JUDGMENT OF THE COURT (Fourth Chamber)

27 October 2016 (*)

(Reference for a preliminary ruling — Free movement of goods — Articles 34 and 36 TFEU — Quantitative restrictions — Parallel imports of veterinary medicinal products — Directive 2001/82/EC — Article 65 — National system of prior authorisation — Livestock farmers excluded from simplified marketing authorisation procedure — Obligation to hold a wholesale trading authorisation — Obligation to have an establishment within the Member State of import — Pharmacovigilance obligations)

In Case C-114/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the cour d'appel de Pau (Court of Appeal, Pau, France), made by decision of 15 January 2015, received at the Court on 6 March 2015, in the criminal proceedings against

**Association des utilisateurs et distributeurs de l'agrochimie européenne (Audace),**

**Association des éleveurs solidaires,**

**Cruzalebes EARL,**

**Des deux rivières EARL,**

**Mounacq EARL,**

**Soulard Max EARL,**

**Francisco Xavier Erneta Azanza,**

**Amestoya GAEC,**

**La Vinardière GAEC reconnu,**

**Lagunarte GAEC,**

**André Jacques Iribarren,**

**Ramuntcho Iribarren,**

**Phyteron 2000 SAS,**

**Cataloune SCL,**

intervening party:

**Conseil national de l'Ordre des vétérinaires,** formerly Conseil supérieur de l'Ordre des vétérinaires,

**Syndicat national des vétérinaires d'exercice libéral,**

**Administration des douanes et des droits indirects,**

THE COURT (Fourth Chamber),

composed of T. von Danwitz, President of the Chamber, E. Juhász, S. Rodin, K. Jürimäe and C. Lycourgos (Rapporteur), Judges,

Advocate General: P. Mengozzi,

Registrar: V. Tourrès, Administrator,

having regard to the written procedure and further to the hearing on 28 January 2016,

after considering the observations submitted on behalf of:

– the Association des utilisateurs et distributeurs de l'agrochimie européenne (Audace) and Phyteron 2000 SAS, by J.-P. Montenot, avocat, and D. Roques,

– the Association des éleveurs solidaires, Amestoya GAEC, Lagunarte GAEC, Des deux rivières EARL, Soulard Max EARL, Cruzalebes EARL, Cataloune SCL and F.X. Erneta Azanza, A.J. Iribarren and R. Iribarren, by P. Moriceau, avocat,

– the Conseil national de l'Ordre des vétérinaires, formerly Conseil supérieur de l'Ordre des vétérinaires, by J. Dechezleprêtre and G. Dechezleprêtre, avocats,

– the French Government, by D. Colas, R. Coesme and F. Gloaguen, acting as Agents,

– the Greek Government, by G. Kanellopoulos and A. Vasilopoulou, acting as Agents,

– the Netherlands Government, by K. Bulterman and J. Langer, acting as Agents,

– the European Commission, by E. Manhaeve, A. Sipos and M. Šimerdová, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 10 March 2016,

gives the following

**Judgment**

1 This request for a preliminary ruling concerns the interpretation of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1), as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ 2009 L 188, p. 14) ('Directive 2001/82'), of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ 2006 L 376, p. 36) and of Articles 34, 36 and 56 TFEU.

2 The request has been made in criminal proceedings against the Association des utilisateurs et distributeurs de l'agrochimie européenne (Audace), Phyteron 2000 SAS ('Phyteron'), the Association des éleveurs solidaires and nine livestock farmers (together 'the livestock farmers involved') concerning unauthorised parallel imports of veterinary medicinal products.

**Legal context**

*EU law*

3 Recitals 2 and 34 of Directive 2001/82 state:

‘(2) The primary purpose of any rules for the production and distribution of veterinary medicinal products must be the safeguarding of public health.

...

(34) Holders of marketing authorisations [(“MAs”)] should be proactively responsible for ongoing pharmacovigilance of the veterinary medicinal products they place on the market.’

4 Article 5 of that directive provides:

‘1. No veterinary 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 unless an [MA] has been granted in accordance with Regulation (EC) No 726/2004 [of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1)].

...

2. The [MA] holder shall be responsible for the marketing of the medicinal product. The designation of a representative shall not relieve the [MA] holder of his legal responsibility.’

5 In accordance with Article 9 of Directive 2001/82, no veterinary medicinal product may be administered to animals unless the MA has been issued, except for the tests of veterinary medicinal products referred to in Article 12(3)(j) of that directive which have been accepted by the competent national authorities, following notification or authorisation, in accordance with the national rules in force.

6 Article 61(1) of Directive 2001/82 is worded as follows:

‘1. The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the immediate packaging and the outer packaging. Member States shall take all appropriate measures to ensure that the package leaflet relates solely to the veterinary medicinal product with which it is included. The package leaflet shall be written in terms that are comprehensible to the general public and in the official language or languages of the Member State in which the medicinal product is marketed.

The first subparagraph shall not prevent the package leaflet from being printed in several languages, provided that the information given is identical in all the languages.

Competent authorities may exempt labels and package leaflets for specific veterinary medicinal products from the obligation for certain particulars to appear and for the leaflet to be in the official language or languages of the Member State in which the product is placed on the market, when the product is intended to be administered only by a veterinarian.’

7 Under Article 62 of that directive, where the provisions of Title V of the directive, concerning the labelling and package insert of veterinary medicinal products, are not observed and a formal notice addressed to the person concerned has been ineffectual, Member States' competent authorities may suspend or revoke the MA.

8 Article 65 of Directive 2001/82, which forms part of Title VI thereof, entitled 'Possession, distribution and dispensing of veterinary medicinal products', provides, as regards the wholesale distribution of veterinary medicinal products:

'1. Member States shall take all appropriate measures to ensure that wholesale distribution of veterinary medicinal products is subject to the holding of an authorisation and to ensure that the time taken for the procedure for granting this authorisation does not exceed 90 days from the date on which the competent authority receives the application.

Member States may exclude supplies of small quantities of veterinary medicinal products from one retailer to another from the scope of the definition of wholesale distribution.

2. In order to obtain the authorisation for distribution, the applicant shall have at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down in the Member State concerned as regards the storage and handling of veterinary medicinal products.

3. The holder of the authorisation for distribution shall be required to keep detailed records. [Certain] information shall be recorded in respect of each incoming or outgoing transaction ...

4. Member States shall take all appropriate measures to ensure that wholesalers supply veterinary medicinal products only to persons permitted to carry out retail activities in accordance with Article 66, or to other persons who are lawfully permitted to receive veterinary medicinal products from wholesalers.

5. Any distributor, not being the [MA] holder, who imports a product from another Member State shall notify the [MA] holder and the competent authority in the Member State to which the product will be imported of his intention to import it. In the case of products which have not been granted an authorisation pursuant to Regulation (EC) No 726/2004, the notification to the competent authority shall be without prejudice to additional procedures provided for in the legislation of that Member State.'

9 Under the first paragraph, point (aa), of Article 67 of Directive 2001/82, without prejudice to stricter Community or national rules relating to dispensing veterinary medicinal products and serving to protect human and animal health, a veterinary prescription shall be required for dispensing to the public veterinary medicinal products for food-producing animals. The second paragraph of Article 67 of that directive provides that 'Member States shall take all necessary measures to ensure that, in the case of medicinal products supplied only on prescription, the quantity prescribed and supplied shall be restricted to the minimum amount required for the treatment or therapy concerned'.

10 Article 68(1) of that directive states:

'1. Member States shall take all measures necessary to ensure that only persons empowered under their national legislation in force possess or have under their control veterinary medicinal products or substances which may be used as veterinary medicinal products that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties.'

11 Under the first paragraph of Article 69 of Directive 2001/82, ‘Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products to such animals for five years after their administration, including when the animal is slaughtered during the five-year period’.

12 Article 72 of that directive provides:

‘1. Member States shall take all appropriate measures to encourage the reporting to the competent authorities of suspected adverse reactions to veterinary medicinal products.

2. Member States may impose specific requirements on veterinary practitioners and other healthcare professionals in respect of the reporting of suspected serious or unexpected adverse reactions and human adverse reactions.’

13 Article 74 of that directive provides:

The [MA] holder shall have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance.

That qualified person shall reside in the Community and shall be responsible for [certain tasks] ...

...’

14 Article 75 of the directive provides:

‘1. The [MA] holder shall be required to maintain detailed records of all suspected adverse reactions occurring either in the Community or in a third country.

Save in exceptional circumstances, these reactions shall be communicated electronically in the form of a report in accordance with the guidelines referred to in Article 77(1).

2. The [MA] holder shall record all suspected serious adverse reactions and human adverse reactions relating to the use of veterinary medicinal products that are brought to his attention, and report them promptly to the competent authority of the Member State on whose territory the incident occurred, and no later than 15 days following receipt of the information.

The [MA] holder shall also record all suspected serious adverse reactions and human adverse reactions related to the use of veterinary medicinal products of which he can reasonably be expected to have knowledge, and report them promptly to the competent authority of Member State on whose territory the incident occurred, and no later than 15 days following receipt of the information.

...’

*French legislation*

15 Article L. 5142-1 of the Code de la santé publique (‘the Public Health Code’) provides:

‘The manufacture, import, export and wholesale distribution of veterinary medicinal products, the manufacture, import, and distribution of medicinal products undergoing clinical trials and the use of veterinary medicinal products are permitted only in the establishments governed by this Chapter.

All undertakings which have at least one of the establishments referred to in the first subparagraph must be owned by a pharmacist, a veterinarian or a company whose management or executive board includes a pharmacist or a veterinarian ...'

16 Article L. 5142-2 of the Public Health Code provides, in particular, that 'the opening of an establishment covered by Article L. 5142-1 is subject to authorisation from the Agence nationale chargée de la sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health and Safety) [("ANSES")]'.

17 Article R. 5141-104 of that code provides:

'An undertaking using a veterinary medicinal product shall be required:

1. to maintain detailed records of all suspected adverse reactions occurring either inside or outside the European Union;

2. to register any suspected adverse reaction in animals and any suspected adverse reaction in humans as a result of use of veterinary medicinal products and any suspected transmission via a veterinary medicinal product of any infectious agent of which it has become aware or which has been brought to its attention and to report it at the latest within 15 days to the Director-General of [ANSES] if that reaction occurred on French territory or to the authorities of the Member State on the territory of which it occurred;

3. to report without delay to the Director-General of [ANSES] any suspected serious unexpected adverse reaction in animals, any suspected adverse reaction in humans and any suspected transmission via a veterinary medicinal product of any infectious agent occurring of a non-Member State of the EU of which it becomes aware and to inform the European Medicines Agency and the competent authorities of the other EU Member States in which the veterinary medicinal product is authorised no later than 15 days following receipt of the information.

...'

18 Article R. 5141-105 of that code provides as follows:

'Without prejudice to the conditions laid down when [an MA] is granted pursuant to the provisions of the fourth subparagraph of Article L. 5141-5, the undertaking using the veterinary medicinal product shall send to the Director-General of [ANSES], in the form of an up-to-date periodic report on security, information on the adverse effects which it has declared, or which have been brought to its attention, along with a scientific assessment of the benefits and risks of the veterinary medicinal product:

...

After issue of the [MA], the undertaking using the veterinary medicinal product may request an amendment of the abovementioned periodicity in accordance with the procedure applicable as regards amendment of the authorisation under consideration.'

19 Article R. 5141-108 of the Public Health Code introduces the obligation on undertakings using veterinary medicinal products to have permanently available the services of a person, pharmacist or veterinarian, resident in the EU, who is responsible for veterinary pharmacovigilance. The name of that person, his status and his details are to be communicated to the Director-General of ANSES and he is responsible for gathering,

handling and making accessible to all persons entitled thereto the information concerning all the suspected adverse reactions of which he has been informed and to keep that information for at least 5 years from the date of its receipt. In addition, that person must prepare the reports referred to in Article R. 5141-105 to be sent to the Director-General of ANSES. He is also to ensure that the requests of the Director-General of ANSES for additional information necessary to veterinary pharmacovigilance are rapidly met in full.

20 Article R. 5141-123-6 of that code provides:

‘The importation of a proprietary veterinary medicinal product with a view to marketing it in France constitutes a parallel import where:

1. The product comes from another Member State of the EU or a State which is a party to the Agreement on the European Economic Area in which it has obtained [an MA] for the same target animals;

2. The product’s quantitative and qualitative composition in terms of the active substances and excipients, pharmaceutical form and therapeutic effects are identical to those of a proprietary veterinary medicinal product which has obtained [an MA] granted by [ANSES].

However, in the circumstances provided for in paragraph I, subparagraphs 3 and 4, of Article R. 5141-123-8, the proprietary product may contain different quantities of active substances, different excipients or excipients of a different nature from those in the proprietary product which has obtained [an MA] granted by [ANSES] where those differences have no therapeutic effect and do not pose a risk to public health.’

21 Article R. 5141-123-7 of that code provides:

‘Unless precluded on human or animal health grounds, parallel import authorisations shall be granted provided that the following conditions are fulfilled:

1. The proprietary veterinary medicinal product has been obtained from an undertaking authorised under Article 65 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 as amended establishing a Community Code for veterinary medicinal products;

2. The batches of that proprietary medicinal product have been released in accordance with Article 55 of that directive.

3. Subject to the provisions of Article R. 5141-123-8, the contents by weight, volume or number of dose-units, the summary of the product characteristics, the conditions for its prescription, supply and administration, the package insert and the labelling of the proprietary veterinary medicinal product to be marketed are identical to those of the proprietary veterinary medicinal product which has been granted [an MA] in France.

Moreover, on human or animal health grounds, the Director-General of ANSES may make the parallel import authorisation subject to a requirement to alter the initially proposed name.’

22 Article L. 5141-123-17 of the code provides:

‘Use, as defined in the second sentence of subparagraph 3 of Article R. 5142-1 and, as regards pharmacovigilance, in Articles R. 5141-104, R. 5141-105 and R. 5141-108, of a

proprietary veterinary medicinal product covered by a parallel import authorisation shall be made by the holder of that authorisation, provided that he has obtained the authorisation to open an establishment provided for in Article L. 5142-2.'

23 Article L. 5142-1 of the Public Health Code provides:

'The following shall mean: ...

3. User: the undertaking comprising one or more veterinary pharmaceutical establishments using veterinary medicinal products other than those subject to clinical trials and than medicated feedingstuffs. Use shall include wholesale transactions or transfer free of charge, advertising, information, pharmacovigilance, consignment tracking and, if appropriate, consignment withdrawal and, if necessary, relevant storage. The use shall be made by the [MA] holder referred to in Article L. 5141-5 or the holder of the registration referred to in Article L. 5141-9 or, on behalf of that holder, either by another undertaking or by both, each, in that case, carrying out one or several categories of operations constituting use of the veterinary medicinal product;

...'

24 Article R. 5142-42 of that code provides:

'Veterinary pharmaceutical establishments shall operate in accordance with the good practices set out in Article L. 5142-3 which are applicable to them. They shall have, in particular:

1. Premises which are equipped, arranged and maintained according to the activities involving medicinal products which are carried out there;

2. The human and material resources necessary in order to carry out those activities.

Every year, they shall provide the Director-General of [ANSES] with a report on their establishment, the form and content of which shall be established on the basis of a proposal from the Director-General of [ANSES] ...'

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

25 In January 2008, the French Veterinary Services inspected a livestock farm in Itxassou (France) where they discovered Spanish veterinary medicinal products, invoices from Landizoo, a Spanish company, and prescriptions made out by a Spanish veterinary surgeon, Dr Francisco Xavier Erneta Azanza, who is registered both with the Spanish Veterinarian Association and the French Veterinarian Association.

26 By letter of 10 April 2008, the Direction départementale des services vétérinaires des Pyrénées-Atlantiques (Pyrénées-Atlantiques Departmental Directorate of Veterinary Services, France) lodged a complaint under the code de procédure pénale (Criminal Procedure Code) with the procureur de la République de Bayonne (Public Prosecutor, Bayonne, France) about the activities of that veterinary surgeon.

27 The preliminary investigation carried out by the service national de la douane judiciaire de Bordeaux (National Judicial Customs Department of Bordeaux, France) revealed that, on the basis of prescriptions signed by that veterinary surgeon, a number of livestock farmers in the south-western region of France had purchased veterinary medicinal products from Landizoo.

The investigation also revealed financial links between Phyteron and the Association des éleveurs solidaires and Landizoo.

28 Searches carried out on the French farms involved revealed the presence of Spanish veterinary medicinal products, some of which were the subject of an MA in Spain, but not in France. In that regard, at the hearing before the Court of Justice, Audace confirmed that Dr Erneta Azanza prepared, for the livestock farmers concerned, prescriptions for veterinary medicinal products and that those farmers then purchased those products from Landizoo.

29 By a judgment of 10 December 2013, the tribunal correctionnel de Bayonne (Criminal Court, Bayonne, France) found all the livestock farmers concerned guilty of the crime of importing veterinary medicinal products without any authorisation, registration or certificate and of the transport of goods deemed to be imported as contraband and imposed various criminal penalties on them.

30 On 13 December 2013, the applicants in the main proceedings appealed against that judgment to the cour d'appel de Pau (Court of Appeal, Pau, France). That court states that no health risk was discovered in the livestock farms inspected, even though that formed the basis for the veterinary services' complaint, which refers to a widespread practice of using illegal imports and the unlawful practice of veterinary medicine. It adds that a number of medicinal products imported from Spain by those appellants have been issued with an MA in that Member State and that Audace and Phyteron submit that, since 2005, a single parallel import authorisation has been issued for veterinary medicinal products, while, at the same time, the price distortions between the French Republic and other Member States have resulted in hundreds of authorisations being issued, as in the plant protection products sector.

31 In those circumstances, the cour d'appel de Pau (Court of Appeal, Pau) decided to stay proceedings and refer the following questions to the Court for a preliminary ruling:

'(1) Does national legislation comply with Articles 34 to 36 TFEU in so far as it reserves access to parallel imports of veterinary medicinal products exclusively to wholesale distributors in possession of the authorisation provided for under Article 65 of Directive [2001/82], thus excluding those with retail distribution rights and livestock farmers?

(2) On a proper construction of Article 65 of Directive [2001/82] and Article 16 of Directive [2006/123], is a Member State entitled not to recognise authorisations for the wholesale distribution of veterinary medicinal products that are issued by the competent authorities of other Member States to their own nationals and to require that those nationals additionally hold wholesale distribution authorisations issued by its own competent authorities in order to be entitled to apply for and to use authorisations for the parallel importation of veterinary medicinal products within that Member State?

(3) Does national legislation comply with Articles 34, 36 and 56 TFEU and Article 16 of Directive [2006/123] in so far as it assimilates parallel importers of veterinary medicinal products to holders of an operating licence which is not required under [Directive 2001/82] and which consequently requires such importers to have available to them an establishment in the territory of the Member State concerned and to have successfully completed all the pharmacovigilance operations provided for under Articles 72 to 79 of Directive [2001/82]?'

**Consideration of the questions referred**

*Admissibility*

32 The French Government submits that this request for a preliminary ruling is not admissible. First of all, it submits that the referring court fails entirely to present the regulatory framework surrounding the dispute in the main proceedings and does not explain the reasons for its view that the provisions of French law apply to that dispute. Next, that court does not give any precise indication of the reasons which led it to query the interpretation of the provisions of EU law referred to in the questions referred or of the need to answer those questions in order to resolve the dispute in the main proceedings. Finally, nor does that court explain the reasons for the choice of provisions of EU law of which it requests an interpretation or the link which it establishes between them and the national legislation applicable to the main proceedings.

33 In that regard, it must be borne in mind that, according to the Court's settled case-law, in the context of the cooperation between the Court and the national courts provided for in Article 267 TFEU, it is solely for the national court before which a dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine, in the light of the particular circumstances of the case, both the need for a preliminary ruling to enable it to deliver judgment and the relevance of the questions which it submits to the Court. Consequently, where questions submitted concern the interpretation of EU law, the Court of Justice is bound, in principle, to give a ruling (judgment of 8 September 2015, *Taricco and Others*, C-105/14, EU:C:2015:555, paragraph 29 and the case-law cited).

34 Accordingly, questions concerning EU law enjoy a presumption of relevance. The Court may refuse to rule on a question referred by a national court for a preliminary ruling only where it is quite obvious that the interpretation of EU law that is sought is unrelated to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (judgment of 8 September 2015, *Taricco and Others*, C-105/14, EU:C:2015:555, paragraph 30 and the case-law cited).

35 It must be borne in mind, in that regard, that, in the context of the cooperation instituted by Article 267 TFEU, the need to provide an interpretation of EU law which will be of use to the national court means that the national court is bound to observe scrupulously the requirements concerning the content of a request for a preliminary ruling, expressly set out in Article 94 of the Rules of Procedure of the Court of Justice, of which the referring court should be aware (see, to that effect, judgment of 5 July 2016, *Ognyanov*, C-614/14, EU:C:2016:514, paragraphs 18 and 19 and the case-law cited).

36 It must also be emphasised in that regard that the information provided in orders for reference serves not only to enable the Court to give useful answers but also to ensure that it is possible for the Governments of the Member States and other interested parties to submit observations in accordance with Article 23 of the Statute of the Court of Justice of the European Union. It is the Court's duty to ensure that that possibility is safeguarded, bearing in mind that, by virtue of the abovementioned provision, only the orders for reference are notified to the interested parties (see, inter alia, judgment of 1 April 1982, *Holdijk and Others*, 141/81 to 143/81, EU:C:1982:122, paragraph 6, and order of 3 July 2014, *Talasca*, C-19/14, EU:C:2014:2049, paragraph 23).

37 In fact, given that it is the order for reference that serves as the basis for the proceedings before the Court, it is essential that the national court should give, in the order for reference

itself, the factual and regulatory context of the case in the main proceedings and at least a minimum amount of explanation of the reasons for the choice of the provisions of EU law it seeks to have interpreted and on the link it establishes between those provisions and the national legislation applicable to the proceedings pending before it (see, inter alia, judgment of 21 February 2013, *Mora IPR*, C-79/12, not published, EU:C:2013:98, paragraph 37, and order of 3 July 2014, *Talasca*, C-19/14, EU:C:2014:2049, paragraph 20).

38 Admittedly, in view of the spirit of judicial cooperation which governs relations between national courts and the Court of Justice in the context of preliminary-ruling proceedings, the fact that the referring court did not make certain initial findings does not necessarily mean, however, that the request for a preliminary ruling is inadmissible if, in spite of those deficiencies, the Court, in the light of the information contained in the case file, considers that it is in a position to provide a useful answer to the referring court (see, to that effect, judgment of 28 January 2016, *CASTA and Others*, C-50/14, EU:C:2016:56, paragraph 48 and the case-law cited, and order of 8 September 2016, *Google Ireland and Google Italy*, C-322/15, EU:C:2016:672, paragraph 24).

39 In the present case, the explanations provided by the referring court as regards the regulatory framework enable the Court to understand the tenor of the national legislation, so that the Court may arrive at an interpretation of EU law which is useful to the referring court. Furthermore, such explanations, as the Advocate General noted in point 42 of his Opinion, enable the Member States and other interested parties, within the meaning of Article 23 of the Statute of the Court of Justice of the European Union, to submit written observations.

40 In addition, the Court considers that the reasoning put forward by the referring court enables it to understand the reasons for that court's view that it was necessary to refer the present questions to it for a preliminary ruling. Finally, it is appropriate to note that those reasons and the indications in the order for reference concerning, inter alia, the facts at issue in the main proceedings, pointing out the unlawfulness, in the light of French legislation, of parallel imports of veterinary medicinal products from Spain made by the appellants in the main proceedings, enable the link which that court establishes between some of the provisions of EU law referred to in the questions referred for a preliminary ruling to be clearly understood, namely Articles 34 and 36 TFEU and Directive 2001/82, and the national legislation which excludes retail distributors and livestock farmers from access to parallel imports of veterinary medicinal products.

41 Consequently, the order for reference contains sufficient information enabling the Court to provide an answer to the referring court useful in the resolution of the dispute in the main proceedings.

42 However, it follows from the file provided to the Court and the information garnered at the hearing that, in the main proceedings, only the livestock farmers brought veterinary medicinal products into France from another Member State, in this case the Kingdom of Spain. Accordingly the first question must be declared inadmissible in so far as it concerns the situation of the holders of retail distribution rights.

43 Moreover, for the reasons set out by the Advocate General in point 46 of his Opinion, the second question must be regarded as hypothetical and therefore, having regard to the case-law cited in paragraph 34 of this judgment, must also be declared inadmissible. As was confirmed at the hearing in the present case, none of the appellants in the main proceedings holds an authorisation for wholesale distribution in a Member State other than the French Republic.

44 Similarly, the third question, in so far as it seeks an interpretation of Article 16 of Directive 2006/123 and of Article 56 TFEU, must be declared inadmissible. It follows from the factors referred to in the order for reference that the sentences delivered at first instance by the tribunal correctionnel de Bayonne (Criminal Court, Bayonne), considered on appeal before the referring court, are based solely on the introduction into France of veterinary medicinal products in breach of French law, no supply of services having been examined as such.

45 It follows from the foregoing considerations that the first question, inasmuch as it relates to holders of retail rights, the second question and the third question, inasmuch as it relates to Article 16 of Directive 2006/123 and Article 56 TFEU, must be declared inadmissible.

*Substance*

Preliminary observations

46 First, it is necessary to note that, despite the wording of the questions referred which relate to parallel imports of veterinary medicinal products, it is not clear from the file provided to the Court by the referring court that the imports made by the livestock farmers concerned are actually parallel imports.

47 It is appropriate to note, in that regard, that, in the case of veterinary medicinal products, a parallel import presupposes, first, that the medicinal product concerned is the subject of an MA in the Member State of export, issued in accordance with the provisions of Directive 2001/82, for the same target animals and, secondly, that, without being identical in all respects to a veterinary medicinal product already authorised in the Member State of import, it has at least a common origin with the latter product, that is to say, it has been manufactured by the same company or by an undertaking connected or working under licence according to the same formulation, using the same active ingredient, and, in addition, it has the same therapeutic effect (see, by analogy with human medicinal products, judgment of 16 December 1999, *Rhône-Poulenc Rorer and May & Baker*, C-94/98, EU:C:1999:614, paragraph 28).

48 Thus, the Court's answers to the questions deemed admissible presuppose that, as regards the veterinary medicinal products at issue in the main proceedings, concerning which it is stated in the order for reference that they are covered by an MA in Spain, there are identical or similar veterinary medicinal products, as defined in the preceding paragraph of this judgment, which have obtained an MA in the Member State of destination, namely in France, in accordance with the procedure laid down in Directive 2001/82, which it is for the referring court to ascertain.

49 Secondly, it is appropriate to note that Article 5(1) of Directive 2001/82 requires no veterinary medicinal product to be placed on the market of a Member State unless an MA has been issued by the competent authorities of that Member State in accordance with that directive. Such a requirement applies even where the medicinal product concerned is already covered by an MA issued by the competent authority of another Member State, given that Directive 2001/82 requires prior authorisation to be obtained from the competent authority of each Member State in which such a medicinal product is placed on the market and used. That obligation placed on the importer of a veterinary medicinal product to obtain, prior to the placing on the market of that medicinal product in a Member State, an MA issued in accordance with Directive 2001/82 cannot, in principle, constitute a restriction on trade between the Member States prohibited by Article 34 TFEU. The same is true of the other obligations and prohibitions provided for in Directive 2001/82, such as the prohibition, laid down in Article 9 of that directive, on administering a medicinal product to animals, when its placing on the market has not first been authorised, excluding exceptions provided for in

the Member State of import (see, by analogy with plant protection products, judgment of 8 November 2007, *Escalier and Bonnarel*, C-260/06 and C-261/06, EU:C:2007:659, paragraphs 24 and 26 and the case-law cited).

50 Consequently, an operator which has acquired a veterinary medicinal product from a Member State in which it is lawfully marketed under an MA issued by the competent authority of that State cannot, in principle, import that product into another Member State, with a view to its being placed on the market or its administration to animals, since it does not have an MA properly issued in that State.

51 However, where a veterinary medicinal product covered by an MA granted in accordance with the provisions of Directive 2001/82 in one Member State is imported into another Member State and that import constitutes a parallel import by reference to a veterinary medicinal product already covered by an MA in the Member State of import, the provisions of that directive on the procedure for the grant of an MA do not apply. The authorisation system for parallel imports must nevertheless be examined in the light of the provisions of the FEU Treaty on the free movement of goods (see, by analogy with pharmaceutical products, judgment of 12 November 1996, *Smith & Nephew and Primecrown*, C-201/94, EU:C:1996:432, paragraph 21, and as regards plant protection products, judgment of 8 November 2007, *Escalier and Bonnarel*, C-260/06 and C-261/06, EU:C:2007:659, paragraph 28).

52 Member States must, in that case, by a simplified procedure, determine whether the import of a veterinary medicinal product which has an MA in another Member State is a parallel import by reference to a veterinary medicinal product which already has an MA in the Member State of import, since they are obliged to ensure compliance with the obligations and prohibitions laid down in Directive 2001/82 (see, by analogy with plant protection products, judgment of 8 November 2007, *Escalier and Bonnarel*, C-260/06 and C-261/06, EU:C:2007:659, paragraphs 29 and 32).

53 If the veterinary medicinal product concerned must be regarded as having already been authorised in the Member State of importation, the competent authorities of that State must, by a simplified procedure, grant livestock farmers, who wish to import veterinary medicinal products for use on their own livestock farms, a parallel import authorisation, unless that is precluded by considerations relating to the effective protection of human and animal health. Accordingly, a Member State cannot be required to issue a parallel import authorisation automatically or absolutely and unconditionally to livestock farmers wishing to import veterinary medicinal products for use on their own livestock farms (see, by analogy with pharmaceutical products, judgment of 12 November 1996, *Smith & Nephew and Primecrown*, C-201/94, EU:C:1996:432, paragraph 29, and as regards plant protection products, judgment of 8 November 2007, *Escalier and Bonnarel*, C-260/06 and C-261/06, EU:C:2007:659, paragraph 30).

54 Thirdly, it is appropriate to note that Article 5(2) of Directive 2001/82 states that the MA holder is to be responsible for the marketing of the medicinal product. It follows therefrom, as the Court has already held as regards plant protection products (judgment of 8 November 2007, *Escalier and Bonnarel*, C-260/06 and C-261/06, EU:C:2007:659, paragraphs 38 to 42 and 50), that livestock farmers, in order to be able to make parallel imports of veterinary medicinal products identical or similar to veterinary medicinal products which, in the Member State of import, have obtained an MA in accordance with Directive 2001/82, must hold an MA issued, even if by a simplified procedure, by the competent national authorities and become responsible for marketing the veterinary medicinal products imported in parallel in the Member State of import.

55 That finding, first, ensures that Article 5(2) of Directive 2001/82, under which the MA holder is responsible for marketing the veterinary medicinal product concerned, is effective and, secondly, guarantees the essential aim of safeguarding public health, as is clear from recital 2 of that directive. A person who has obtained authorisation to import a veterinary medicinal product in parallel is best placed to bear, in respect of that medicinal product, the responsibilities connected with the marketing of the veterinary medicinal product in question. In addition, since MAs may be re-examined and may be cancelled, Member States must, in such cases, be able to ensure the withdrawal as soon as practicable of all the products concerned on their territory, which would not be possible if an MA was not personal and if, in circumstances such as those of the main proceedings, every livestock farmer wishing to import in parallel veterinary medicinal products for the needs of his livestock farm were not required to obtain an MA (see, by analogy as regards plant protection products, judgment of 8 November 2007, *Escalier and Bonnarel*, C-260/06 and C-261/06, EU:C:2007:659, paragraph 41).

56 Fourthly, it must be noted that although, as has been stated in paragraph 51 of this judgment, in the event of parallel import of a veterinary medicinal product, the provisions of Directive 2001/82 concerning the procedure for issue of an MA do not apply, that is not the case of the other provisions of that directive. There is nothing to justify the non-application of those stringent provisions, concerning in particular the possession, dispensing, labelling and information leaflet and pharmacovigilance, which form part of the coherent system of measures put into place by that directive in order to ensure a high level of protection of public health, in cases of parallel imports. On the contrary, if those provisions did not apply in cases of parallel imports, there would be a risk that the operators in the veterinary medicinal product sector would circumvent the obligations laid down in Directive 2001/82 by importing such medicinal products in parallel.

57 The first paragraph, point (aa), of Article 67 of Directive 2001/82 is of particular importance in circumstances such as those at issue in the main proceedings. That provision states that, without prejudice to stricter EU or national rules relating to dispensing veterinary medicinal products and serving to protect human and animal health, a veterinary prescription is to be required for dispensing to the public veterinary medicinal products for food-producing animals. The second paragraph of Article 67 of that directive provides that Member States are to take all necessary measures to ensure that, in the case of medicinal products supplied only on prescription, the quantity prescribed and supplied is restricted to the minimum amount required for the treatment or therapy concerned.

58 It follows therefrom that, to avoid depriving those provisions of Directive 2001/82 of their effectiveness, a Member State must ensure that all veterinary medicinal products covered by the provisions of Article 67 of Directive 2001/82 are dispensed to a livestock farmer who holds a parallel import authorisation for veterinary medicinal products for the needs of his livestock farm only after presentation of a veterinary prescription, in accordance with those provisions, in the quantities stated therein, on each occasion that he brings veterinary medicinal products onto the market of the Member State concerned. The livestock farmer who is the end user of that veterinary medicinal product must, in that regard, be deemed part of the ‘public’ to which a veterinary medicinal product is dispensed, within the meaning of the first paragraph of Article 67 of that directive. Thus, the mere fact of holding a parallel import authorisation for veterinary medicinal products for the needs of his livestock farm does not relieve the livestock farmer, as the end user of a veterinary medicinal product, of his associated obligation flowing from Article 67 of that directive to obtain such a prescription before acquiring those medicinal products.

59 Furthermore, it is appropriate to note that, under Article 68(1) of Directive 2001/82, Member States are to 'take all measures necessary to ensure that only persons empowered under their national legislation in force possess or have under their control veterinary medicinal products or substances which may be used as veterinary medicinal products that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties'. Since such national legislation precludes possession by the livestock farmers, as end users, of veterinary medicinal products of that type for the purpose of administering them to animals, the issue of a parallel import authorisation cannot have the effect of making possession of those veterinary medicinal products by those livestock farmers possible.

60 Furthermore, it must be added that the Member State of destination of the veterinary medicinal product imported in parallel must, in accordance with Article 61(1) of Directive 2001/82, take all measures necessary so that the information leaflet included in the packaging of that medicinal product is written in terms that are comprehensible to the general public and in the official language or languages of that Member State. In order to give full effect to the requirement flowing from that provision, livestock farmers who import veterinary medicinal products in parallel for the needs of their livestock farms must ensure that those medicinal products include leaflets complying with that requirement. That enables those livestock farmers to have the information necessary for the proper use and handling of those medicinal products.

61 The importance of such a requirement is, moreover, emphasised in Article 62 of Directive 2001/82, pursuant to which, where the provisions of Title V of that directive on the labelling and the package insert of veterinary medicinal products are not observed, the competent authorities of the Member States may suspend or withdraw the MA.

62 It is in the light of those considerations that it is appropriate for the Court to answer the questions referred which are admissible.

The first question

63 By the admissible part of its first question, the referring court asks, in essence, whether Articles 34 and 36 TFEU must be interpreted as precluding national legislation which restricts access to parallel imports of veterinary medicinal products to wholesale distributors holding the authorisation laid down in Article 65 of Directive 2001/82 and which, consequently, excludes from access to such imports the livestock farmers wishing to import veterinary medicinal products for the needs of their own livestock farms.

64 First of all, it is appropriate to note that the French Government disputes the fact that, as the wording of the first question suggests, the French legislative framework restricts access to parallel imports of veterinary medicinal products to wholesale distributors holding the authorisation laid down in Article 65 of Directive 2001/82. That government is of the view that that question should be understood as referring to national legislation which provides, as follows from Article R. 5141-123-17 of the Public Health Code, that only those establishments holding an authorisation to open an establishment may use a parallel import authorisation, which excludes, first, holders of retail rights and, secondly, private individuals such as, inter alia, livestock farmers.

65 In that regard, apart from the fact that the interpretation of the national legislation given by the French Government does not differ greatly from that given by the referring court, it should also be noted that it is not for the Court, in the context of a reference for a preliminary ruling, to give a ruling on the interpretation of provisions of national law or to decide whether the interpretation given by the national court of those provisions is correct. Indeed, only the national courts are competent to decide upon the interpretation of domestic

law (judgment of 17 December 2015, *Tall*, C-239/14, EU:C:2015:824, paragraph 35 and the case-law cited).

66 Consequently, as regards the first question as set out in paragraph 63 of this judgment, it must be observed that, in accordance with settled case-law, all measures of a Member State which are capable of hindering, directly or indirectly, actually or potentially, trade within the European Union are to be considered as measures having an effect equivalent to quantitative restrictions on imports within the meaning of Article 34 TFEU (see, inter alia, judgments of 11 July 1974, *Dassonville*, 8/74, EU:C:1974:82, paragraph 5, and of 23 December 2015, *Scotch Whisky Association and Others*, C-333/14, EU:C:2015:845, paragraph 31).

67 In that regard, the view must be taken that the legislation at issue in the main proceedings, because it requires a livestock farmer to obtain a wholesale distribution authorisation, such as that provided for in Article 65 of Directive 2001/82, in order to be able to have a parallel import authorisation for a veterinary medicinal product for the needs of his livestock farm, is likely to hinder access to the national market concerned of a veterinary medicinal product lawfully marketed in the Member State of provenance and, in consequence, constitutes a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 34 TFEU.

68 The French Government has confirmed, both in its written observations and at the hearing, that the livestock farmers are deprived of the possibility of obtaining a parallel import authorisation for veterinary medicinal products. It submits, nevertheless, that such legislation is capable of being justified on grounds of protection of human and animal health.

69 In accordance with settled case-law, a measure having equivalent effect to a quantitative restriction on imports can be justified, for example, on grounds of the protection of human and animal health only if that measure is appropriate for securing the achievement of the objective pursued and does not go beyond what is necessary in order to attain it (see, to that effect, judgment of 23 December 2015, *Scotch Whisky Association and Others*, C-333/14, EU:C:2015:845, paragraph 33 and the case-law cited).

70 As regards the objective pursued by the legislation at issue in the main proceedings, it must be noted that public health ranks foremost among the assets or interests protected by Article 36 TFEU and it is for the Member States, within the limits imposed by EU law, to decide on the degree of protection which they wish to afford to human health and on the way in which that protection is to be achieved (see, inter alia, judgments of 11 December 2003, *Deutscher Apothekerverband*, C-322/01, EU:C:2003:664, paragraph 103, and of 9 December 2010, *Humanplasma*, C-421/09, EU:C:2010:760, paragraph 32).

71 The French Government justifies the fact that it is impossible for livestock farmers to obtain a parallel import authorisation for veterinary medicinal products by arguing, in essence, that only veterinary pharmaceutical establishments subject, under French rules, to the obligations which follow from wholesale distribution, within the meaning of Directive 2001/82, in particular to a code of good practice and the obligation to have the necessary equipment and staff resources, are in a position to achieve the objectives of protection of human and animal health and of the environment. Furthermore, that government notes that any parallel import of veterinary medicinal products can give rise to a wholesale distribution thereof in the Member State of import and that all parallel importers must therefore fulfil the obligations placed on wholesale distributors by Article 65(2) to (4) of Directive 2001/82. That government adds that it is not possible to impose measures which are less restrictive as regards the free movement of goods without increasing the risks to human and animal

health, given that it is, inter alia, impossible to place the same requirements as regards staff and equipment on the livestock farmers concerned as those placed on the veterinary pharmaceutical establishments authorised to carry out, inter alia, wholesale distribution.

72 In that regard, it must be noted that a national system which restricts access to parallel imports of veterinary medicinal products only to persons holding a wholesale distribution authorisation, within the meaning of Article 65 of Directive 2001/82, appears to be such as to ensure achievement of the objective of the protection of human and animal health. An applicant for a wholesale distribution authorisation must fulfil the obligations flowing from Article 65 thereof, which require, in particular, as is clear from paragraph 2 thereof, wholesale distribution to be carried out in conditions meeting the requirements concerning the storage and handling of veterinary medicinal products.

73 However, the obligation to have technically competent staff, suitable and adequate premises and equipment which meet the requirements concerning the storage and handling of veterinary medicinal products in the Member State concerned, within the meaning of Article 65(2) of the directive, cannot be imposed, in the context of the procedure to obtain an MA, on livestock farmers who import in parallel veterinary medicinal products for the needs of their own livestock farms. That Article 65(2) specifically concerns operators who wish to obtain a wholesale distribution authorisation for veterinary medicinal products and sets out obligations as regards staff, premises and equipment which are necessary in order to be able to carry out that type of distribution. In the context of their agricultural activities, those livestock farmers do not carry out any wholesale distribution of the veterinary medicinal products which they import. It follows that to impose obligations which seek to circumscribe and regulate wholesale distribution of veterinary medicinal products on those livestock farmers goes beyond what is necessary to ensure protection of human and animal health.

74 That conclusion cannot be overturned by the mere supposition, raised by the French Government, that any parallel import operation may, subsequently, become a wholesale distribution activity. Furthermore, in the present case, that supposition is manifestly incorrect, since the question examined concerns parallel imports of veterinary medicinal products carried out by livestock farmers solely for the needs of their own livestock farms.

75 It thus follows from the foregoing considerations that the answer to the first question is that Articles 34 and 36 TFEU must be interpreted as precluding national legislation which restricts access to parallel imports of veterinary medicinal products to wholesale distributors holding the authorisation laid down in Article 65 of Directive 2001/82 and which, consequently, excludes from access to such imports the livestock farmers wishing to import veterinary medicinal products for the needs of their own livestock farms.

The third question

76 By the admissible part of its third question, the referring court asks, in essence, whether Articles 34 and 36 TFEU must be interpreted as precluding national legislation which requires livestock farmers who import in parallel veterinary medicinal products for the needs of their own livestock farms to have an establishment in the Member State of destination and to fulfil all the pharmacovigilance obligations laid down in Articles 72 to 79 of Directive 2001/82.

77 As regards, first, the pharmacovigilance obligations laid down in Directive 2001/82, it follows from the file provided to the Court that Articles R. 5141-104, R. 5141-105 and R. 5141-108 of the Public Health Code set out, in essence, the requirements laid down in Articles 74 and 75 of that directive.

78 As has been pointed out in paragraph 55 of this judgment, livestock farmers who obtain a parallel import authorisation for veterinary medicinal products for the needs of their livestock farms are holders of MAs for those medicinal products and are responsible for placing them on the market. It follows therefrom that those livestock farmers are required to comply with the rules connected with the placing on the market of veterinary medicinal products, laid down, in particular, in Title VII of Directive 2001/82 concerning pharmacovigilance as regards those veterinary medicinal products.

79 In that regard, it is clear from Articles 74 and 75 of Directive 2001/82 that the obligations laid down therein must be accepted by the MA holders, that finding being confirmed in recital 34 of that directive, according to which the MA holders accept responsibility for continued and preventive pharmacovigilance as regards the veterinary medicinal products which they place on the market.

80 Consequently, it is appropriate to find that the articles of the Public Health Code relating to the pharmacovigilance obligations, cited in paragraph 77 of this judgment, merely comply with the rules of pharmacovigilance laid down in Directive 2001/82. Those articles cannot thus be classified as measures having an effect equivalent to a quantitative restriction on imports within the meaning of Article 34 TFEU (see, to that effect, judgment of 23 March 2000, *Berendse-Koenen*, C-246/98, EU:C:2000:153, paragraph 25).

81 Secondly, with regard to the obligation to have an establishment in the Member State of destination of the veterinary medicinal products imported in parallel, it must be pointed out that the obligations flowing from Article 65 of Directive 2001/82 and, in particular, those relating to the premises which the persons concerned must have, in so far as they seek, as has been stated in paragraph 73 of this judgment, specifically to circumscribe the conditions of wholesale distributions of veterinary medicinal products, cannot apply to livestock farmers who import veterinary medicinal products in parallel for the needs of their own livestock farms.

82 In those circumstances, it is appropriate to examine that obligation to have an establishment in the Member State of destination of veterinary medicinal products imported in parallel in the light of Articles 34 and 36 TFEU. It must be found, as the Advocate General noted in point 86 of his Opinion, that such an obligation does not impose upon the livestock farmers who import in parallel veterinary medicinal products any condition which they are not already fulfilling. In the exercise of their activities, those livestock farmers of necessity have a farm and therefore an establishment in that Member State. That obligation cannot, therefore, constitute a measure having equivalent effect to a quantitative restriction on imports, within the meaning of Article 34 TFEU.

83 In consequence, the answer to the third question is that Articles 34 and 36 TFEU must be interpreted as not precluding national legislation which requires livestock farmers who import in parallel veterinary medicinal products for the needs of their own livestock farms to have an establishment in the Member State of destination and to fulfil all the pharmacovigilance obligations laid down in Articles 72 to 79 of Directive 2001/82.

**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 (Fourth Chamber) hereby rules:

1. **Articles 34 and 36 TFEU must be interpreted as precluding national legislation which restricts access to parallel imports of veterinary medicinal products to wholesale distributors holding the authorisation laid down in Article 65 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 and which, consequently, excludes from access to such imports the livestock farmers wishing to import veterinary medicinal products for the needs of their own livestock farms.**

2. **Articles 34 and 36 TFEU must be interpreted as not precluding national legislation which requires livestock farmers who import in parallel veterinary medicinal products for the needs of their own livestock farms to have an establishment in the Member State of destination and to fulfil all the pharmacovigilance obligations laid down in Articles 72 to 79 of Directive 2001/82, as amended by Regulation No 596/2009.**

[Signatures]

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* Language of the case: French.