Reports of Cases

OPINION OF ADVOCATE GENERAL
MENGOZZI
delivered on 10 March 2016[1]

Case C-114/15

Association des utilisateurs et distributeurs de l'agrochimie européenne (Audace),
Phyteron 2000 SAS,
Association des éleveurs solidaires,
Cruzalebes EARL,
Des deux rivières EARL,
Mounacq EARL,
v
GAEC Reconnu La Vinardière,
Ministère public(Request for a preliminary ruling

from the cour d'appel de Pau (Court of Appeal, Pau, France))

(Parallel imports of veterinary medicinal products — Exclusion of individuals (livestock farmers and veterinarians) from eligibility for the simplified marketing authorisation procedure — Directive 2001/82/EC — Free movement of goods — Obligation to have an establishment in the territory of the importing Member State — Pharmacovigilance obligations — Recognition of wholesale distribution authorisations granted by the competent authorities of another Member State — Directive 2006/123/EC — Freedom to provide services)

1. In the present case, the Court is called upon to rule on the authorisation procedure used by the competent authorities of a Member State when veterinary medicinal products are imported, in parallel with the manufacturer's distribution network, by an individual (a livestock farmer or a veterinarian) with no links to that manufacturer.

2. Due to the specific nature of veterinary medicinal products, they, like medicinal products for human use and plant protection products, cannot be placed on the market unless a marketing authorisation ('MA') has been granted by the competent authorities of the Member State concerned (or, where appropriate, by the European Union).[2] That is provided for in Article 5 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,[3] as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 ('Directive 2001/82 as amended').

1 — Original language: French.

2 — The marketing authorisation may be granted not by a Member State, but by the EU, in accordance with the centralised procedure applicable to certain types of medicinal products provided for in 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). In such circumstances, the marketing authorisation is automatically valid in all Member States (see Article 38(1) of Regulation No 726/2004). This is not relevant in the present case.

3 — OJ 2001 L 311, p. 1.

3. However, the Court has held that, where an imported medicinal product is already covered by a marketing authorisation in the importing Member State, that Member State may not, without infringing Article 34 TFEU and Article 36 TFEU, do any more than compel the parallel importer to undergo a *simplified* marketing authorisation procedure. After all, the importing Member State already has in its possession all the necessary particulars for the purpose of checking that the medicinal product is effective and not harmful. [4]

4. This case concerns an issue which has been addressed superficially in case-law, [5] namely, imports effected in parallel with the manufacturer's distribution network not by an economic operator intending to sell the imported products on, but by a livestock farmer importing them solely for the needs of his farm, or by a veterinarian. The Court is asked to consider whether legislation under which livestock farmers and veterinarians are ineligible for the simplified marketing authorisation procedure complies with, in particular, Article 34 TFEU and Article 36 TFEU.

I – **Legal context**

A – *EU law*

5. Article 1 of Directive 2001/82 as amended, provides:

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

(17) Wholesale dealing in veterinary medicinal products:

Any activity which includes the purchase, sale, import, export, or any other commercial transaction in veterinary medicinal products, whether or not for profit, except for:

— the supply by a manufacturer of veterinary medicinal products manufactured by himself,

— retail supplies of veterinary medicinal products by persons entitled to carry out such supplies in accordance with Article 66.'

6. The first sentence of Article 5(1) of Directive 2001/82 as amended provides that 'no veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been granted by the competent authorities of that Member State in accordance with this Directive or a marketing authorisation has been granted in accordance with Regulation (EC) No 726/2004'.

7. Article 65 of Directive 2001/82 as amended provides:

'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.

4 — See, inter alia, judgments in *de Peijper* (104/75, EU:C:1976:67, paragraphs 20-32); *Smith & Nephew and Primecrown* (C-201/94, EU:C:1996:432, paragraphs 19-32) and *British Agrochemicals Association* (C-100/96, EU:C:1999:129, paragraphs 31-36).

5 — See, however, judgments in *Commission* v *France* (C-212/03, EU:C:2005:313) and *Escalier and Bonnarel* (C-260/06 and C-261/06, EU:C:2007:659) to which I shall refer again later.

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. The following minimum information shall be recorded in respect of each incoming or outgoing transaction:

(a) date;

(b) precise identity of the veterinary medicinal product;

(c) manufacturer's batch number, expiry date;

(d) quantity received or supplied;

(e) name and address of the supplier or recipient.

At least once a year a detailed audit shall be carried out to compare incoming and outgoing medicinal supplies with supplies currently held in stock, any discrepancies being recorded.

These records shall be available for inspection by the competent authorities for a period of at least three years.

3a. The holder of a distribution authorisation shall have an emergency plan guaranteeing the effective implementation of any recall operation ordered by the competent authorities or undertaken in cooperation with the manufacturer of the medicinal product in question or the holder of the marketing authorisation.

...'

8. Article 69 of Directive 2001/82 as amended provides as follows:

'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.

In particular, Member States may require the maintenance of a record giving at least the following information:

(a) date;

(b) name of the veterinary medicinal product;

(c) quantity;

(d) name and address of the supplier of the medicinal product;

(e) identification of the animals treated.'

9. Article 70 of Directive 2001/82 as amended provides:

'By way of derogation from Article 9 and without prejudice to Article 67, Member States shall ensure that veterinarians providing services in another Member State can take with them and administer to animals small quantities of veterinary medicinal products not exceeding daily requirements other than immunological veterinary medicinal products which are not authorised for use in the Member State in which the services are provided (hereinafter: 'host Member State'), provided that the following conditions are satisfied:

(a) the authorisation to place the product on the market provided for in Articles 5, 7 and 8 has been issued by the competent authorities of the Member State in which the veterinarian is established;

(b) the veterinary medicinal products are transported by the veterinarian in the original manufacturer's packaging;

(c) the veterinary medicinal products intended for administration to food-producing animals have the same qualitative and quantitative composition in terms of active substances as the medicinal products authorised in accordance with Articles 5, 7 and 8 in the host Member State;

(d) the veterinarian providing services in another Member State acquaints himself with the good veterinary practices applied in that Member State and ensures that the withdrawal period specified on the labelling of the veterinary medicinal product concerned is complied with, unless he could reasonably be expected to know that a longer withdrawal period should be specified to comply with these good veterinary practices;

(e) the veterinarian shall not furnish any veterinary medicinal product to the owner or keeper of the animals treated in the host Member State unless this is permissible on the basis of the rules of the host Member State; in this case he shall, however, supply only in relation to animals under his care and only the minimum quantities of veterinary medicinal product necessary to complete the treatment of animals concerned on that occasion;

(f) the veterinarian shall be required to keep detailed records of the animals treated, the diagnosis, the veterinary medicinal products administered, the dosage administered, the duration of treatment and the withdrawal period applied. These records shall be available for inspection by the competent authorities of the host Member State for a period of at least three years;

(g) the overall range and quantity of veterinary medicinal products carried by the veterinarian shall not exceed that generally required for the daily needs of good veterinary practice.'

10. According to Article 72 of Directive 2001/82 as amended:

'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 health-care professionals in respect of the reporting of suspected serious or unexpected adverse reactions and human adverse reactions.'

11. The first subparagraph of Article 74, of Directive 2001/82 as amended provides that 'the marketing authorisation holder shall have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance'.

12. The first sentence of Article 75(1) of Directive 2001/82 as amended provides that 'the marketing authorisation holder shall maintain detailed records of all suspected adverse reactions occurring within the Community or in a third country'.

13. Article 16(2) of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market,[6] provides as follows:

'Member States may not restrict the freedom to provide services in the case of a provider established in another Member State by imposing any of the following requirements:

(a) an obligation on the provider to have an establishment in their territory;

(b) an obligation on the provider to obtain an authorisation from their competent authorities including entry in a register or registration with a professional body or association in their territory, except where provided for in this Directive or other instruments of Community law;

...'

14. The first sentence of Article 16(3) of Directive 2006/123/EC provides that 'the Member State to which the provider moves shall not be prevented from imposing requirements with regard to the provision of a service activity, where they are justified for reasons of public policy, public security, public health or the protection of the environment and in accordance with paragraph 1'.

B – *The French legislation*

15. Article L. 5142-1 of the Code de la santé publique (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 French Agency for Food, Environmental and Occupational Health and Safety (Agence nationale [chargée] de [la] sécurité sanitaire de l'alimentation, de l'environnement et du travail)'.

17. Article R. 5141-123-6 of the Public Health 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 European Community or a State which is a party to the Agreement on the European Economic Area in which it has obtained a marketing authorisation for the same target animals;

6 — OJ 2006 L 376, p. 36.

(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 a marketing authorisation granted by the French Agency for Food, Environmental and Occupational Health and Safety.

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 a market authorisation granted by the French Agency for Food, Environmental and Occupational Health and Safety where those differences have no therapeutic effect and do not pose a risk to public health.'

18. Article R. 5141-123-7 of the Public Health 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 a marketing authorisation in France.

Moreover, on human or animal health grounds, the Director General of the French Agency for Food, Environmental and Occupational Health and Safety may make the parallel import authorisation subject to a requirement to alter the initially proposed name.'

19. Article R. 5141-123-17 of the Public Health 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 an import parallel 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.'

20. Article R. 5142-42 of the Public Health 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 the French Agency for Food, Environmental and Occupational Health and Safety 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 the French Agency for Food, Environmental and Occupational Health and Safety by decree of the ministers for agriculture and health.'

21. Article L. 5141-105 of the Public Health Code provides:

'Without prejudice to the conditions laid down when a marketing authorisation 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 the French Agency for Food, Environmental and Occupational Health and Safety, 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 ...'

II – **The facts, the main proceedings and the questions referred for a preliminary ruling**

22. In January 2008, an inspection of veterinary services led to the discovery, at a farm in Itxassou (Pyrénées-Atlantiques, France), of Spanish veterinary medicinal products. The preliminary investigation conducted after that inspection by the National Judicial Customs Department of Bordeaux (Service national de la douane judiciaire de Bordeaux) and the subsequent judicial investigation revealed that, between October 2006 and October 2009, some livestock farmers in the Southwest region of France had purchased Spanish veterinary medicinal products from Landizoo, an undertaking based in the Venta Peio border shopping complex in Dancharia (Spain).

23. Landizoo is authorised by the government of Navarre (Spain) to sell veterinary medicinal products. Its main suppliers are the company Albaitaritza and the latter's subsidiary, Sengadai, both of which are established in Spain. The medicinal products were purchased on the basis of prescriptions written by Dr Erneta, a Spanish veterinarian registered with the Spanish veterinary association and the French veterinary association. The livestock farmer or farm manager imported the products by travelling to Spain himself to collect them.

24. None of the medicinal products imported is covered by a parallel import authorisation granted by the competent French authority.

25. By a judgment of 10 December 2013, the tribunal correctionnel de Bayonne (France) (Bayonne Criminal Court, France) found the livestock farmers guilty of, inter alia, the offence of importing veterinary medicinal products without authorisation and ordered them to pay a fine of EUR 1 000 each with stay of payment.

26. The applicant, the Association des [utilisateurs et distributeurs] de l'agrochimie européenne ('Audace') (Association of Users and Distributors of AgroChemicals in Europe) has the aims of informing its members on the EU rules which are applicable to them, comparing the legislation of different Member States on the subject and protecting the interests of its members, including through legal action, if a Member State infringes an EU rule. According to the judgment of the tribunal correctionnel de Bayonne (Bayonne Criminal Court), it was at the initiative of Audace and of the Association des éleveurs solidaires ('AES') (Unified Livestock Farmers' Association), which represents livestock farmers from Aquitaine, that the accused purchased veterinary medicinal products in Spain. In that regard, the tribunal correctionnel de Bayonne (Bayonne Criminal Court) observed, in its judgment, that 'Dr Erneta described the practice, namely, that after receiving a simple telephone request from French livestock farmers, who he did not necessarily know, he wrote prescriptions remotely and left them at Landizoo for the livestock farmer who came to collect the medicinal products. He acknowledged that he had also left prescriptions, pre-signed by him, at Landizoo, which

managed the dispensing of the medicinal products itself. That modus operandi was confirmed by the livestock farmers. They cited the low cost of the medicinal products purchased in Spain as a justification for this, and explained that they had been induced by Audace and AES['']. The tribunal correctionnel de Bayonne (Bayonne Criminal Court) thus found Dr Erneta, Audace and AES guilty of, inter alia, being accessories to the offence of importing medicinal products without authorisation.

27. Audace contended before the tribunal correctionnel de Bayonne (Bayonne Criminal Court) that permitting only those establishments which have obtained an authorisation to open by the French Agency for Food, Environmental and Occupational Health and Safety (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail) ('ANSES')[7] to effect parallel imports of veterinary medicinal products, and prohibiting livestock farmers from doing so, as well as refusing to recognise the wholesale distribution authorisations granted by the competent authorities of other Member States, Decree No 2005-558 of 27 May 2005 on imports of veterinary medicinal products amending the Public Health Code (regulatory part)[8] ('the Decree of 27 May 2005') was infringing Article 34 TFEU and Article 36 TFEU. Audace also informed the tribunal correctionnel de Bayonne (Bayonne Criminal Court) that, in July 2013, it had brought before the Conseil d'État (France) (Council of State, France) an action for annulment on the ground of misuse of powers against the decision by which the Prime Minister had implicitly rejected its request for the partial repeal of the Decree of 27 May 2005, and that it had, in the course of that action, proposed to the Conseil d'État (Council of State) to refer three questions to the Court for a preliminary ruling.[9] However, the tribunal correctionnel de Bayonne (Bayonne Criminal Court) refused to stay the proceedings pending the judgment of the Conseil d'État (Council of State). It also refused to make its own request for a preliminary ruling to the Court.

28. Having been convicted at first instance, Audace, AES, Dr Erneta and the livestock farmers brought an appeal before the cour d'appel de Pau (Court of Appeal, Pau, France) against the judgment of the tribunal correctionnel de Bayonne (Bayonne Criminal Court).

29. The Criminal Chamber of the cour d'appel de Pau (Court of Appeal, Pau) observed that, according to Audace, since 2005, only one parallel import authorisation has been issued in France for veterinary medicinal products imported from Spain, although the difference between the prices in Spain and the higher prices on the French market should have led to hundreds of parallel import licences being issued.

30. The cour d'appel de Pau (Court of Appeal, Pau) decided to stay the proceedings and to 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 as amended], thus excluding those with retail distribution rights and livestock farmers?

(2) On a proper construction of Article 65 of Directive [2001/82 as amended] 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

7 — Within ANSES, the French Agency for Veterinary Medicinal Products (Agence nationale du médicament vétérinaire) is responsible for assessing and managing the risks posed by veterinary medicinal products.

8 — *Journal officiel de la République française* (Official Journal of the French Republic) of 28 May 2005.

9 — Conseil d'État (Council of State), 9 April 2015, Association des utilisateurs et distributeurs de l'agrochimie européenne (Association of Users and Distributors of AgroChemicals in Europe) (application No. 370350). See, in that regard, point 50 of this Opinion.

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 as amended], establishing a Community Code for veterinary medicinal products, 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?'

III – **Assessment**

31. Since the French Government has raised a plea of inadmissibility as regards the request for a preliminary ruling, I shall examine that plea before turning to the substance of the case.

A – *Admissibility*

32. The French Government claims that, by failing to establish the factual and legislative context and to state the reasons for asking whether the national legislation is compatible with EU law and, in particular, with Article 65 of Directive 2001/82 as amended, Article 56 TFEU and Article 16 of Directive 2006/123, the referring court has infringed Article 94 of the Rules of Procedure of the Court.

33. The plea of inadmissibility raised by the French Government should be upheld only as regards, first, the second question referred for a preliminary ruling, and secondly, the third question referred for a preliminary ruling in so far as it concerns Article 56 TFEU and Article 16 of Directive 2006/123.

34. I note that, under the first paragraph of Article 94 of the Rules of Procedure of the Court, the request for a preliminary ruling is to contain, first, 'a summary of the subject-matter of the dispute and the relevant findings of fact', secondly 'the tenor of any national provisions' applicable, and thirdly 'a statement of the reasons which prompted the referring court or tribunal to inquire about the interpretation or validity of certain provisions of EU law'.

35. As regards, first, the factual context of the dispute, it is true that the presentation of the facts in the request for a preliminary ruling is succinct.

36. However, the request for a preliminary ruling does mention the search of the veterinary facilities at a farm in Pyrénées-Atlantiques, which gave rise to criminal proceedings being brought before the referring court, as well as the preliminary investigation which followed, and the discovery, during the course of that investigation, of medicinal products imported from Spain without authorisation. It also mentions the subject matter of the criminal proceedings: it states that the livestock farmers, the veterinarian and the associations in question appealed against their conviction as perpetrators of, or accessories to, the offences of importing veterinary medicinal products without authorisation, and of importing prohibited merchandise without declaring it.

37. Furthermore, the judgment of the tribunal correctionnel de Bayonne (Bayonne Criminal Court), which is included in the national case file sent to the Court, contains a detailed account of the relevant facts, which is reproduced in points 26 and 27 of this Opinion. It is clear from the case-law that the Court may use information it needs from the national case file to provide an answer which is of use

to the referring court.[10]

38. It is true, as stated by the French Government, that the request for a preliminary ruling does not indicate whether the livestock farmers, the veterinarian and the associations prosecuted applied to the competent French authorities for an import authorisation and had their application rejected. The tribunal correctionnel de Bayonne (Bayonne Criminal Court) makes no reference to this either. However, I note that the French Government acknowledges, in the observations it made on the first question referred for a preliminary ruling, that livestock farmers and those with retail distribution rights cannot obtain a parallel import authorisation.[11] Therefore, by the French Government's own admission, livestock farmers, the veterinarian and the associations at issue in the present case could not obtain such an authorisation regardless of whether or not they applied for one: the Court does not require such information in order to answer the questions referred for a preliminary ruling. Only if there were any doubt regarding the tenor of the French legislation[12] (that is to say, if there were any doubt as to whether livestock farmers and those with retail distribution rights could have access to parallel imports) would it be essential for the Court to know, for the purpose of providing a useful answer to the referring court, whether, in this case, an application for a parallel import authorisation had been made and rejected.

39. Secondly, as regards the national legislative context, it is true that the request for a preliminary ruling refers to certain provisions of, inter alia, the Public Health Code[13] and the Decree of 27 May 2005 without quoting them or setting out the tenor thereof.

40. Nonetheless, I note that the judgment of the tribunal correctionnel de Bayonne (Bayonne Criminal Court), which is among the documents in the present case and from which the Court, as I have said,[14] may use the information it needs in order to examine the questions referred for a preliminary ruling, states that 'an application for the parallel import of veterinary medicinal product[s] must be authorised by the [competent French authorities] and may be authorised only for an operator, namely, a veterinary pharmaceutical establishment'. It is therefore clear from the case file that only a veterinary pharmaceutical establishment may obtain a parallel import authorisation.

41. Moreover, I note that the purpose of the requirement imposed on the referring court to describe the legislative and factual context is to enable the Court to provide it with a useful answer.[15] In this case, the parties, in particular, the French Government and Audace, set out the French legislation in great detail. Therefore, the Court is perfectly well placed to understand the French legislation and to provide a useful answer to the referring court.

42. Admittedly, the requirement for the referring court to establish, in particular, the legislative context also serves the purpose of enabling the interested parties, within the meaning of Article 23 of the Statute of the Court, namely, the parties in the proceedings before the referring court, the Member States and the Commission and the institution, body, office or agency of the Union which adopted the

10 — See, in that regard, judgment in *Europièces* (C-399/96, EU:C:1998:532, paragraph 24), in which the Court rejected a plea of inadmissibility as regards the request for a preliminary ruling on the ground, inter alia, that 'the case-file forwarded by the national court contains sufficient information to enable the Court to interpret the rules of Community law in respect of the situation arising in the main proceedings'.

11 — See, in that regard, point 61 of this Opinion.

12 — I do not think it would be useful to dwell on the French Government's argument that the referring court erred in its interpretation of the French legislation. See, in that regard, point 52 of this Opinion.

13 — The request for a preliminary ruling quotes only Articles L. 5441-8, L. 5441-11, L. 5124-7 and L. 5141-8 from the Public Health Code. Under the first of those articles, it is an offence to import veterinary medicinal products without authorisation; the second lays down the additional penalties applicable; the third provides that veterinary medicinal product imports are subject to authorisation by the competent French authorities and the fourth gives the meaning of veterinary medicinal product. Therefore, the request for a preliminary ruling does not make reference to the essential provisions of the Public Health Code, with the exception of Article L. 5142-7, which are mentioned in points 15 to 21 of this Opinion. However, the operative part of the judgment of the cour d'appel de Pau (Court of Appeal, Pau) refers to the Decree of 27 May 2005, which amended some of those provisions.

14 — See point 37 of this Opinion.

15 — See, in that regard, judgment in *Europièces* (C-399/06, EU:C:1998:532, paragraph 23).

act the validity or interpretation of which is in dispute, to submit written observations.[16] However, it seems to me that, in order for the Member States to be able to submit meaningful observations, it is essential, in particular, that they know that livestock farmers and those with retail rights are not eligible to obtain parallel import authorisations under the French legislation; a point which is made clearly in the questions referred for a preliminary ruling. It is this point which is central to the present request for a preliminary ruling, in respect of which the specifics of the French procedure for the grant of those authorisations are, ultimately, secondary.

43. Thirdly, as regards the reasons which prompted the national court to refer questions to the Court, it is true that they are stated only briefly in the request for a preliminary ruling.

44. However, the request states that, as the prices of veterinary medicinal products on the Spanish market are significantly lower than those in France, it is strange that only one parallel import authorisation has been issued since 2005.[17] Therefore, it does not seem to me that the first question referred for a preliminary ruling, relating to Article 34 TFEU and Article 36 TFEU, can be considered as inadmissible on the ground that the referring court failed to state the reasons which prompted it to refer questions to the Court.

45. However, I have doubts as to the admissibility, first, of the second question referred for a preliminary ruling and, secondly, of the third question referred for a preliminary ruling in so far as the latter concerns Article 56 TFEU and Article 16 of Directive 2006/123.

46. The second question relates to the compatibility with EU law of the national legislation which provides that, in order for a parallel importer to 'use' a parallel import authorisation, that is, to engage in the wholesale distribution of imported veterinary medicinal products in the territory of that Member State, he must hold a wholesale distribution authorisation granted by the competent authorities in that Member State, even if he is already in possession of a wholesale distribution authorisation granted by another Member State. In other words, the referring court asks the Court whether EU law, and more specifically, Article 65 of Directive 2001/82 as amended and Article 16 of Directive 2006/123, impose an obligation of mutual recognition of wholesale distribution authorisations. It is not apparent from the request for a preliminary ruling or from the judgment of the tribunal correctionnel de Bayonne (Bayonne Criminal Court) that one of the parties in the national proceedings became engaged in the wholesale distribution of the imported medicinal products. After all, the livestock farmers did not import the veterinary medicinal products in question in order to sell them on, but rather for their own use: there is no distribution. As regards the veterinarian, the tribunal correctionnel de Bayonne (Bayonne Criminal Court)[18] states that he merely signed the prescriptions which enabled the livestock farmers to purchase veterinary medicinal products in Spain, and he neither purchased nor, consequently, resold any veterinary medicinal products in Spain himself. He was thus convicted not for committing the offence of importing without an authorisation, but for being an accessory to that offence. When questioned on this point at the hearing, Audace confirmed that the veterinarian had not purchased any medicinal products himself and that it was the livestock farmers who had gone to Spain to purchase the medicinal products at issue. Audace also stated that none of the parties in the

16 — See, in that regard, order in *Laguillaumie*, according to which 'the information furnished in the decision making the reference does not serve only to enable the Court to give helpful answers, but also to enable the governments of the Member States and other interested parties to submit observations in accordance with Article 20 of the EC Statute of the Court of Justice ... 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 decision making reference is notified to the interested parties' [order in *Laguillaumie* (C-116/00, EU:C:2000:350, paragraph 14)].

17 — In that connection, according to the grounds of the request for a preliminary ruling: '... Audace and SAS Phyteron state that, since 2005, only one parallel import authorisation has been issued for veterinary medicinal products, while the price distortions between France and the other Member States should have led to hundreds of authorisation[s] being issued, as was the case in the plant protection products sector'.

18 — See point 26 of this Opinion.

main proceedings held a wholesale distribution authorisation issued by the Spanish competent authorities which the competent French authorities had been asked to recognise.[19] Therefore, the second question referred for a preliminary ruling must, in my opinion, be considered as inadmissible on the ground that it is hypothetical.[20]

47. The third question referred for a preliminary ruling relates to the compatibility with Article 34 TFEU, Article 36 TFEU and Article 56 TFEU and Article 16 of Directive 2006/123 of the national legislation which requires parallel importers, first, to have available to them an establishment in the national territory and, secondly, to fulfil the pharmacovigilance obligations provided for in Articles 72 to 79 of Directive 2001/82 as amended. It is not apparent from the case file that the parties in the national proceedings were providing services. The livestock farmers imported veterinary medicinal products solely for the needs of their farms: they did not provide any services to third parties. The veterinarian merely wrote prescriptions, without distributing the parallel-imported veterinary medicinal products. It does not even appear that the prescriptions were written for the animals that he was treating, since the judgment of the tribunal correctionnel de Bayonne (Bayonne Criminal Court) states that he was writing prescriptions purely on the basis of a telephone request from the livestock farmers. I doubt that merely writing a prescription could be considered as a service within the meaning of Article 56 TFEU and of Directive 2006/123. Therefore, I take the view that the third question referred for a preliminary ruling should be rejected as inadmissible, but only in far as it relates to whether the French legislation complies with Article 56 TFEU and Article 16 of Directive 2006/123. It is, in my opinion, admissible in so far as it relates to whether that legislation complies with Article 34 TFEU and Article 36 TFEU.

48. Therefore, I propose that the plea of inadmissibility raised by the French Government should be rejected as regards the first question referred for a preliminary ruling, but upheld as regards, first, the second question referred for a preliminary ruling in its entirety, and secondly, the third question referred for a preliminary ruling, but only in so far as it relates to whether the French legislation complies with Article 56 TFEU and Article 16 of Directive 2006/123.

49. However, since I have only partial knowledge of the facts in the present case, I shall carry out a brief examination of the second question referred for a preliminary ruling and of the third question referred for a preliminary ruling in so far as it relates to whether the French legislation complies with Article 56 TFEU and Article 16 of Directive 2006/123.

50. Before examining the substance of the questions referred by the national court, I would like to draw the attention of the Court to the fact that an action for annulment of the Decree of 27 May 2005 is pending before the French Conseil d'État (Council of State), which has decided to stay the proceedings pending the judgment of the Court in this case. That action was brought by Audace, and it raises questions which are similar to those which are now before Court.[21] I note also that, when an

19 — In its written observations, Audace referred to the application for a parallel import authorisation submitted to the French authorities by Sendagai, the Spanish wholesaler which supplies Landizoo, which sold the disputed veterinary medicinal products to the livestock farmers in the present case. According to Audace, the French authorities rejected that application for a parallel import authorisation on the ground that Sendagai was in possession of a wholesale distribution licence granted by the Spanish authorities, rather than a wholesale distribution licence granted by the French authorities. However, Sendagai is not a party in the proceedings before the referring court: it is the livestock farmers, not Sendagai, who are charged with the offence of importing without an authorisation.

20 — See, in particular, judgment in *Kamberaj* (C-571/10, EU:C:2012:233, paragraph 42).

21 — Audace seeks to have the Decree of 27 May 2005 annulled as *ultra vires* on the ground, in particular, that Article R. 5141-123-17 of the Public Health Code is contrary to Article 34 TFEU and Article 56 TFEU, to the objectives of Directive 2001/82 and to Article 16 of Directive 2006/123 because, first, it 'assimilate[s] parallel importers of veterinary medicinal products to holders of [marketing authorisations] and impose[s] on them the pharmacovigilance obligations provided for in Articles R. 5141-104, R. 5141-105 and R. 5141-108 of the Public Health Code', and secondly, it 'require[s] parallel importers of veterinary medicinal products to use their parallel import authorisations through an establishment authorised under Article L. 5142-2 of the Public Health Code and established in France'. See Conseil d'État (Council of State), 9 April 2015, Association of Users and Distributors of AgroChemicals in Europe (application No. 370350).

action for annulment of that same decree was brought before it in 2006, the French Conseil d'État (Council of State) refrained from making a request to the Court for a preliminary ruling,[22] as did the Cour de cassation (France) (Court of Cassation, France) in 2014, before which a plea of illegality of that decree had been raised.[23]

B – *Substance*

1. The first question referred for a preliminary ruling

51. By the first question referred for a preliminary ruling, the national court asks the Court whether Article 34 TFEU and Article 36 TFEU must be interpreted as precluding national legislation which '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 [as amended], thus excluding those with retail distribution rights and livestock farmers'.

52. As stated above, the French Government does not appear to have interpreted the French legislation in the same way as the referring court.[24] It maintains that Article R. 5141-123-7 of the Public Health Code provides that the parallel import authorisation is granted when, inter alia, the veterinary medicinal product is '*obtain[ed] from* an undertaking authorised under Article 65 of Directive 2001/82, [as amended]',[25] and not, as stated in the first question referred for a preliminary ruling, when the parallel import authorisation applicant *is himself the holder* of the wholesale distribution authorisation provided for in Article 65. However, the French Government does not dispute that livestock farmers and those with retail distribution rights, that is, veterinarians and pharmacists, 'are not eligible to obtain a parallel import authorisation'. Therefore, it is not necessary, for the purpose of providing a useful answer to the referring court, to address the difference between the interpretations of the French Government and the referring court. It is sufficient for the Court to reformulate slightly the first question referred for a preliminary ruling in order to remove all references to the wholesale distribution authorisation provided for in Article 65 of Directive 2001/82 as amended.

53. Therefore, I propose that the first question referred for a preliminary ruling be reformulated as follows: must Article 34 TFEU and Article 36 TFEU be interpreted as precluding national legislation under which parallel import authorisations may not be granted to livestock farmers and to those with retail distribution rights?

22 — Conseil d'État (Council of State), 6 December 2006, Association of Users and Distributors of AgroChemicals in Europe (application No. 282417. Recueil Lebon 498; AJDA 2007. 607; RDSS 2007. 165, Mergelin note). In the context of that action, Audace complained, in particular, that Article R. 5141-123-17 of the Public Health Code did not allow livestock farmers to parallel-import veterinary medicinal products from other Member States directly. The Conseil d'État (Council of State) rejected that complaint.

23 — Cour de cassation (Court of Cassation), Criminal Chamber, 17 December 2014, No 13-86.686. The cour d'appel de Poitiers (France) (Court of Appeal, Poitiers, France) had rejected the plea of illegality of the Decree of 27 May 2005 stating that, in the light of the judgment of the Conseil d'État (Council of State) of 6 December 2006, the decree in question was enforceable against the accused. The Cour de cassation (Court of Cassation) censured the judgment of the cour d'appel (Court of Appeal) on a point of procedure and referred the case back to the cour d'appel de Bordeaux (Court of Appeal, Bordeaux).

24 — See footnote 18 in the present Opinion.

25 — Emphasis added. In its written observations, the French Government claims that 'it is not apparent [from Articles L. 5142-1, L. 5142-2, R. 5141-123-7 and R. 5141-123-17 of the Public Health Code] that, under the French legislation, only wholesale distributors may obtain a parallel import authorisation, as the referring court seems to consider in its first question referred for a preliminary ruling. However, it is apparent from those provisions that only a veterinary pharmaceutical establishment which imports veterinary medicinal products from an undertaking that holds a wholesale distribution authorisation for veterinary medicinal products under Article 65 of Directive 2001/82 [as amended] may obtain a parallel import authorisation for veterinary medicinal products'.

a) Preliminary observations

54. I note that, under Article 5(1) of Directive 2001/82 as amended, 'no veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been granted by the competent authorities of that Member State'. I note also that there is no obligation under that directive of mutual recognition of marketing authorisations granted by other Member States. [26] Therefore, where a veterinary medicinal product has a marketing authorisation in the exporting Member State, but not in the importing Member State, the importing Member State is entitled to make the import subject to obtaining a marketing authorisation granted by its own authorities. Importing the product is, after all, regarded as placing that product on the market in the importing Member State and is, as such, subject to authorisation. [27]

55. However, as I stated in the introduction, where a veterinary medicinal product is parallel-imported, the importing Member State may not do any more than compel the parallel importer to undergo a *simplified* marketing authorisation procedure. [28] In that regard, the Communication from the Commission defines parallel importation as follows: '[trade] is known as "parallel" to the extent that it takes place outside and — in most cases — in parallel with the distribution network that the manufacturers or original suppliers have established for their products at a Member State [level], while it concerns products which are in every respect similar to the ones marketed by the distribution networks'. [29] According to settled case-law, where a medicinal product is parallel-imported, it cannot be regarded as being placed on the market for the first time in the importing Member State since, in theory, it is identical to a product which has a marketing authorisation in that Member State. Therefore, according to the case-law, Article 5 of Directive 2001/82 as amended, which provides that no medicinal product can be placed on the market in a Member State without a marketing authorisation, does not apply to parallel imports. [30]

56. Therefore, according to settled case-law, national legislation which requires parallel importers to obtain marketing authorisations must be examined in the light of Article 34 TFEU and Article 36 TFEU. The Court has held that, in the case of parallel imports, the sole purpose of the examination carried out by the competent authorities of the importing Member State must be to verify that the

26 — See the judgment in *Escalier and Bonnarel* (C-260/06 and C-261/06, EU:C:2007:659, paragraph 23) in which the Court points out, as regards Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1), that 'the system set up by the Directive does not rest on any obligation of mutual recognition by the Member States of the plant protection product marketing authorisations granted in other Member States, but on an obligation that such product must obtain an authorisation falling within the competence of the Member States, which are not bound by marketing authorisations granted in another Member State'.
The same finding can be made as regards Directive 2001/82 as amended. Member States are required to recognise a marketing authorisation granted in another Member State only where, as provided for in Articles 31 to 43 of that directive, the marketing authorisation has been obtained by means of the decentralised procedure (whereby the marketing authorisation applicant may obtain a marketing authorisation which is valid in several Member States) or by means of the mutual recognition procedure (whereby, having been granted a marketing authorisation, the applicant may obtain the recognition of that marketing authorisation by other Member States). Other than in those two situations, both of which require action to be taken by the marketing authorisation applicant/holder, no obligation of mutual recognition is imposed on Member States.

27 — See judgment in *Bruyère and Others* (C-297/94, EU:C:1996:124, paragraph 21).

28 — See judgments in *Escalier and Bonnarel* (C-260/06 and C-261/06, EU:C:2007:659, paragraph 32); *Mac* (C-108/13, EU:C:2014:2346, paragraphs 30 to 32).

29 — Commission Communication of 30 December 2003 on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted (COM(2003) 839 final), paragraph 2. See also the Opinion of Advocate General Léger in *Smith & Nephew and Primecrown* (C-201/94, EU:C:1996:19, point 17), according to which 'the phenomenon occurs when traders outside the manufacturer's official distribution network purchase products on the market from wholesalers or retailers in the country of production or in other intermediary countries where prices are low, and export them to countries where prices are high. The parallel importer's aim is to exploit those price differences, which are sometimes very large, in order to obtain a profit, while keeping his price below the manufacturer's official sale price'.

30 — See, inter alia, judgment in *Smith & Nephew and Primecrown* (C-201/94, EU:C:1996:432, paragraph 21), in which the Court held, as regards Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ English Special Edition 1965-1966, p. 20), that 'the provisions of [that] directive concerning the procedure for issue of marketing authorisations cannot apply to a proprietary medicinal product covered by a marketing authorisation in one Member State which is being imported into another Member State as a parallel import of a product already covered by a marketing authorisation in that other Member State. In such a case, the imported proprietary medicinal product cannot be regarded as being placed on the market for the first time in the Member State of importation'. See also judgment in *British Agrochemicals Association* (C-100/96, EU:C:1999:129, paragraphs 31 and 32).

imported medicinal product may be covered by the marketing authorisation already issued,[31] that is to say, to verify whether or not it is identical in all respects to a medicinal product already authorised in that State, or it has at least been manufactured according to the same formulation, using the same active ingredient, and has the same therapeutic effects.[32] Any national legislation requiring a more detailed examination would be contrary to Article 34 TFEU and Article 36 TFEU. The case-law has specified that, in the context of a simplified procedure, the importer need not supply the information that would be required of him in the context of the ordinary legal procedure relating to marketing authorisations. The competent authorities of the importing Member States already have in their possession all the particulars necessary for the purpose of checking that the medicinal product is effective and not harmful, having obtained them when they examined the previous marketing authorisation application: it is therefore unnecessary to ask the parallel importer to provide those particulars again.[33]

57. I note that, in this case, it is not known whether there was a veterinary medicinal product authorised in the importing Member State (France) to which the medicinal products imported by the livestock farmers were identical in all respects or which had been manufactured according to the same formulation, using the same active ingredient, and had the same effects.[34] It should be considered, nonetheless, that such a medicinal product existed. The questions referred for a preliminary ruling relate to 'parallel imports' and Article R. 5141-123-6 of the Health Code defines parallel importation as the importation of a veterinary medicinal product which, on the one hand, has obtained a marketing authorisation in the exporting Member State and, on the other hand, *has a quantitative and qualitative composition, in terms of the active substances, which is identical to [that] of a medicinal product which has obtained a marketing authorisation in France*.[35]

58. I note that it is common ground in this case that the French legislation provides for a simplified marketing authorisation procedure: namely, the parallel import authorisation procedure provided for in Article R. 5141-123-6 et seq. of the Public Health Code.[36]

59. However, the French legislation excludes individuals, including livestock farmers and veterinarians, from eligibility for the simplified marketing authorisation procedure. The first question referred for a preliminary ruling relates to whether the exclusion of individuals from eligibility for the simplified marketing authorisation procedure complies with Article 34 TFEU and Article 36 TFEU.

31 — See judgment in *Escalier and Bonnarel* (C-260/06 and C-261/06, EU:C:2007:659, paragraph 32).

32 — See judgments in *British Agrochemicals Association* (C-100/96, EU:C:1999:129, paragraph 33); *Kohlpharma* (C-112/02, EU:C:2004:208, paragraphs 18-20) and *Mac* (C-108/13, EU:C:2014:2346, paragraph 24).

33 — See judgment in *Smith & Nephew and Primecrown* (C-201/94, EU:C:1996:432, paragraph 22), according to which 'if the public health authorities of the Member State of importation already have in their possession, as a result of importation on a previous occasion, all the pharmaceutical particulars relating to the medicinal product in question and considered to be absolutely necessary for the purpose of checking that the product is effective and not harmful, it is clearly unnecessary, in order to protect the health and life of humans, for those authorities to require a second trader who has imported a medicinal product which is in every respect the same or whose differences have no therapeutic effect, to produce these particulars again'.
See, also, judgment in *Rhône-Poulenc Rorer and May & Baker* (C-94/98, EU:C:1999:614, paragraph 40), according to which 'it follows from [Article] [34 TFEU and Article 36 TFEU] that national authorities must not obstruct parallel imports by requiring parallel importers to satisfy the same requirements as those which are applicable to undertakings applying for the first time for a marketing authorisation for a medicinal product'.

34 — More specifically, it is not known whether *all* the medicinal products imported were identical in all respects to medicinal products authorised in France, or had at least been manufactured according to the same formulation, using the same active ingredient, and had the same effects. It is stated in the request for a preliminary ruling that veterinary medicinal products 'some of which did not have a [marketing authorisation]' were found on the farms inspected.

35 — See point 17 of this Opinion.

36 — Moreover, an action for failure to fulfil obligations was brought against the French Republic on the ground that the legislation in force at that time did not provide for a specific procedure for parallel imports. See judgments in *Commission* v *France* (C-263/03, EU:C:2004:612) and *Commission* v *France* (C-122/03, EU:C:2003:673). The Decree of 27 May 2005 at issue in the present case post-dates those two judgments.

60. As we have seen, under Article R. 5141-123-7 of the Public Health Code, only the undertaking which buys from the holder of the wholesale distribution authorisation, and not the undertaking which is itself the holder of a wholesale distribution authorisation, may obtain a parallel import authorisation. Moreover, Article R. 5141-123-17 of the Public Health Code provides that 'use ... of a proprietary veterinary medicinal product covered by an import parallel 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*'.[37] Articles L. 5142-1 and L. 5142-2 of the Public Health Code provide that, inter alia, the manufacture, import and wholesale distribution of veterinary medicinal products are permissible only for a pharmaceutical establishment, that is to say, an establishment which, on the one hand, is owned by a pharmacist, a veterinarian or a company whose management or executive board includes a pharmacist or a veterinarian, and on the other hand, has been granted an authorisation to open by ANSES. Consequently, under the French legislation, only a pharmaceutical establishment, that is to say, a *legal person* which is either owned by a pharmacist or veterinarian or has a pharmacist or veterinarian among its directors, may use a parallel import authorisation.

61. In that regard, the French Government itself acknowledges in its written observations that 'on the one hand, those with retail distribution rights, namely, under French law, ... pharmacists and veterinarians ..., and on the other hand, individuals, such as, in particular, livestock farmers, are not eligible to obtain a parallel import authorisation'.

62. I take the view that such legislation cannot be considered to be in compliance with Article 34 TFEU and Article 36 TFEU.

b) Article 34 TFEU

63. Since the French legislation excludes individuals from eligibility for the simplified marketing authorisation procedure, those of them who wish to parallel-import veterinary medicinal products are obliged to apply for a marketing authorisation under the procedure under ordinary law. However, they do not have in their possession all the information needed in order to obtain a marketing authorisation under that procedure. Directive 2001/82 as amended, requires marketing authorisation applicants to provide, inter alia, the qualitative and quantitative composition in terms of the active substances,[38] but parallel importers do not have that information. Only the manufacturer of the imported medicinal product and its authorised distributors are in possession of such information. Accordingly, Advocate General Mayras observes, in *De Peijper*, that the parallel importer 'does not have in its possession documents emanating from the producer which are likely to enable it to prove ... that the processes used for the ... treatment of the medicinal preparations which it sells could not cause their constituents to deteriorate and that it is not in a position ... to adduce this evidence by analyses made in its own laboratory. ... you might just as well search for a needle in a haystack'. The absence of a simplified marketing authorisation procedure therefore leads to the creation, in the words of Advocate General Mayras, of 'what is in fact a legal import monopoly for the benefit of the foreign manufacturer'.[39]

37 — Emphasis added. See point 19 of this Opinion.

38 — See Article 12(3)(c) of Directive 2001/82/EC as amended. See, also, Annex I, Title I, Part 2, Section A of Directive 2001/82 as amended.

39 — Opinion of Advocate General Mayras in *de Peijper* (104/75, EU:C:1976:43, pp. 645-646).

64. I note, in that regard, that in the judgment in *Escalier and Bonnarel*, the Court held that a farmer who effects a parallel importation of a plant protection product is not exempt from the obligation to undergo a marketing authorisation procedure even if he is importing that product solely for the needs of his farm.[40] Admittedly, as it is a parallel import, the procedure to which he is subject is a simplified marketing authorisation procedure. However, he must still obtain a marketing authorisation even if he has no intention of placing the imported medicinal products on the market.

65. I note also that it does not follow from Article 70 of Directive 2001/82 as amended, that a veterinarian is exempt from the obligation to undergo a marketing authorisation procedure when he effects the parallel importation of veterinary medicinal products. In that regard, I would point out that, according to Article 70 *ab initio* and Article 70(c) of that directive, veterinarians providing a service in another Member State may 'take with them and administer to animals small quantities of veterinary medicinal products', provided that, in particular, 'the veterinary medicinal products intended for administration to food-producing animals have the same qualitative and quantitative composition in terms of active substances as the medicinal products authorised in accordance with Articles 5, 7 and 8 in the ... Member State [in which the service is being provided]'. Article 70(c) provides for parallel importation, since it refers to circumstances in which the imported medicinal products are not identical to products already authorised in the importing Member State, but have the same composition as them in terms of active substances. In such circumstances, Member States are to ensure that the veterinarian 'can take with [him]' the medicinal products in question without being required to obtain a marketing authorisation. However, I note that the veterinarian is to be exempt from undergoing a marketing authorisation procedure only under very strict conditions, including the conditions that the quantities at issue do 'not [exceed] daily requirements' and that the veterinarian does not 'furnish any ... medicinal product to the owner or keeper of the animals ... under his care' (unless national rules provide otherwise). Therefore, the exemption from the marketing authorisation obligation provided for in Article 70 of Directive 2001/82 as amended, appears to be an exception: when veterinarians wish to take into another Member State quantities exceeding daily requirements, they must undergo a marketing authorisation procedure, or where appropriate, a simplified procedure.[41]

66. Therefore, in the present case, individuals, namely the livestock farmers and veterinarians, will never[42] be able to import veterinary medicinal products to France as they are not exempt from the obligation to obtain a marketing authorisation, they are not eligible for the parallel import authorisation procedure provided for in Article R. 5141-123-6 et seq. of the Public Health Code and they do not have in their possession the information needed for the marketing authorisation application dossier under the ordinary legal procedure.

67. Therefore, in so far as the French legislation excludes individuals from eligibility for the parallel import authorisation procedure, it must be considered to constitute a restriction on trade between the Member States, which is contrary to Article 34 TFEU.

40 — See judgment in *Escalier and Bonnarel* (C-260/06 and C-261/06, EU:C:2007:659), according to which 'a Member State is entitled to require that a person who intends to effect a parallel importation of a plant protection product already authorised on its territory be subject to a simplified marketing authorisation procedure, *even when the importer is a farmer who is importing that product solely for the needs of his farm*' (paragraph 36 — emphasis added). The Court holds that if farmers who import products solely for the needs of their farms were relieved of the obligation to comply with a simplified marketing authorisation procedure, it would fall to the farmers to assess whether the imported product may be covered by a marketing authorisation issued in favour of another product, in other words, to assess whether the two products are identical in all respects or have at least been manufactured according to the same formulation, using the same active substance, and have the same effects, although such an assessment is the responsibility of the national authorities in the importing State, and farmers do not have the resources to be able to carry out an assessment which can be relied upon. The Court also held that, if farmers were relieved of the marketing authorisation obligation, the effectiveness of the control mechanism for products placed on the market and the use thereof, which must be operated by Member States under Directive 91/414, would be undermined (paragraphs 34 and 35).

41 — See, in that regard, judgment in *Bruyère and Others* (C-297/06, EU:C:1996:124, paragraph 22).

42 — Other than in the circumstances provided for in Article 70(c) of Directive 2001/82 as amended, whose scope of application is, nonetheless, very limited: the veterinarian is exempt from the marketing authorisation obligation only if the quantities are small and do not exceed daily requirements.

68. That legislation can be justified only on grounds of the protection of public health, in accordance with Article 36 TFEU.

c) Article 36 TFEU

69. In that regard, the French Government submits that, since livestock farmers do not have the material resources to ensure the monitoring of veterinary medicinal products and they do not register or process returns of those products, it would undermine the protection of human and animal health if they were authorised to import medicinal products. Furthermore, the French Government notes that any parallel importation of veterinary medicinal products could lead to the wholesale distribution of those products and that all parallel importers must therefore fulfil the obligations which are imposed on wholesale distributors under Article 65(2) to 65(4) of Directive 2001/82. However, livestock farmers are not capable of fulfilling those obligations. Thus, they should not be granted parallel import authorisations.

70. In my opinion, the exclusion of individuals, notably livestock farmers, from eligibility for the simplified marketing authorised procedure cannot be justified on grounds of the protection of public health.

71. First, I note that the imported veterinary medicinal product is both identical in all respects to a medicinal product already authorised in the importing Member State and has been manufactured according to the same formulation, using the same active substance and has the same effects as that product. I note also that, in the context of the marketing authorisation procedure for the medicinal product already authorised, the competent authorities of that State have duly considered whether that product posed a risk to public health and concluded that there was no such risk. For parallel imports, the purpose of the examination carried out by the competent authorities in the importing Member State is to assess whether the imported medicinal product may be covered by the marketing authorisation already issued.[43] In other words, that examination has the purpose of 'ensur[ing] ... that the medicinal product imported as a parallel product, even if not identical in all respects to that already authorised by them, has the same active ingredient and the same therapeutic effect *and does not pose a problem of quality, efficacy or safety*'.[44] The examination to establish whether the imported medicinal product and the authorised medicinal product are identical therefore includes an assessment of the risk to public health posed by the former. Moreover, if, in the context of that assessment, the competent authorities of the importing Member State find that the imported medicinal product cannot be covered by the marketing authorisation issued to the authorised medicinal product on account of the differences between the two products, the importer will have to undergo not the simplified marketing authorisation procedure, but the marketing authorisation procedure provided for in Directive 2001/82 as amended,[45] in the context of which the risk to health posed by the imported medicinal product will be examined *ex novo*.

72. Secondly, I note that Directive 2001/82 as amended, imposes on livestock farmers obligations relating to the monitoring of the veterinary medicinal products which they administer to animals in their care, or simply the veterinary medicinal products in their possession. Article 69 of that directive provides that the owners or keepers of food-producing animals are to provide proof of purchase, possession and administration of veterinary medicinal products to such animals for five years after

43 — See point 56 of this Opinion.

44 — Judgment in *Rhône-Poulenc Rorer and May & Baker* (C-94/98, EU:C:1999:614, paragraph 45, emphasis added).

45 — Judgment in *British Agrochemicals Association* (C-100/96, EU:C:1999:129, paragraphs 36 and 37).

their administration, and that they are to keep records to that effect.[46] It seems to me to be unnecessary to require livestock farmers to fulfil other pharmacovigilance obligations, and in particular to require them to fulfil the obligations imposed on wholesale distributors under Article 65(2) and (3) of Directive 2001/82 as amended.

73. The French Government's argument that, since any parallel importation could lead to the wholesale distribution of the imported products, parallel importers should be subject to the pharmacovigilance obligations imposed on wholesale distributors under Directive 2001/82 as amended, is not convincing. It is true that Article 1(17) of that directive defines wholesale distribution as 'any activity which includes the purchase, sale, *import*, export, or any other commercial transaction in veterinary medicinal products, whether or not for profit, except for: ... retail supplies of veterinary medicinal products by persons entitled to carry out such supplies in accordance with Article 66'.[47] However, it does not follow from that provision that all importers must obtain a wholesale distribution authorisation as provided for in Article 65 of Directive 2001/82 as amended, or that all importers must fulfil the obligations which that directive imposes on the holders of such authorisations. Article 1(17) of Directive 2001/82 as amended, defines wholesale distribution as a 'commercial transaction in veterinary medicinal products'; however, a livestock farmer importing veterinary medicinal products solely for the needs of his farm is not carrying out a commercial transaction *in those medicinal products*. The import effected by that livestock farmer does serve a purpose which is perhaps commercial, or at least professional (in that those imported medicinal products are administered to the animals which he rears and then sells). But it is not a commercial transaction in the imported medicinal products: that would be the case only if the livestock farmer sold them on. Therefore, importing the products solely for use by the importer cannot be regarded as wholesaling them: no *distribution* of the veterinary medicinal products takes place. In the present case, the livestock farmer importing veterinary medicinal products in order to administer them to the animals under his care could not be required to fulfil the obligations that Directive 2001/82 as amended imposes on wholesale distributors, namely, as laid down in Article 65(2) and (3) of that directive, the obligations to have at his disposal 'technically competent staff and suitable and sufficient premises' and to keep detailed records of the quantities received and supplied.[48]

74. Moreover, I note that, according to the wording of Article 65(2) of Directive 2001/82 as amended, the purpose of the obligations imposed on wholesale distributors is to ensure compliance with the 'requirements laid down in the Member State concerned as regards the storage and handling of veterinary medicinal products'. However, the quantities imported by a livestock farmer to fulfil the needs of the animals in his care are far smaller than the quantities imported by a wholesale distributor: the livestock farmer thus has no need to have at his disposal the premises, equipment and staff which are essential to the wholesale distributor.

75. Thirdly, I note that, while Directive 2001/82 as amended, expressly imposes the pharmacovigilance obligations set out in Articles 74 and 75[49] on the sole holder of the marketing authorisation, namely, the manufacturer of the veterinary medicinal product or its representative, the obligation to report to the competent authorities of the concerned Member State suspected adverse reactions to veterinary medicinal products, which is laid down in Article 72(1) can, in my view, be imposed on livestock farmers by Member States, since it is not specified in that article on whom the Member States may

46 — See point 8 of this Opinion. As regards the applicability of Article 69 of Directive 2001/82 as amended to livestock farmers who parallel-import veterinary medicinal products, I would point out that, according to the case-law of the Court, the provisions of that directive relating to the procedure for granting marketing authorisations do not apply to parallel imports: parallel imports remain subject to the other provisions of that directive, in particular, those relating to the monitoring of medicinal products and to pharmacovigilance.

47 — Emphasis added.

48 — See point 7 of this Opinion.

49 — A case in point is the obligation 'to have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance', laid down in Article 74 of Directive 2001/82 as amended, and the obligation to keep detailed records of suspected adverse reactions, to log them and to report them to the competent authority of the concerned Member State, laid down in Article 75 of that directive.

impose that reporting obligation. Contrary to what is claimed by the French Government, such an obligation adequately ensures the monitoring of parallel-imported veterinary medicinal products, particularly given that there is also an obligation imposed on veterinarians and pharmacists. Article 72(2) of Directive 2001/82 as amended, imposes 'on veterinary practitioners and other health-care professionals' the reporting of suspected 'serious or unexpected' adverse reactions and suspected 'human' adverse reactions. Once the reports have been submitted, it falls to the competent authorities of the concerned Member State to send them to the competent authorities of the other Member States via the data-processing network set up to allow such an exchange [50] and, where appropriate, to ask the holder of the marketing authorisation to supply the necessary information. [51]

76. Fourthly, if it became necessary to recall a veterinary medicinal product, it would be perfectly feasible for the competent authorities in the importing Member State to inform parallel importers of this. Marketing authorisations are personal, that is to say, all importers are subject to a simplified marketing authorisation procedure even if the parallel import product has already obtained a marketing authorisation in favour of another parallel importer. [52] Consequently, the competent authorities of the importing Member State know exactly which livestock farmer has imported which medicinal product and can, where appropriate, inform them of the recall.

77. Therefore, protection of public health is guaranteed, in my opinion, by imposing on livestock farmers the obligations laid down in Article 69 and Article 72(1) of Directive 2001/82 as amended, and by imposing on veterinarians the obligation laid down in Article 72(2) of that directive. It is not necessary, in order to achieve such an objective, to exclude livestock farmers and veterinarians from eligibility for the simplified marketing authorisation procedure, as the French legislation does.

78. Therefore, the Court's answer to the referring court should be that Article 34 TFEU and Article 36 TFEU preclude national legislation under which parallel import authorisations may not be granted to livestock farmers and to those with retail distribution rights.

2. The second question referred for a preliminary ruling

79. The second question referred for a preliminary ruling must, in my opinion, be considered as inadmissible on the ground that it is hypothetical. [53] However, I shall carry out a brief examination of the substance of that question in order to provide the Court with some points for consideration in the event that it holds the question to be admissible (which, it seems to me, could be the case only if the veterinarian at issue in the main proceedings had purchased and resold the veterinary medicinal products himself).

80. By that question, the referring court asks the Court, in essence, whether Article 65 of Directive 2001/82 as amended and Article 16 of Directive 2006/123 preclude a Member State from requiring an operator who intends to engage in the wholesale distribution of veterinary medicinal products in its territory to be the holder of a wholesale distribution authorisation granted by its own competent authorities, even if he is already the holder of a wholesale distribution authorisation granted by another Member State.

81. First, I note that Article 65(1) of Directive 2001/82 as amended, makes wholesale distribution subject to possession of an authorisation granted by the Member States, and that that directive makes no provision for the mutual recognition of wholesale distribution authorisations granted by other Member States.

50 — See, in that regard, Articles 76 and 77 of Directive 2001/82 as amended.

51 — See, in that regard, judgment in *Rhône-Poulenc Rorer and May & Baker* (C-94/98, EU:C:1999:614, paragraph 46).

52 — See, in that regard, judgment in *Escalier and Bonnarel* (C-260/06 and C-261/06, EU:C:2007:659, paragraph 43).

53 — See point 46 of this Opinion.

82. Furthermore, under Article 65(2) of Directive 2001/82 as amended, the applicant for such an authorisation must establish that he has at his disposal, inter alia, the premises necessary for the storage and handling of veterinary medicinal products. Although not expressly stated in that provision, it seems to me that those premises must necessarily be located in the territory of the Member State from which the wholesale distribution authorisation has been requested. Where large quantities of veterinary medicinal products are to be distributed, these must be stored in appropriate conditions. The fact that the applicant is the holder of a wholesale distribution authorisation in Spain, which implies that he has appropriate premises in Spain, does not mean that he also has such premises in France. In particular, it seems to me to be essential that the emergency plan applicable in the event of the recall of a veterinary medicinal product, provided for in Article 65(3) of Directive 2001/82 as amended, be adapted to the national territory in question so that it may be implemented quickly.

83. Secondly, as regards Article 16 of Directive 2006/123,[54] I note that, although Article 16(2) *ab initio* and Article 16(2)(b) provides that Member States may not impose on service providers the obligation to obtain an authorisation from their own competent authorities, Article 3 of that directive provides for an exception relating to public health. Therefore, it seems to me that the reasoning set out above in respect of Article 36 TFEU could also be applied in respect of Article 16(3) of Directive 2006/123.

84. Therefore, assuming that Article 65 of Directive 2001/82 as amended and Article 16 of Directive 2006/123 are applicable, they do not preclude a Member State from requiring an operator who intends to engage in the wholesale distribution of veterinary medicinal products in its territory to be the holder of a wholesale distribution authorisation granted by its own competent authorities, even if he is already the holder of a wholesale distribution authorisation granted by another Member State.

3. The third question referred for a preliminary ruling

85. The third question referred for a preliminary ruling should, in my opinion, be considered to be admissible only in so far as it relates to the compatibility with Article 34 TFEU and Article 36 TFEU of national legislation which requires parallel importers, first, to have an establishment in their own territory and, secondly, to fulfil the pharmacovigilance obligations laid down in Articles 72 to 79 of Directive 2001/82 as amended.[55]

86. First, as concerns the obligation to have an establishment in the territory of the importing Member State, I would point out that Article R. 5141-123-17 of the Public Health Code, in so far as it requires the holder of the parallel import authorisation to be authorised by ANSES to open a pharmaceutical establishment, does require him to have an establishment in French territory (otherwise, ANSES would not be competent to authorise the opening of that establishment). However, such a requirement is not, in my view, contrary to Article 34 TFEU and Article 36 TFEU. The livestock farmers have a farm in France, therefore the requirement to have an establishment on French soil does not impose upon them any condition which they are not fulfilling by definition.

87. Secondly, as regards the pharmacovigilance obligations laid down in Articles 72 to 79 of Directive 2001/82 as amended, I note that those articles impose on livestock farmers only the obligation to report suspected adverse effects. Moreover, Article 69 of that directive provides that livestock farmers who keep food-producing animals are to provide proof of purchase, possession and administration of

54 — I would point out that wholesale distribution is a service falling within the scope of application of Directive 2006/123. See recital 33 of that directive, which makes reference to 'distributive trades'. See also the Commission handbook on the implementation of that directive, according to which 'the following can be mentioned as examples of services covered by the Directive: … distributive trades (including retail and wholesale of goods and services)' (Commission Handbook on Implementation of the Services Directive, available on the Commission website at: http://ec.europa.eu/growth/single-market/services/services-directive/implementation/index_en.htm). I would also point out that, while Article 2(2)(f) of Directive 2006/123 provides that the Directive does not apply to healthcare services, the Commission handbook on the implementation of that directive states that that exclusion does not apply to veterinary services: 'it should be clear that the exclusion of health services concerns services relating to human health and should not be understood as covering the services of veterinaries'.

55 — See point 47 of this Opinion.

veterinary medicinal products to such animals for five years. The other pharmacovigilance obligations laid down in Directive 2001/82 as amended apply to holders of marketing authorisations. As I explained previously, it is contrary to Article 34 TFEU and Article 36 TFEU for individuals (livestock farmers or veterinarians) who parallel-import veterinary medicinal products to be required to fulfil the obligations which Directive 2001/82 as amended, imposes on wholesale distributors (Article 65). [56]

88. In that regard, I note, in particular, that Article R. 5142-[4]2 of the Public Health Code imposes on parallel importers the obligation to have at their disposal appropriate premises, staff and equipment and to provide ANSES with an annual report on their establishment. That obligation corresponds to that imposed on wholesale distributors by Article 65(2) and (3) of that directive. Therefore, Article R. 5142-2 of the Public Health Code does not seem to be compatible with Article 34 TFEU and Article 36 TFEU.

89. A fortiori, it is contrary to Article 34 TFEU and Article 36 TFEU for individuals who parallel-import veterinary medicinal products to be required to fulfil the obligations which Directive 2001/82 as amended imposes on holders of a marketing authorisation and which are more burdensome than those imposed on wholesale distributors (Articles 74 and 75) .

90. In particular, I note that Article R. 5141-105 of the Public Health Code imposes on parallel importers the obligation to submit to ANSES a report on the adverse effects of veterinary medicinal products, 'along with a scientific assessment of the benefits and risks of the veterinary medicinal product'. While it seems consistent with Article 72(1) of Directive 2001/82 as amended to require livestock farmers to report suspected adverse effects to the competent national authority, it is, rather, the holder of the marketing authorisation who is subject, under that directive, to the obligation to produce a detailed report on the adverse effects and submit it to the competent authorities concerned (Articles 74 and 75 of that directive). Article R. 5141-105 of the Public Health Code is therefore not, in my opinion, compatible with Article 34 TFEU and Article 36 TFEU.

91. Finally, even if Directive 2006/123 were applicable in the present case (that is to say, if the veterinarian were distributing the imported medicinal products in France), [57] Article 16 of that directive does not preclude national legislation which requires the parallel importer to have an establishment in France, at least not where the parallel importer is engaged in the wholesale distribution of the imported medicinal products in France. The aim of the obligation to have an establishment in France is to guarantee good conditions for the storage and handling of veterinary medicinal products, and thus falls within the public health exception provided for in Article 16(3) of Directive 2006/123.

92. Therefore, the Court's answer to the referring court should be that Article 34 TFEU and Article 36 TFEU do not preclude national legislation which requires livestock farmers who parallel-import veterinary medicinal products to have available to them an establishment in the national territory, but that they do preclude national legislation which requires livestock farmers to fulfil the pharmacovigilance obligations laid down in Articles 73 to 79 of Directive 2001/82 as amended.

IV – **Conclusion**

93. In the light of the foregoing considerations, I propose that the Court reply to the questions referred for a preliminary ruling by the cour d'appel de Pau (Court of Appeal, Pau, France) as follows:

(1) Article 34 TFEU and Article 36 TFEU preclude national legislation under which parallel import authorisations may not be granted to livestock farmers and to those with retail distribution rights.

56 — See points 72-75 of this Opinion.

57 — See point 79 of this Opinion.

(2) The second question referred for a preliminary ruling is inadmissible.

(3) The third question referred for a preliminary ruling is inadmissible in so far as it relates to the compatibility with Article 56 TFEU and Article 16 of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market of national legislation which requires parallel importers to have available to them an establishment in the national territory and to fulfil the pharmacovigilance obligations provided for in Articles 72 to 79 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.

(4) Article 34 TFEU and Article 36 TFEU do not preclude national legislation which requires livestock farmers who parallel-import veterinary medicinal products to have available to them an establishment in the national territory.

(5) Article 34 TFEU and Article 36 TFEU preclude national legislation which requires livestock farmers who parallel-import veterinary medicinal products to fulfil the pharmacovigilance obligations laid down in Articles 73 to 79 of Directive 2001/82 as amended by Regulation No 596/2009.