain specialised areas.’

5 Article 71 of that directive sets out the criteria to be taken into account to determine whether medicinal products should be subject to medical prescription. According to Article 71(3):

‘Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors:

…

– the medicinal product is intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.’

6 Title VII of Directive 2001/83, which comprises Articles 76 to 85b, covers wholesale distribution and brokering of medicinal products. Article 77 of that directive provides:

‘1. Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorisation to engage in activity as a wholesaler in medicinal products, stating the premises located on their territory for which it is valid.

2. Where persons authorised or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the authorisation provided for in paragraph 1.

…’

7 The second paragraph of Article 81 of Directive 2001/83 provides:

'The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.'

Directive 2011/24

8 Recitals 10, 11, 16, 36 and 53 of Directive 2011/24 state:

'(10) This Directive aims to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility …

(11) This Directive should apply to individual patients who decide to seek healthcare in a Member State other than the Member State of affiliation. …

…

(16) … The definition of cross-border healthcare should cover … the situation in which the patient purchases such medicinal products and medical devices in a Member State other than that in which the prescription was issued.

…

(36) This Directive should provide for the right for a patient to receive any medicinal product authorised for marketing in the Member State of treatment, even if the medicinal product is not authorised for marketing in the Member State of affiliation, …

…

(53) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a member of a regulated health profession within the meaning of Directive 2005/36/EC [of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255, p. 22)] for an individual named patient, it should, in principle, be possible for such prescriptions to be medically recognised and for the medicinal products to be dispensed in another Member State in which the medicinal products are authorised. … The implementation of the principle of recognition should be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products. These measures should include the adoption of a non-exhaustive list of elements to be included in prescriptions. …'

9 Article 1(1) and (2) of that directive provides:

'1. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare …

2. This Directive shall apply to the provision of healthcare to patients, …'

10 Article 3(k) of that directive provides:

‘For the purpose of this Directive, the following definitions shall apply:

…

(k) “prescription” means a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued.’

11 Article 11 of Directive 2011/24, headed ‘Recognition of prescriptions issued in another Member State’, provides:

‘1. If a medicinal product is authorised to be marketed on their territory … Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force, and that any restrictions on recognition of individual prescriptions are prohibited unless such restrictions are:

(a) limited to what is necessary and proportionate to safeguard human health, and non-discriminatory; or

(b) based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription.

The recognition of such prescriptions shall not affect national rules governing prescribing and dispensing, if those rules are compatible with Union law, including generic or other substitution. …

…

2. In order to facilitate implementation of paragraph 1, the Commission shall adopt:

(a) measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing a non-exhaustive list of elements to be included in the prescriptions …

…

(c) measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, …

(d) measures to facilitate the comprehensibility of the information to patients concerning the prescription …

…

6. Paragraph 1 shall not apply to medicinal products subject to special medical prescription provided for in Article 71(2) of Directive [2001/83].'

Implementing Directive 2012/52/EU

12 Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State (OJ 2012 L 356, p. 68), provides, in Article 1 thereof, that that directive 'lays down measures for the uniform implementation of Article 11(1) of Directive 2011/24/EU concerning the recognition of medical prescriptions issued in another Member State'.

13 Under Article 2 of that implementing directive:

'This Directive shall apply to prescriptions, as defined in point (k) of Article 3 of Directive 2011/24/EU, which are issued further to a request of a patient who intends to use them in another Member State.'

14 Article 3 of that implementing directive provides that 'Member States shall ensure that prescriptions contain at least the elements set out in the Annex'. That annex contains a non-exhaustive list of elements to be included in medical prescriptions, including, inter alia, in respect of the 'identification of the patient', the following elements:

'Surname(s)

First name(s) (written out in full, i.e. no initials)

Date of birth'.

Hungarian law

15 The emberi felhasználásra kerülő gyógyszerek rendeléséről és kiadásáról szóló 44/2004 ESzCsM rendelet (Regulation No 44/2004 of the Minister for Health, Labour Affairs and Family on the prescription and dispensing of medicinal products for human use), of 28 April 2004 (*Magyar Közlöny* 2004/58. (IV.28.)), as applicable to the dispute in the main proceedings ('Regulation of the Minister for Health'), provides in Article 1(1) thereof:

'For the purposes of the present regulation, "medical prescription" means the communication addressed by the medical doctor prescribing the medicinal product to the pharmacist who dispenses or prepares it or, in the cases provided for by the special rules, to the assistant pharmacist. The following shall be considered medical prescriptions:

(a) prescriptions *stricto sensu*; and

(b) order forms.'

16 Paragraphs 9/A(1) to (3) of that regulation states that:

'1. Medical doctors shall use order forms in the exercise of their healthcare activities to order medicinal products that they use in the treatment of patients.

2. Order forms shall be used to order medicinal products or medicinal products specially prepared in a pharmacy which are authorised to be placed on the market. …

3. Various types of medicinal product may be ordered at the same time by means of one order form. The name of the medical doctor ordering the medicinal products, his or her identification stamp and handwritten signature, the number of persons for whose treatment the medicinal product is ordered, the name and address of the establishment or company using the medicinal product in question and the date of the order shall be recorded on the order form. The name of the medicinal product ordered, including the pharmaceutical form and – where the product is placed on the market in various dosages – the dosage and total quantity of the medicinal product, shall be recorded on the order form.'

17 Paragraph 12 of that regulation provides that:

'1. Prescription-only medicinal products may be dispensed only on prescription or on the basis of an order form which meets the requirements established in this regulation or in the special rules.

2. Only one type of medicinal product may be dispensed per prescription *stricto sensu*.

3. Various types of medicinal product may be dispensed on the basis of an order form. …'

18 According to Paragraph 20 of that regulation:

'1. Medicinal products subject to prescription which have been prescribed by a person not registered on the register of practitioners, but who is legally authorised to prescribe medicinal products in another Member State, may only be dispensed if the identity, quantity and dosage of the medicinal product prescribed can be determined.

…

3. Medicinal products subject to prescription that are prescribed in accordance with subparagraph 1 shall be dispensed on the basis of a prescription stricto sensu only if

(a) the name of the person prescribing the medicinal product and the address or identification of his or her surgery, in addition to the date on which the medicinal product was prescribed and the signature of the person legally authorised to prescribe that product, may be determined; and

(b) the name and date of birth of the patient are included on the prescription.

…'

The dispute in the main proceedings and the question referred for a preliminary ruling

19 VIPA is a commercial company incorporated under Hungarian law which operates a pharmacy. During an inspection, the Institute found that VIPA had, on 25 occasions between 1 January 2014 and 15 September 2015, unlawfully dispensed prescription-only medicinal products on the basis of order forms issued by prescribing agents not authorised by the Hungarian health authorities to exercise healthcare activities. That finding concerned 21 order

forms issued by a medical company established in the United Kingdom and 4 order forms issued by a doctor practising in Austria. Consequently, by decision of 31 August 2016, the Institute imposed a fine of 45 000 000 forint (HUF) (approximately EUR 140 000), prohibited any further unlawful supply of medicinal products to the pharmacy in question and withdrew the pharmacy's operating licence.

20 VIPA brought an action against that decision before the Fővárosi Közigazgatási és Munkaügyi Bíróság (Administrative and Labour Court, Budapest, Hungary), the referring court. In support of its action, VIPA contends, in particular, that Directive 2011/24 contains only the definition of 'prescription' and that, according to Hungarian law, both prescriptions *stricto sensu* and order forms are prescriptions. Accordingly, those two categories of document should be recognised in Hungary, provided that they are issued by a person authorised to issue prescriptions in a Member State other than Hungary (which, VIPA contends, is not disputed in the present case). The Institute's position, for which there can be no justification, amounts to recognising the qualifications of health professionals of Member States other than Hungary only where they issue prescriptions *stricto sensu*, as opposed to order forms. VIPA also relies on the Court of Justice's case-law on the prohibition of measures having equivalent effect to quantitative restrictions.

21 The Institute maintains, on the other hand, that medicinal products may be lawfully dispensed on the basis of an order form only where that order form is issued by a healthcare provider authorised by the Hungarian health authorities to exercise a healthcare activity. Article 11(1) of Directive 2011/24, it asserts, relates only to prescriptions issued for a named patient. Furthermore, although in the case of a prescription *stricto sensu* the fact that it indicates the patient's name guarantees the end use to which the medicinal product will be put, that is not true of order forms. The issue of the end use of the medicinal product is, however, of crucial importance, because what are at issue are prescription-only medicinal products and the purpose of Directive 2011/24 is to protect health. Therefore, order forms, whether issued by a health care provider exercising his or her activity in Hungary or a health care provider exercising his or her activity in another Member State, fall outside the scope of EU law.

22 The referring court states that under Hungarian law there are two categories of prescription, that is to say, medical prescriptions *stricto sensu* and order forms, which can be used by doctors to order medicinal products for treating patients in the course of their healthcare activities, but that Hungarian law does not recognise the concept of 'foreign order form'. The medicinal products in question were therefore found to have been dispensed unlawfully on the ground that they were dispensed on the basis of order forms issued by healthcare professionals not entitled to practise in Hungary.

23 That court states that it has difficulty in determining whether the Hungarian legislation in question is compatible with the meaning of 'prescription' as defined in EU law and with the rule, that medical prescriptions should be mutually recognised, laid down in Article 11(1) of Directive 2011/24. The referring court is of the view that, when transposing Directive 2011/24, the Hungarian legislature laid down provisions on the prescribing and dispensing of medicinal products that are incompatible with EU law, in so far as medicinal products cannot be dispensed under the same conditions for both categories of prescriptions provided for under Hungarian law, depending on whether or not the person issuing the prescription is entitled to provide healthcare services in Hungary.

24 The referring court therefore considers it necessary to ascertain whether the prescriptions for a named patient referred to in Article 11(1) of Directive 2011/24 refer only to prescriptions issued for a specific patient or whether, in accordance with Article 71(3) of Directive 2001/83, that category also covers prescriptions whereby a specialist orders a preparation.

25 The referring court states that the Hungarian case-law is inconsistent on that point. Thus, the Fővárosi Közigazgatási és Munkaügyi Bíróság (Administrative and Labour Court, Budapest) held that Paragraph 20(1) of the Regulation of the Minister for Health contains no prohibition to the effect that doctors who are not entitled to practise in Hungary can order medicinal products subject to prescription only by means of a prescription *strictu sensu*. On the other hand, the Kúria (Supreme Court, Hungary) held that the effect of that provision is that only by means of a prescription can prescription-only medicinal products be ordered by persons who are not registered on the Hungarian register of practitioners, but who are entitled to prescribe medicinal products in another Member State. The referring court adds that, according to the Kúria (Supreme Court), order forms fall outside the scope of EU law.

26 In those circumstances, the Fővárosi Közigazgatási és Munkaügyi Bíróság (Administrative and Labour Court, Budapest) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

‘Must Article 3(k) and Article 11(1) of Directive [2011/24] be interpreted as meaning that national legislation which distinguishes between two categories of prescriptions and, only in the case of one of those categories, allows medicinal products to be dispensed to a doctor who exercises his or her healthcare activity in a State other than the Member State concerned, contrary to the mutual recognition of prescriptions and to the freedom to provide services, and therefore incompatible therewith?’

Consideration of the question referred

27 By its question, the referring court asks, in essence, whether Article 3(k) and Article 11(1) of Directive 2011/24 must be interpreted as precluding legislation of a Member State under which it is not permissible for a pharmacy in that Member State to dispense prescription-only medicinal products on the basis of an order form where that order form was issued by a health professional authorised to prescribe medicines and to exercise his or her activity in another Member State, whereas medical products may be dispensed where such an order form was issued by a health professional authorised to exercise his or her activity in the first Member State, bearing in mind that, under that legislation, such order forms do not contain the name of the patient concerned.

28 While the Institute disputes the jurisdiction of the Court of Justice with respect to that question on the ground that, by that question, the referring court does not seek an interpretation of EU law by the Court, but rather the Court’s ruling on the conformity of Hungarian law with EU law, it should be noted, as a preliminary point, that it is indeed not for the Court, in proceedings under Article 267 TFEU, to rule upon the compatibility of provisions of national law with EU law or to interpret national legislation or regulations (judgments of 1 March 2012, *Ascafor and Asidac*, C-484/10, EU:C:2012:113, paragraph 33 and the case-law cited, and of 6 October 2015, *Consorci Sanitari del Maresme*, C-203/14, EU:C:2015:664, paragraph 43). The Court does, however, have jurisdiction to give the referring court full guidance on the interpretation of EU law in order to

enable it to determine the issue of compatibility for the purposes of the case before it (judgments of 1 March 2012, *Ascafor and Asidac*, C-484/10, EU:C:2012:113, paragraph 34 and the case-law cited, and of 26 July 2017, *Europa Way and Persidera*, C-560/15, EU:C:2017:593, paragraph 35).

29 In the present case, by its question, the referring court expressly asks the Court to interpret EU law and, in particular, Article 3(k) and Article 11(1) of Directive 2011/24. In addition, it is apparent from the grounds of the order for reference that the referring court seeks an interpretation of the EU law provisions in order to give judgment on the case before it, concerning the lawfulness of the administrative decision penalising VIPA for the marketing of medicinal products at issue before that court.

30 The Court is thus called on not to rule on the conformity of Hungarian law with EU law, but to provide the referring court with the criteria for the interpretation of EU law, in order to enable it to assess whether, under EU law, it should or should not uphold the action brought before it by VIPA. Consequently, the Court has jurisdiction with respect to that question.

31 Moreover, the Institute claims that the question referred does not satisfy the requirements of Article 267 TFEU, in so far as it contains a substantive inaccuracy concerning the person or entity to which the medicinal products concerned are dispensed. In that regard, it is sufficient to point out that, when answering questions referred for a preliminary ruling, the Court must take account, under the division of jurisdiction between the Court and the national courts, of the factual and legislative context, as described in the order for reference (judgments of 21 October 2010, *Padawan*, C-467/08, EU:C:2010:620, paragraph 22 and the case-law cited, and of 6 December 2018, *Preindl*, C-675/17, EU:C:2018:990, paragraph 24 and the case-law cited). Moreover, as is apparent from paragraph 27 above, the alleged substantive inaccuracy is irrelevant to the substance of the question referred by the national court.

32 As regards that question, it must be recalled that Article 3(k) of Directive 2011/24 defines 'prescription', within the meaning of that directive, as being a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession who is legally entitled to do so in the Member State in which the prescription is issued. As regards the first subparagraph of Article 11(1) of Directive 2011/24, it provides that, if the marketing of a medicinal product is authorised on their territory, Member States are to ensure, first, that prescriptions issued for that medicinal product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force, and, secondly, that any restriction on recognition of individual prescriptions is prohibited, unless certain conditions, as specified in that provision, are met.

33 Since only the condition relating to the prescription being issued in respect of a named patient is at issue in the main proceedings, all that has to be determined is whether the obligation to recognise prescriptions provided for in Article 11(1) of Directive 2011/24 must be interpreted as applying to order forms, such as those at issue in the main proceedings, which do not contain the name of the patient for whom the medicinal products ordered are intended.

34 In accordance with the Court's settled case-law, when interpreting a provision of EU law, it is necessary to consider not only its wording but also its context and the objectives pursued by the rules of which it is part (judgments of 17 November 1983, *Merck*, 292/82, EU:C:1983:335, paragraph 12, and of 4 October 2018, *ING-DiBa Direktbank Austria*, C-191/17, EU:C:2018:809, paragraph 19 and the case-law cited).

35 As regards the wording of the provisions in question, it should be noted that Article 3(k) of Directive 2011/24, as worded, does not specify whether a prescription, within the meaning of that provision, must include the name of the patient for whom the medicinal product or medical device prescribed is intended. By contrast, it is clear from the wording of Article 11(1) of Directive 2011/24 that, in essence, in respect of medicinal products authorised to be marketed on their territory, that provision requires Member States to ensure that prescriptions issued for that medicinal product in another Member State for a named patient may, in principle, be dispensed on their territory.

36 As the Commission has stated, Article 11(1), in its Hungarian version, refers to 'prescriptions identifying the patient' (*névre szóló rendelvény*). The doubts expressed by the referring court as to the scope of that provision, set out in paragraph 24 of the present judgment, thus appear to stem from the wording of that provision in Hungarian and its comparison with the wording of the third indent of Article 71(3) of Directive 2001/83, which refers, in the same language version, to the fact that a specialist orders the preparation (*hogy a készíthousehold szakorvos rendelje MeG*).

37 However, the Court has repeatedly held that the wording used in one language version of a provision of EU law cannot serve as the sole basis for the interpretation of that provision, or be made to override the other language versions in that regard. Provisions of EU law must be interpreted and applied uniformly in the light of the versions existing in all EU languages. Where there is divergence between the various language versions of an EU legislative text, the provision in question must be interpreted by reference to its context and the objectives pursued by the rules of which it is part (judgment of 5 February 2015, *M. and Others*, C-627/13 and C-2/14, EU:C:2015:59, paragraphs 48 and 49 and the case-law cited).

38 In the present case, with the exception of the Hungarian and Portuguese versions of Article 11(1) of Directive 2011/24, all the other language versions of that provision expressly refer to a prescription referring to a patient who is named, designated by name, particular, precise, defined, specific or individual.

39 However, although the wording of that provision in Hungarian may appear less precise than that used in almost all the other language versions of that provision, it is apparent from its context and from the objectives pursued by Directive 2011/24 that such wording is not inconsistent with those other language versions, from which it follows that the obligation to recognise the requirements laid down in Article 11(1) does not apply to order forms, such as those at issue in the main proceedings, which do not contain the name of the patient for whom the medicinal product(s) ordered are intended.

40 In accordance with Article 11(2) of Directive 2011/24, Article 11(1) has been the subject of measures designed to facilitate its uniform application, which are set out in Implementing Directive 2012/52. That implementing directive states, in Article 2 thereof, that it is to apply to prescriptions, as defined in Article 3(k) of Directive 2011/24, which are issued further to a request of a patient who intends to use them in another Member State. Article 3 of that implementing directive states that Member States are to ensure that prescriptions contain at least the elements set out in the annex to that implementing directive, including the identification data for the patient, consisting of his or her surname(s) and first name(s) written out in full and his or her date of birth.

41 Implementing Directive 2012/52 thus establishes that the obligation to recognise prescriptions provided for in Article 11(1) of Directive 2011/24 does not apply to order forms, such as those at issue in the main proceedings, which do not contain the name of the patient for whom the medicinal products ordered are intended.

42 That interpretation, resulting from the context of Article 11(1), is supported by the objectives pursued by Directive 2011/24. According to Article 1(1) and (2) of that directive, read in the light of recitals 10 and 11 thereof, that directive aims to establish rules for facilitating access for individual patients to safe and high-quality cross-border healthcare. In that regard, recital 16 of that directive concerns, inter alia, the situation in which a patient purchases such medicinal products in a Member State other than that in which the prescription was issued. As regards recital 36 of that directive, it refers to the right of a patient to receive any medicinal product authorised for marketing in the Member State of treatment.

43 Similarly, recital 53 of Directive 2011/24, which relates specifically to the recognition, in one Member State, of medical prescriptions issued in another Member State, refers, in almost all its language versions, to the fact that, where medicinal products are authorised within a Member State and have been prescribed in that Member State by a member of a regulated health profession for a named patient, it should, in principle, be possible for such prescriptions to be medically recognised and for the medicinal products to be dispensed in a Member State other than that in which the medicinal products are authorised.

44 Recital 53 of that directive also states that the implementation of the principle of recognition is to be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, which are to include the adoption of a non-exhaustive list of elements to be included in prescriptions. It is precisely for the purpose of safeguarding patient safety that Implementing Directive 2012/52 was adopted, an implementing directive from which, as has been found in paragraphs 40 and 41 of the present judgment, it can be inferred unequivocally that only prescriptions which include the surname(s) and first name(s) of the patient concerned may qualify for recognition as prescriptions under Article 11(1) of Directive 2011/24.

45 First, order forms such as those at issue in the main proceedings, in so far as they do not include data for identifying the patient for whom the medicinal product or medicinal products ordered are intended, do not make it possible to guarantee the health and safety of the patient to whom those medicinal products are ultimately administered, that patient being, at the time those order forms are drawn up, still unknown. Secondly, as is apparent from the order for reference, order forms such as those at issue in the main proceedings are designed not to enable a patient to obtain medicinal products, but for a health professional, or an institution which provides healthcare, to obtain supplies of medicinal products with a view to their subsequent use in their healthcare activities.

46 In the light of those factors, it would be contrary to the objectives of Directive 2011/24, as set out in paragraphs 42 to 44 of this judgment, to consider order forms, such as those at issue in the main proceedings, to fall within the scope of the obligation to recognise prescriptions laid down in Article 11(1) of Directive 2011/24.

47 Since that provision is not, therefore, applicable to such order forms, it is necessary to interpret Article 3(k) and Article 11(1) of Directive 2011/24 as not precluding legislation of a Member State under which a pharmacy in that Member State is not permitted to dispense prescription-only medicinal products on the basis of an order form where that order form has

been issued by a health professional authorised to prescribe medicines and to exercise his or her activity in another Member State, although prescription-only medicinal products may be dispensed where such an order form has been issued by a health professional authorised to exercise his or her activity in the first Member State, bearing in mind that, under that legislation, such order forms do not contain the name of the patient concerned.

48 It does not, however, follow from that interpretation that, in circumstances such as those in the main proceedings, such national legislation automatically falls outside the scope of EU law, as the Institute submitted before the referring court, or is automatically compatible with that law, as the Hungarian Government essentially argued in its written observations.

49 As is apparent from the order for reference, those circumstances are characterised by a situation linked to trade between Member States, since VIPA was penalised by the competent authority of the Member State on whose territory it is established for having dispensed medicinal products on the basis of order forms issued by health professionals authorised to prescribe medicinal products and to exercise their activity in Member States other than that in which that pharmacy is established. Where the national legislation at issue in a dispute applies to situations that are linked to trade, the issue raised by that dispute may fall within the scope of the provisions of the FEU Treaty relating to the fundamental freedoms (see, to that effect, judgments of 15 December 1982, *Oosthoek's Uitgeversmaatschappij*, 286/81, EU:C:1982:438, paragraph 9, and of 23 February 2006, *Keller Holding*, C-471/04, EU:C:2006:143, paragraph 24).

50 In that regard, it should be borne in mind that, in the procedure laid down by Article 267 TFEU providing for cooperation between national courts and the Court of Justice, it is for the latter to provide the national court with an answer which will be of use to it and enable it to determine the case before it. Consequently, even if, formally, the referring court has limited its question to the interpretation of a specific provision of EU law, that does not prevent this Court from providing the referring court with all the elements of interpretation of EU law that may be of assistance in adjudicating in the case before it, whether or not the referring court has referred to them in the wording of its questions. It is, in that regard, for the Court to extract from all the information provided by the national court, in particular from the grounds of the order for reference, the points of EU law which require interpretation in view of the subject matter of the dispute (see, to that effect, judgments of 13 June 2013, *Hadj Ahmed*, C-45/12, EU:C:2013:390, paragraph 42 and the case-law cited, and of 21 June 2016, *New Valmar*, C-15/15, EU:C:2016:464, paragraphs 28 and 29).

51 In the present case, as follows from paragraph 49 of the present judgment, the information provided in the order for reference indicates that, in view of the subject matter of the dispute in the main proceedings, the Court must, in order to give a useful answer to the referring court, interpret other provisions of EU law.

52 In that regard, it should be noted that any national measure concerning an area which has been the subject of exhaustive harmonisation at EU level must be assessed in the light of the provisions of that harmonising measure and not in the light of primary law (judgments of 1 July 2014, *Ålands Vindkraft*, C-573/12, EU:C:2014:2037, paragraph 57 and the case-law cited, and of 12 November 2015, *Visnapuu*, C-198/14, EU:C:2015:751, paragraph 40 and the case-law cited).

53 In the present case, although Directive 2011/24 harmonised, inter alia, the conditions under which medical prescriptions issued in one Member State must be recognised in another Member State, it has not carried out an exhaustive harmonisation of the conditions for the dispensing of medicinal products by pharmacies.

54 Furthermore, although Articles 70 to 75 of Directive 2001/83 concern the classification of medicinal products and specify, inter alia, the different categories of medical prescriptions which the Member States may provide for, it must be noted, as was observed by the Advocate General in point 61 of his Opinion, that the concept of an 'order form' for medicinal products issued by a health professional for the purposes of his or her own healthcare activity or the activity of a health care establishment, such as that at issue in the main proceedings, is not covered by specific provisions in Directive 2001/83, even though it is by those means that the dispensing of medicinal products is ordered.

55 Moreover, although Directive 2001/83, and in particular Articles 79 to 82 thereof, harmonised the minimum requirements to be satisfied by applicants for and holders of an authorisation for the wholesale distribution of medicinal products (see, to that effect, judgment of 28 June 2012, *Caronna*, C-7/11, EU:C:2012:396, paragraph 44), it is not apparent from the case file before the Court or the arguments before it that VIPA was penalised under the Hungarian legislation on the wholesale distribution of medicinal products, within the meaning of Article 1(17) of Directive 2001/83, a matter which is, however, for the referring court to determine. In that regard, it should be noted that a company, such as VIPA, which operates a pharmacy may, where appropriate, engage in the activity of wholesale distribution of medicinal products only if it satisfies all the conditions imposed in that regard by Directive 2001/83 and, in particular, only if it is authorised to engage in activity as a wholesaler in medicinal products, within the meaning of Article 77 of that directive (see also, to that effect, judgment of 28 June 2012, *Caronna*, C-7/11, EU:C:2012:396, paragraphs 28, 29, 37, 41 and 44 to 50).

56 In those circumstances, it is necessary for the Court to carry out its analysis on the basis that what is at issue in the main proceedings is not activities involved in the wholesale distribution of medicinal products, but rather the conditions applicable to the dispensing, by pharmacies, of prescription-only medicinal products where those products are ordered by health professionals with a view to their use in the context of their healthcare activity, and for the Court to find that the national legislation relating to those conditions for the dispensing of medicinal products does not fall within a harmonised area of EU law. Consequently, the determination of the relevant rules remains within the competence of the Member States, subject to the limits laid down by the provisions of FEU Treaty, and in particular those relating to the fundamental freedoms (see, by analogy, judgments of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 25 and the case-law cited, and of 28 June 2012, *Caronna*, C-7/11, EU:C:2012:396, paragraph 43).

57 National legislation, such as that at issue in the main proceedings, may concern both the freedom to provide services, mentioned by the referring court in its question, in so far as it applies to pharmacies whose activities include the retail sale of medicinal products, and to the free movement of goods, since it governs the conditions for the issue of certain types of medicinal products, by pharmacies, to health professionals authorised to prescribe medicinal products and to exercise their activity in a Member State other than that in which those pharmacies are established.

58 Where a national measure relates to both the free movement of goods and the freedom to provide services, the Court will in principle examine that measure in relation to only one of those two fundamental freedoms if it is apparent that one of them is entirely secondary in relation to the other and may be considered together with it (judgments of 22 January 2002, *Canal Satélite Digital*, C-390/99, EU:C:2002:34, paragraph 31 and the case-law cited, and of 4 October 2011, *Football Association Premier League and Others*, C-403/08 and C-429/08, EU:C:2011:631, paragraph 78).

59 The national legislation at issue in the main proceedings does not, however, concern the exercise of the activity of pharmacist as such, nor is it intended to govern the conditions under which, in Hungary, the status of members of a regulated health profession lawfully authorised to issue prescriptions in another Member State is recognised, as VIPA submitted before the national court. Nor is the cross-border performance of a healthcare activity by professionals who are authorised to exercise their activity in other Member States at issue in the main proceedings, as the Spanish Government, in essence, suggested, as those professionals are not the subject matter of the proceedings before the referring court.

60 However, that national legislation, which lays down the conditions subject to which pharmacies may dispense prescription-only medicinal products, prohibits, in certain circumstances, the sale by pharmacies of certain medicinal products, which, moreover, as is not disputed, come under the definition of 'goods' for the purposes of the provisions of the FEU Treaty on the free movement of goods (see, to that effect, judgment of 8 June 2017, *Medisanus*, C-296/15, EU:C:2017:431, paragraph 53 and the case-law cited). The cross-border element which renders the provisions of the FEU Treaty applicable in the main proceedings is, moreover, the sale, from one Member State to other Member States, of prescription-only medicinal products, and, therefore, the cross-border movement of goods. Consequently, the aspect of free movement of goods prevails, in the present case, over that of freedom to provide services and, as a result, reference must be made to the provisions of the FEU Treaty relating to the first of those freedoms.

61 Moreover, since the case in the main proceedings does not concern the import, but rather the export of prescription-only medicinal products from Hungary to other Member States, only Article 35 TFEU, which prohibits measures having equivalent effect to quantitative restrictions on exports between Member States, is applicable.

62 In accordance with the Court's case-law, a national measure applicable to all traders active in the national territory which has a greater effect on goods leaving the market of the exporting Member State than on the marketing of goods in the domestic market of that Member State is covered by the prohibition laid down by Article 35 TFEU (judgments of 21 June 2016, *New Valmar*, C-15/15, EU:C:2016:464, paragraph 36 and the case-law cited, and of 28 February 2018, *ZPT*, C-518/16, EU:C:2018:126, paragraph 43).

63 Furthermore, any restriction on trade, even minor, is prohibited by Article 35 TFEU provided that it is not too uncertain or too indirect, in which case it escapes that classification (see, to that effect judgments of 21 June 2016, *New Valmar*, C-15/15, EU:C:2016:464, paragraphs 37 and 45 and the case-law cited, and of 28 February 2018, *ZPT*, C-518/16, EU:C:2018:126, paragraph 44).

64 In the present case, the national legislation at issue provides that the dispensing by a pharmacy, on the basis of order forms, of prescription--only medicinal products is permitted where that order form has been issued by a healthcare professional authorised to exercise his or her activity in Hungary. By contrast, where an order form for prescription-only medicinal products has been

issued by a healthcare professional authorised to prescribe medicinal products and to carry on his or her activity in a Member State other than in Hungary, the effect of that legislation is that such dispensing is not permitted by law. It is also apparent from the order for reference that the purpose of order forms is to enable healthcare professionals to order medicinal products used in the treatment of patients in connection with their healthcare activities.

65 Consequently, where prescription-only medicinal products are ordered by means of order forms by healthcare professionals who are not authorised to exercise their activity in Hungary, but are entitled to prescribe medicinal products and to exercise their activity in other Member States, those medicinal products are in all probability intended to be used for the purpose of the treatment of patients on the territory of another Member State and, consequently, are in all probability intended to leave the territory of that first Member State.

66 Such national legislation, in so far as it has the effect of preventing the export by a pharmacy of a Member State of prescription-only medicinal products on the basis of order forms, although the sale by a pharmacy of the same medicinal products by means of the same order forms is permitted on the national territory has, therefore, a greater impact on the export of such medicinal products from the market of the exporting Member State, namely Hungary, than on the marketing of those medicinal products on the domestic market of that Member State. Accordingly, it is caught by the prohibition laid down in Article 35 TFEU. Furthermore, the restrictive effects of that legislation cannot be considered to be too uncertain or too indirect for it to be regarded, in accordance with the Court's case-law referred to in paragraph 63 of the present judgment, as not constituting a restriction within the meaning of that article.

67 A national measure which restricts the free movement of goods may, however, be justified, inter alia, by Article 36 TFEU, in particular on grounds of the protection of human health and human life (see, to that effect, judgments of 2 December 2010, *Ker-Optika*, C-108/09, EU:C:2010:725, paragraph 57, and of 12 November 2015, *Visnapuu*, C-198/14, EU:C:2015:751, paragraph 110).

68 As the Hungarian Government specifically relies on the need to ensure the protection of the health of the Hungarian public, and in particular on the need to ensure a stable, reliable and high-quality supply of medicinal products to that public, it must be borne in mind that the Court has previously recognised that the need to ensure that a country has reliable supplies for essential medical purposes, in particular a supply of medicinal products to the public that is reliable and of good quality, may, under Article 36 TFEU, justify a restriction on trade between Member States if that objective contributes to protecting human health and human life (see, to that effect, judgments of 28 March 1995, *Evans Medical and Macfarlan Smith*, C-324/93, EU:C:1995:84, paragraph 37, and of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraph 31).

69 Legislation which is capable of restricting a fundamental freedom guaranteed by the FEU Treaty, such as the free movement of goods, can, however, be properly justified only if it is appropriate for securing the attainment of the objective pursued and does not go beyond what is necessary in order to attain it (judgments of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 48 and the case-law cited, and of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraph 34).

70 It is, in each particular case, for the national authorities to provide the necessary evidence to that effect. Where a national court examines national legislation in the light of the justification relating to protection of human health and human life under Article 36 TFEU, that court must examine

objectively whether it may reasonably be concluded from the evidence submitted by the Member State concerned that the means chosen are appropriate for the attainment of the objectives pursued and whether it is possible to attain those objectives by measures that are less restrictive of the free movement of goods (see, to that effect, judgments of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 50, and of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraphs 35 and 36 and the case-law cited).

71 That said, it must be borne in mind that, when assessing whether the principle of proportionality has been observed in the field of public health, account must be taken of the fact that human health and human life rank foremost among the assets and interests protected by the FEU Treaty and that it is for the Member States to determine the degree of protection which they wish to afford to public health and the way in which that degree of protection is to be achieved. Since the degree of protection may vary from one Member State to another, Member States must be allowed a measure of discretion (judgments of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 19 and the case-law cited, and of 8 June 2017, *Medisanus*, C-296/15, EU:C:2017:431, paragraph 82 and the case-law cited). Consequently, the fact that one Member State imposes less strict rules than those imposed by another Member State does not mean that the latter's rules are disproportionate (see, to that effect, judgments of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 51 and the case-law cited, and of 9 December 2010, *Humanplasma*, C-421/09, EU:C:2010:760, paragraph 40).

72 As regards the suitability of national legislation, such as that at issue in the main proceedings, to achieve the stated objective, it must be borne in mind that, where there is uncertainty as to the existence or extent of risks to human health, a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. Furthermore, a Member State may take the measures that reduce, as far as possible, a public-health risk, including, more specifically, a risk to the reliability and quality of the provision of medicinal products to the public (judgment of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 30 and the case-law cited).

73 In that context, attention must be drawn to the very particular nature of medicinal products, and in particular prescription-only medicinal products, which are alone at issue in the main proceedings, in that the therapeutic effects of medicinal products distinguish them substantially from other goods (see, to that effect, judgments of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 31 and the case-law cited, and of 11 December 2003, *Deutscher Apothekerverband*, C-322/01, EU:C:2003:664, paragraph 117).

74 In the present case, it must be held that the legislation at issue in the main proceedings, in so far as it does not permit the dispensing of prescription-only medicinal products on the basis of order forms where those forms have been issued by a health professional who is not authorised to exercise his or her activity on the territory of the Member State in which the pharmacy which dispenses the medicinal product is established, does limit the export of such medicinal products from the territory of the first Member State. Such legislation is thus capable of ensuring that those medicinal products benefit the public of the first Member State, thereby helping to guarantee a stable, reliable and high-quality supply of prescription-only medicinal products to the public of that Member State.

75 In that regard, it should further be pointed out that under the second paragraph of Article 81(2) of Directive 2001/83, the holder of a marketing authorisation for a medicinal product and the distributors of that medicinal product which is in fact placed on the market in a Member State are, within the limits of their responsibilities, to ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

76 Whilst, by means of order forms, such as those at issue in the main proceedings, the export of prescription-only medicinal products, in quantities which may be significant, for the purpose of treatment of patients on the territory of another Member State, was possible, that could lead, given the obligation laid down in the second paragraph of Article 81, to pharmacies being insufficiently supplied and, accordingly, to inadequate coverage of the needs of patients in the Member State concerned for prescription-only medicinal products.

77 In the light of those factors, such legislation appears appropriate for the purpose of achieving the objective, relied on by the Hungarian Government, of guaranteeing a stable, reliable and high-quality supply of medicinal products to the public of that Member State.

78 As regards the proportionality of that legislation, it should be noted that such legislation does not appear to have the effect of preventing any dispensing by a pharmacy of medicinal products on the basis of a prescription issued by a healthcare professional authorised for that purpose in another Member State or from preventing any form of export of medicinal products from Hungary to other Member States. First, it has not been claimed that named prescriptions which comply with the conditions laid down in Article 11(1) of Directive 2011/24 and which are dispensed in a Member State other than Hungary are not recognised in Hungary. Secondly, the Hungarian Government argued at the hearing that the supply to healthcare professionals of other Member States of prescription-only medicinal products in Hungary, although it is not actually permitted on the basis of order forms, such as those at issue in the main proceedings, is nevertheless possible by other means, such as the wholesale distribution of medicinal products, referred to in Directive 2001/83, which it is for the national court to determine.

79 Contrary to what the Commission maintained at the hearing, it is not clear that less restrictive measures, such as a restriction on the quantity of medicinal products which may be ordered by means of such order forms, or legislating to enable pharmacies to honour such order forms according to the stock of the medicinal product concerned which they hold, are such as to ensure that the objective pursued by the national legislation at issue is achieved with the same effectiveness. In that regard, it must be noted that such restrictions do not necessarily exclude the effects on the stocks of prescription-only medicinal products, available in pharmacies, resulting from the cumulative use of such order forms, nor do they make it possible to compensate for the fact that, as stated in paragraph 75 above, pharmacies in the Member States are in principle supplied according to the needs of the public on the territory of the Member State concerned.

80 In addition, and more importantly, as the Advocate General, in essence, also noted in points 110 and 111 of his Opinion, it must be found that, when they are exported by means of such order forms, prescription-only medicinal products, the public supply of which needs to be strictly controlled (see, to that effect, judgment of 11 December 2003, *Deutscher Apothekerverband*, C-322/01, EU:C:2003:664, paragraph 117), leave the distribution system for those medicinal products established by that Member State. However, none of the measures envisaged by the

Commission enables Hungary to ensure, as effectively as by the legislation at issue, but less restrictively, monitoring of the conditions under which such medicinal products are distributed on the territory for which it is responsible.

81 In the light of those factors and the discretion enjoyed by the Member States as to the determination of the degree of protection which they wish to afford to public health and the way in which that degree of protection is to be achieved, referred to in paragraph 71 above, such legislation is therefore also proportionate to the objective pursued.

82 It follows from those considerations, subject to the determinations to be made by the referring court, that Articles 35 and 36 TFEU must be interpreted as not precluding national legislation, such as that at issue in the main proceedings, in so far as that legislation is justified by the objective of protecting human health and human life, is appropriate for securing the attainment of that objective and does not go beyond what is necessary to attain it.

83 In the light of all the foregoing considerations, the answer to the question referred is that:

– Article 3(k) and Article 11(1) of Directive 2011/24 must be interpreted as not precluding legislation of a Member State under which it is not permissible for a pharmacy in that Member State to dispense prescription-only medicinal products on the basis of an order form where that order form has been issued by a healthcare professional authorised to prescribe medicinal products and to exercise his or her activity in another Member State, whereas such dispensing of those products is permitted where that order form has been issued by a healthcare professional authorised to exercise his or her activity in the first Member State, bearing in mind that, under that legislation, such order forms do not contain the name of the patient concerned;

– Articles 35 and 36 TFEU must be interpreted as not precluding such legislation of a Member State, in so far as that legislation is justified by the objective of protecting human health and human life, is appropriate for securing the attainment of that objective and does not go beyond what is necessary to attain it, which is for the national court to determine.

Costs

84 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fifth Chamber) hereby rules:

Article 3(k) and Article 11(1) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare must be interpreted as not precluding legislation of a Member State under which it is not permissible for a pharmacy in that Member State to dispense prescription-only medicinal products on the basis of an order form where that order form has been issued by a healthcare professional authorised to prescribe medicinal products and to exercise his or her activity in another Member State, whereas such dispensing of those products is permitted where that order form has been issued by a healthcare professional authorised to

exercise his or her activity in the first Member State, bearing in mind that, under that legislation, such order forms do not contain the name of the patient concerned.

Articles 35 and 36 TFEU must be interpreted as not precluding such legislation of a Member State, in so far as that legislation is justified by the objective of protecting human health and human life, is appropriate for securing the attainment of that objective and does not go beyond what is necessary to attain it, which is for the national court to determine.

[Signatures]