

Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

1 March 2018*

(Reference for a preliminary ruling — Directive 2006/123/EC — Services in the internal market — National legislation limiting the right to retail, use and administer veterinary medicinal, anti-parasitic and organic products to veterinary practitioners — Freedom of establishment — Requirement that the share capital of establishments retailing veterinary medicinal products be held only by veterinary practitioners — Protection of public health — Proportionality)

In Case C-297/16,

REQUEST for a preliminary ruling under Article 267 TFEU from the Curtea de Apel București (Court of Appeal, Bucharest, Romania), made by decision of 1 March 2016, received at the Court on 25 May 2016, in the proceedings

Colegiul Medicilor Veterinari din România (CMVRO)

V

Autoritatea Națională Sanitară Veterinară și pentru Siguranța Alimentelor,

intervening parties:

Asociația Națională a Distribuitorilor de Produse de Uz Veterinar din România,

THE COURT (Third Chamber),

composed of L. Bay Larsen, President of the Chamber, J. Malenovský (Rapporteur), M. Safjan, D. Šváby and M. Vilaras, Judges,

Advocate General: N. Wahl,

Registrar: I. Illéssy, Administrator,

having regard to the written procedure and further to the hearing on 28 June 2017,

after considering the observations submitted on behalf of:

- the Colegiul Medicilor Veterinari din România (CMVRO), by R.-I Ciocaniu, avocat,
- the Asociația Națională a Distribuitorilor de Produse de Uz Veterinar din România, by L. Gabor and C.V. Toma, avocat,
- the Romanian Government, by R.-H. Radu, A. Wellman and L. Liţu, acting as Agents,

^{*} Language of the case: Romanian.



 the European Commission, by L. Nicolae, H. Tserepa-Lacombe and by L Malferrari, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 21 September 2017,

gives the following

Judgment

- This request for a preliminary ruling concerns the interpretation of Article 15 of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ 2006 L 376, p. 36) and Article 63(1) TFEU.
- The request has been made in proceedings between the Colegiul Medicilor Veterinari din România (CMVRO) (College of Veterinary Physicians of Romania) and the Autoritatea Națională Sanitară Veterinară și pentru Siguranța Alimentelor (National Veterinary Health and Food Safety Authority), Romania ('the Veterinary Health and Food Safety Authority'), supported by the Asociația Națională a Distribuitorilor de Produse de Uz Veterinar din România (National Association of Distributors of Veterinary Products of Romania) ('the Association of Distributors of Veterinary Products'), concerning an application for the annulment of an order issued by the National Veterinary Health and Food Safety Authority, the adoption of which had the effect, according to the CMVRO, of abolishing the requirement for the share capital of establishments retailing veterinary medicinal products to be held only by veterinary practitioners.

Legal context

European Union law

Directive 2006/123

Recital 22 of Directive 2006/123 states as follows:

'The exclusion of healthcare from the scope of this Directive should cover healthcare and pharmaceutical services provided by health professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the Member State in which the services are provided.'

4 Article 2 of that directive, entitled 'Scope', provides in paragraph 2 thereof as follows:

'This Directive shall not apply to the following activities:

(f) healthcare services whether or not they are provided via healthcare facilities, and regardless of the ways in which they are organised and financed at national level or whether they are public or private;

...,

- 5 Article 3 of Directive 2006/123, entitled 'Relationship with other provisions of Community law', provides as follows:
 - '1. If the provisions of this Directive conflict with a provision of another Community act governing specific aspects of access to or exercise of a service activity in specific sectors or for specific professions, the provision of the other Community act shall prevail and shall apply to those specific sectors or professions.

...

- 3. Member States shall apply the provisions of this Directive in compliance with the rules of the Treaty on the right of establishment and the free movement of services.'
- 6 Chapter III of Directive 2006/123 is entitled 'Freedom of establishment for providers'. Section 2 of Chapter III is entitled 'Requirements prohibited or subject to evaluation' and Articles 14 and 15 of the directive form part of that section.
- Article 15 of Directive 2006/123, entitled 'Requirements to be evaluated', is worded as follows:
 - '1. Member States shall examine whether, under their legal system, any of the requirements listed in paragraph 2 are imposed and shall ensure that any such requirements are compatible with the conditions laid down in paragraph 3. Member States shall adapt their laws, regulations or administrative provisions so as to make them compatible with those conditions.
 - 2. Member States shall examine whether their legal system makes access to a service activity or the exercise of it subject to compliance with any of the following non-discriminatory requirements:

...

- (c) requirements which relate to the shareholding of a company;
- (d) requirements, other than those concerning matters covered by Directive 2005/36/EC [of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255, p. 22)] or provided for in other Community instruments, which reserve access to the service activity in question to particular providers by virtue of the specific nature of the activity;

• • •

- 3. Member States shall verify that the requirements referred to in paragraph 2 satisfy the following conditions:
- (a) non-discrimination: requirements must be neither directly nor indirectly discriminatory according to nationality nor, with regard to companies, according to the location of the registered office;
- (b) necessity: requirements must be justified by an overriding reason relating to the public interest;
- (c) proportionality: requirements must be suitable for securing the attainment of the objective pursued; they must not go beyond what is necessary to attain that objective and it must not be possible to replace those requirements with other, less restrictive, measures which attain the same result.

. . .

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Directive 2001/82/EC

Article 66(1) of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1), as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ 2009 L 188, p. 14) ('Directive 2001/82'), is worded as follows:

'Member States shall take all appropriate measures to ensure that the retail supply of veterinary medicinal products is conducted only by persons who are permitted to carry out such operations by the legislation of the Member State concerned.'

9 Article 67 of that directive provides as follows:

'Without prejudice to stricter Community or national rules relating to dispensing veterinary medicinal products and serving to protect human and animal health, a veterinary prescription shall be required for dispensing to the public the following veterinary medicinal products:

...,

10 Under Article 68(1) of Directive 2001/82:

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

11 The first paragraph of Article 69 of that directive 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.'

Directive 2005/36/EC

Article 38(3) of Directive 2005/36, as amended by Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 (OJ 2013 L 354, p. 132) ('Directive 2005/36'), provides as follows:

'Training as a veterinary surgeon shall provide an assurance that the professional in question has acquired the following knowledge and skills:

(a) adequate knowledge of the sciences on which the activities of a veterinary surgeon are based and of the Union law relating to those activities;

...'

Romanian law

Law No 160/1998

Article 2(1) of the legea nr. 160/1998 pentru organizarea și exercitarea profesiunii de medic veterinar (Law No 160/1998 on the organisation and practice of the profession of veterinary practitioner, *Monitorul Oficial al României*, Part I, No 289 of 6 August 1998, as republished in *Monitorul Oficial al României*, Part I, No° 433 of 23 May 2005) ('Law No 160/1998'), provides as follows:

'The profession of veterinary practitioner may be practised in Romania by any person who is a Romanian citizen and holds a legally recognised diploma in veterinary medicine, and by citizens of a Member State of the European Union ... who hold a diploma in veterinary medicine, a certificate, or other qualification provided for by law and issued by an educational establishment of the State concerned.'

14 Article 4 of that Law states as follows:

'Those practicing as veterinary surgeons shall enjoy exclusive rights in the following spheres of competence:

• • •

(i) the retail supply and use of organic products, special purpose anti-parasitic products and veterinary medicinal products.

...

- 15 Under Article 16 of Law No 160/1998:
 - '(1) Membership of the [CMVRO] may be awarded to any veterinary practitioner who is a citizen of Romania or of a Member State of the European Union and who:
 - (a) lawfully exercises the profession of veterinary practitioner in Romania in accordance with Article 2 of this law;
 - (b) does not find himself in a situation of disgrace, as provided by law;
 - (c) is medically fit to exercise the profession of veterinary practitioner.
 - (2) Any person wishing to practice as a veterinary practitioner must be a Member of the [CMVRO].'
- 16 Article 39 of Law No 160/1998 is worded as follows:

'A set of rules drawn up by the [CMVRO] in collaboration with the [Veterinary Health and Food Safety Authority] shall establish the responsibilities and competences of independent veterinary surgeons and certain public duties they are required to perform.'

The Charter of Veterinary Practitioners

Article 1 of the Charter of Veterinary Practitioners, adopted by Decision No 3/2013 of the CMVRO (*Monitorul Oficial al României*, Part I, No 676 of 16 September 2014) ('the Charter of Veterinary Practitioners'), provides as follows:

'For the purposes of this Charter, the following definitions shall apply:

• • •

(m) "single register of veterinary practices, whether or not having legal personality" — official public document managed by the National Council of the Executive Board [of the CMVRO], which shall include the following:

– ...;

 veterinary pharmacies and veterinary pharmaceutical outlets, if their capital is exclusively held by veterinary practitioners or if it is otherwise amassed in the wake of subsequent legislative amendments;

...

¹⁸ Article 37(1) of the Charter of Veterinary Practitioners provides as follows:

'In the retailing of veterinary medicinal products, registered veterinary practitioners shall be organised exclusively as legal persons ... and shall carry out their activities within the following authorised veterinary structures:

- (a) veterinary pharmaceutical outlets;
- (b) veterinary pharmacies.

...

- 19 Article 38(3) and (4) of that charter states as follows:
 - '(3) Veterinary medicinal products, anti-parasitic products and organic veterinary products shall be used and administered exclusively by veterinary practitioners owning, or employed within, veterinary care or advisory structures ...
 - (4) By way of derogation from paragraph 3, animal owners may administer veterinary medicinal products that have been prescribed or recommend by a veterinary practitioner holding a valid practice certificate. This derogation does not extend, however, to veterinary medicinal products in injectable form.'

Veterinary Health Rules

The Veterinary Health and Food Safety Authority adopted l'ordinul nr. 83/2014 pentru aprobarea Normei sanitare veterinare privind condițiile de organizare și funcționare a unităților farmaceutice veterinare, precum și procedura de înregistrare sanitară veterinară/autorizare sanitară veterinară a unităților și activităților din domeniul farmaceutic veterinar (Order No 83/2014 approving veterinary health rules concerning the conditions for the organisation and operation of veterinary pharmaceutical structures, the veterinary health registration procedure and the procedure for the veterinary health

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authorisation of structures and activities in the veterinary pharmaceutical sector, *Monitorul Oficial al României*, Part I, No 541 of 22 July 2014), as subsequently amended and supplemented ('the Veterinary Health Rules').

21 Article 1 of the Veterinary Health Rules provides as follows:

'The present veterinary health rules lay down the conditions for the organisation and operation of veterinary pharmaceutical structures and the procedure for veterinary health registration and for the veterinary health authorisation of structures and activities in the veterinary pharmaceutical sector.'

22 Article 3 of those rules is worded as follows:

'For the purposes of the present veterinary health rules, the following definitions shall apply:

- (a) "veterinary pharmacy" a veterinary pharmaceutical establishment which possesses and retails veterinary medicinal products ... and other veterinary products ...
- (h) "veterinary pharmaceutical outlet" a veterinary pharmaceutical establishment the activity of which consists of retail trade limited to prescription-free veterinary medicinal products, other veterinary products ...

•••

23 Article 11 of the Veterinary Health Rules states as follows:

'The specialist staff of a veterinary pharmacy shall consist of:

- (a) staff with specialised higher education in the field of veterinary medicine;
- (b) staff with specialised secondary education in the field of veterinary medicine, human medicine, pharmacology, chemistry, biology;
- (c) administrative staff.'
- 24 Article 12(2) and (3) of those rules states as follows:
 - '(2) The management of a veterinary pharmacy requires the presence of a veterinary practitioner who holds a certificate for the practice of that profession issued by the [CMVRO].
 - (3) The placing on the market of veterinary medicinal products by a veterinary pharmacy shall be carried out, only by means of retail supply, by the staff referred to in Article 11(a) and (b).'
- Article 23 of the Veterinary Health Rules provides that rules analogous to those set out in Articles 11 and 12(2) of those rules are to apply to veterinary pharmaceutical outlets.

Order No 31/2015

By order No 31/2015 of 26 March 2015 amending and supplementing the Veterinary Health Rules approved by Order No 83/2014 of the Veterinary Health and Food Safety Authority (*Monitorul Oficial al României*, No 235 of 7 April 2015) ('Order No 31/2015'), the Veterinary Health and Food Safety Authority repealed Article 43(j) and Article 51(g) of those rules.

Those articles provided, in essence, that in order to be issued with a veterinary health permit for the operation of veterinary pharmacies or veterinary pharmaceutical outlets respectively, the legal representative of the structure concerned was required to file with the competent national veterinary health and food safety authority an application enclosing a copy of the certificate of entry in the single register of veterinary practices, whether or not having legal personality.

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

- The CMVRO brought proceedings before the referring court seeking the annulment of Order No 31/2015.
- In support of its action, the CMVRO submitted, inter alia, that that order infringes Article 4(i) of Law No 160/1998, which established that veterinary practitioners alone are entitled to retail and use organic products, special purpose anti-parasitic products and veterinary medicinal products. Such exclusivity entails a right to make decisions on the part of veterinary surgeons, which can be effective only if all, or a significant majority, of the share capital of veterinary pharmacies and veterinary pharmaceutical outlets is held by registered veterinary practitioners. Moreover, that is why the Charter of Veterinary Practitioners provides that only pharmacies or pharmaceutical outlets all of whose shareholders are veterinary practitioners may be registered in the single register of veterinary practices. However, as the requirement to submit a certificate of entry in that register was abolished by Order No 31/2015 of the Veterinary Health and Food Safety Authority, there can no longer be any guarantee that the requirement relating to the holding of share capital will be observed.
- For its part, the Veterinary Health and Food Safety Authority maintains that the abolition of the requirement to submit a certificate of entry in the single register of veterinary practices was necessary because the provisions in question did not comply with Directive 2006/123 and, according to a memorandum of the Consiliul Concurenței (Competition Council, Romania), they were liable to restrict competition on the retail market for veterinary products.
- The Association of Distributors of Veterinary Products, which intervened in support of the Veterinary Health and Food Safety Authority, disputes the interpretation of Article 4(i) of Law No 160/1998 advocated by the CMVRO to the effect that the exclusive competence enjoyed by the veterinary profession with regard to the use of certain products is not at odds with the consumer's right to purchase and have in his possession veterinary medicinal products, which Articles 67 and 69 of Directive 2001/82 conferred on the owners and keepers of animals.
- The referring court states that the European Commission submitted a request for information to Romania concerning possible breaches of EU law as a result of national legislation applicable to veterinary pharmacies, in particular the share capital holding requirements. Furthermore, that court is of the view that, even though the Court of Justice has previously ruled on the subject of professions or activities that are in some respects similar to the profession of veterinary practitioner or the activity of selling and using veterinary medicinal products, the situation of veterinary practitioners has certain particularities, which may justify a different outcome.
- In those circumstances, Curtea de Apel București (Court of Appeal, Bucharest, Romania) decided to stay proceedings and refer the following questions to the Court of Justice for a preliminary ruling:
 - '(1) Does EU law preclude national legislation which provides that veterinary surgeons are to have an exclusive right in relation to the retailing and use of organic products, special purpose anti-parasitic products and veterinary medicinal products?

(2) If such an exclusive right is compatible with EU law, does the latter preclude such a right from additionally concerning the structures through which the sale of such products takes place, in the sense that such structures must be mainly or exclusively owned by one or more veterinary surgeons?'

Admissibility of the request for a preliminary ruling

- The Association of Distributors of Veterinary Products contends that the present request for a preliminary ruling is inadmissible since the questions referred, as currently worded, do not mention the rule or rules of EU law in respect of which an interpretation is sought.
- It should be noted, in that regard, that the requirements to be satisfied by a request for a preliminary ruling laid down by Article 94 of the Court's Rules of Procedure include, as set out in Article 94(c) of those rules, the requirement that it should contain 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 and the relationship between those provisions and the national legislation applicable to the main proceedings.
- In the present case, the referring court states that, although the Court has previously handed down rulings concerning activities which are similar in some respects to the activity of selling and using veterinary medicinal products, the case before it has certain particularities, as a result of which it is not possible to apply the case-law in which the Court specified the implications of freedom of establishment in connection with those activities. Consequently, as regards the main proceedings, that court considers it necessary to refer the matter to the Court of Justice, as one of the pleas for annulment raised before it may be upheld only if the exclusive rights enjoyed by veterinary practitioners as regards the retail supply and use of organic products, special purpose anti-parasitic products and veterinary medicinal products are compatible with the principle of freedom of establishment.
- As the referring court has, therefore, set out in sufficient detail the reasons which have prompted it to inquire about the interpretation of certain provisions of EU law and the relationship between those provisions and the national legislation applicable to the main proceedings, the Court finds that the present request for a preliminary ruling is admissible.

Consideration of the questions referred

Preliminary observations

- It should be noted at the outset that, in the main proceedings, the referring court is required to apply national legislation concerning the pursuit, on a stable basis, of activities entailing the retail supply and use of organic products, special purpose anti-parasitic products and veterinary medicinal products, which may, in principle, fall within Chapter 3 of Directive 2006/123, concerning freedom of establishment.
- It is clear from Article 2(2)(f) of Directive 2006/123 that 'healthcare services' are expressly excluded from the scope of that directive. However, recital 22 of the directive states that the services that are excluded are those 'provided by health professionals to patients to assess, maintain or restore their state of health', which suggests that they are provided to human beings.
- While activities entailing the retail supply and use of organic products, special purpose anti-parasitic products and veterinary medicinal products do indeed fall within the healthcare sector, they do not constitute healthcare services for human beings.

- Accordingly, such activities fall outside the exception provided for in Article 2(2)(f) of Directive 2006/123.
- Moreover, as the referring court has referred principally, in its request, to Directive 2001/82, which lays down various principles relating to the distribution of veterinary medicinal products, it is necessary to examine whether those principles preclude the application of Directive 2006/123 in a situation such as that in the main proceedings.
- Article 3(1) of Directive 2006/123 states that if the provisions of that directive conflict with a provision of another EU act governing specific aspects of access to or exercise of a service activity in specific sectors or for specific professions, the provision of the other EU act are to prevail and to apply to those specific sectors or professions.
- However, while Directive 2001/82 covers certain aspects of the distribution of veterinary medicinal products with a view to protecting public health, it nevertheless cannot be regarded as governing the conditions under which Member States must authorise persons who are not veterinary practitioners to retail the various veterinary substances at issue in the main proceedings to use those substances and, therefore, to administer them.
- 45 Admittedly, certain rules governing those activities are set out in Articles 66(1) and 68(1) of that directive. However, Article 66(1) provides that Member States are to reserve the activity of retailing veterinary medicinal products to persons who are permitted to carry out such operations under national law, leaving the Member States free to lay down the conditions governing such permission. As a consequence, that article entrusts to Member States the task of establishing the conditions governing access to those activities.
- 46 Article 68(1) of Directive 2001/82 provides that Member States are required to take all measures necessary to ensure that only persons empowered possess or have under their control veterinary medicinal products or substances which may be used as veterinary medicinal products that have anti-parasitic properties, but does not go on to specify who such 'persons empowered' are.
- In that connection, it is also necessary to reject the interpretation of Directive 2001/82 advocated by the Association of Distributors of Veterinary Products, to the effect that a right may be inferred from Articles 67 and 69 of that directive for animal owners themselves to administer to their animals veterinary medicinal products that have been prescribed for them.
- It is sufficient to observe in that regard, first, that while Article 67 of Directive 2001/82 is intended to impose limits on the dispensing of medicinal products to the public, that article states that it is applicable without prejudice to stricter national rules for the protection of human and animal health. Second, while Article 69 of that directive requires animal owners to be able to justify the use of any veterinary medicinal product for a period of five years, that provision does not state that animal owners have the right to administer such products themselves.
- It follows that the two questions submitted, which refer only to 'EU law', without identifying specific provisions of that law, must be examined in the light of Directive 2006/123 alone, in particular Article 15 thereof.

The first question

The national court's first question must be understood as asking, in essence, whether Article 15 of Directive 2006/123 is to be interpreted as precluding national legislation, such as that at issue in the main proceedings, under which veterinary practitioners have an exclusive right to retail and use organic products, special purpose anti-parasitic products and veterinary medicinal products.

- As a preliminary point, it should be recalled that, under Article 15(1) of Directive 2006/123, Member States are required, first of all, to examine whether, under their legal system, any of the requirements listed in paragraph 2 of that article are imposed and, then, if so, are to ensure that any such requirement is compatible with the conditions laid down in paragraph 3 and, lastly, where necessary, to adapt their laws, regulations or administrative provisions so as to make them compatible with those conditions.
- The 'requirements to be evaluated', as referred to in Article 15(2) of Directive 2006/123, include that of ensuring that access to an activity is reserved to particular providers by virtue of the specific nature of the activity, set out in point d of that provision.
- In the present case, it should be noted that national legislation such as that at issue in the main proceedings reserves access to activities entailing the retail supply and use of certain veterinary products to veterinary practitioners and imposes a requirement of the kind referred to in Article 15(2)(d) of Directive 2006/123.
- As a consequence, such a requirement must satisfy the three conditions laid down in Article 15(3) of that directive, that is, they must be non-discriminatory, necessary and proportionate to the attainment of an overriding requirement relating to the public interest.
- As regards, first of all, the first of those conditions, there is nothing in the file submitted to the Court to suggest that the requirement referred to in paragraph 53 above is directly or indirectly discriminatory, within the meaning of Article 15(3)(a) of Directive 2006/123.
- Next, with regard to the second of those conditions, it should be noted that the Romanian Government has indicated that the requirement in question is intended to protect public health.
- It is the Court's established case-law that the protection of public health is one of the overriding requirements relating to the public interest recognised by EU law and that such a requirement may justify the adoption by a Member State of measures to ensure that the provision of medicinal products to the public is reliable and of good quality (see, to that effect, inter alia, judgment of 5 December 2013, *Venturini and Others*, C-159/12 to C-161/12, EU:C:2013:791, paragraphs 41 and 42).
- Lastly, as regards the third condition laid down in Article 15(3) of Directive 2006/123, it is satisfied only if three elements are present: (i) the requirement must be suitable for securing the attainment of the objective pursued; (ii) it must not go beyond what is necessary for the attainment of that objective, and (iii) it must not be possible to replace the requirement with a less restrictive measure that could achieve the same result.
- With regard to the first element, in general terms, attention must be drawn to the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods (judgment of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 31).
- Accordingly, the Court has accepted, in particular, that a requirement designed to restrict the sale of medicinal products to certain professionals may be justified because of the safeguards which such professionals must provide and the information which they must be in a position to furnish to consumers (see, to that effect, inter alia, judgment of 19 May 2009, *Commission* v *Italy*, C-531/06, EU:C:2009:315, paragraph 58).
- Although the Court has ruled to that effect with regard to medicinal products for human use, it should be noted, in particular, that certain animal diseases may be transmitted to humans and that food products of animal origin may endanger human health if they are derived from animals that are sick

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or carry treatment-resistant bacteria and if they contain traces of medicinal products used for the treatment of animals. If veterinary substances are not administered correctly or are administered in inappropriate quantities, either they may have no therapeutic effect or, if used in too great a quantity, they may, in particular, result in the presence of such traces in food products of animal origin and, in some instances, in the long term, in resistance to treatment for certain bacteria present in the food chain.

- 62 It follows that the considerations pertaining to trade in medicinal products for human use set out in the preceding paragraph may, in principle, be transposed to the field of trade in medicinal products for veterinary use and similar products. Nevertheless, as such medicinal products have only indirect effects on human health, the extent of the discretion enjoyed by Member States in the latter field is not necessarily the same as that prevailing with regard to trade in medicinal products for human use.
- As a consequence, the exclusive right granted to veterinary practitioners as regards trade in and use of certain veterinary substances, because they have the professional knowledge and skills required to administer those substances themselves correctly and in appropriate quantities or to instruct correctly other persons concerned, constitutes a measure that is suitable for attaining the objective of protecting public health identified in paragraph 57 above.
- With regard to the second element of the third condition, namely that the requirement concerned should not go beyond what is necessary to attain the objective in question, it should be noted that the protection of public health ranks foremost among the assets or interests protected by the EU Treaty and that it is for the Member States to determine the degree of protection which it wishes to afford to public health and the way in which that degree of protection is to be achieved. As this may vary from one Member State to another, Member States must be allowed a measure of discretion (see, to that effect, judgment of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 51).
- Such discretion is especially important where, if there is uncertainty as to the existence or extent of risks to human health, a Member State must be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. In particular, Member States must be able to take any measure capable of reducing, as far as possible, a health risk, including a risk to the reliability and quality of the provision of medicinal products to the public (see, to that effect, judgment of 5 December 2013, *Venturini and Others*, C-159/12 and C-161/12, EU:C:2013:791, paragraph 60).
- It is apparent from the provisions cited by the referring court that the Republic of Romania specifically made a distinction between veterinary products according to the seriousness of the risk to health entailed. While the legislation in question does not allow animal owners to administer medicinal products prescribed in an injectable form, which obviously entails additional risks, it gives them on the other hand the right to administer such medicinal products themselves in non-injectable forms.
- Moreover, there is nothing in the file submitted to the Court to suggest that, by adopting the national legislation at issue in the main proceedings, the Member State concerned exceeded the discretion it enjoys in this field.
- Lastly, as regards the third element of the third condition laid down in Article 15(3) of Directive 2006/123, namely that no less restrictive measures should be available that would enable the same objective to be attained, the Commission maintains that the objective of protecting public health could be attained just as effectively by a measure which allows the products in question to be sold by other duly qualified professionals, such as pharmacists or other persons having undergone advanced professional training in the pharmaceutical field.

- 69 However, while such other professionals may in fact have in-depth knowledge as regards the properties of the various components of veterinary medicinal products, there is nothing to suggest that they have received special training appropriate to animal health.
- Therefore, it is not evident that the measure proposed by the Commission is liable to give the same result as that provided for by national legislation such as that at issue in the main proceedings.
- As regards the fact, also alluded to by the Commission, that certain veterinary medicinal products are available for sale only on prescription, it being understood that the prescription will indicate how the product is to be administered and the dosage, bearing in mind the discretion enjoyed by the Member States, the latter are entitled to take the view that, in itself, a prescription is not sufficient to rule out the risk that medicinal products thus prescribed may be administered incorrectly or in inappropriate quantities (see, by analogy, judgment of 16 December 2010, *Commission* v *France*, C-89/09, EU:C:2010:772, paragraph 60).
- In those circumstances, the Court finds that the requirement laid down by national legislation such as that at issue in the main proceedings complies with the third condition laid down in Article 15(3) of Directive 2006/123.
- It follows from all the foregoing that the answer to the first question is that Article 15 of Directive 2006/123 is to be interpreted as not precluding national legislation, such as that at issue in the main proceedings, under which veterinary practitioners have an exclusive right to retail and use organic products, special purpose anti-parasitic products and veterinary medicinal products.

The second question

- Py its second question, the referring court seeks to ascertain, in essence, whether Article 15 of Directive 2006/123 is to be interpreted as precluding national legislation, such as that at issue in the main proceedings, under which the shares in establishments retailing veterinary medicinal products must be owned exclusively or, at the very least mainly, by one or more veterinary practitioners.
- That being said, as the Commission was correct to point out, the provisions of national law cited by the referring court simply provide that all the share capital of establishments retailing veterinary medicinal products must be owned by veterinary practitioners, no mention being made of any provision for a simple majority holding.
- Accordingly, this question must be answered simply on the basis that it concerns the compatibility with EU law of national legislation which requires that the share capital of establishments engaged in the retail supply of veterinary medicinal products must be owned solely by one or more veterinary practitioners.
- For the purposes of answering that question, it should be borne in mind that Article 15(2)(c) of Directive 2006/123 mentions, among the requirements to be evaluated, those which relate to the shareholding of a company. Therefore, national legislation which imposes such a requirement relating to the status of the shareholders of the establishment concerned will be compatible with Article 15 of the directive only if it satisfies the three conditions set out in Article 15(3).
- ⁷⁸ In the present case, first, it is common ground that the legislation at issue in the main proceedings satisfies the first of those conditions, which requires that there should be no discrimination on grounds of nationality.

- Next, with regard to the second condition, namely whether the requirement in question is necessary, it is clear that, by adopting such legislation, the Romanian legislature intended, inter alia, to guarantee that the operation of retail outlets selling veterinary medicinal products should be monitored effectively by veterinary practitioners.
- As is apparent from the answer to the first question, such an objective must be regarded as forming part of the wider objective of protecting public health, which constitutes an overriding requirement relating to the public interest.
- As regards, lastly, the third condition, relating to the proportionality of the requirement, that condition requires, in the first place, that the legislation at issue should be suitable for securing the attainment of the objective pursued.
- In that regard, bearing in mind the discretion enjoyed by Member States, as indicated in paragraph 64 above, the latter may consider that there is a risk that, if persons who are not veterinary practitioners are in a position to exert influence on the operation of establishments retailing veterinary medicinal products, such persons may adopt economic strategies that may undermine the objective of providing animal owners with medicinal products which are reliable and of good quality and compromise the independence of veterinary practitioners who are involved in such establishments, inter alia by encouraging them to sell off medicinal products which it is no longer profitable to keep in stock or by making reductions in operating costs (see, by analogy, judgment of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 40).
- By requiring that the operation of the establishments in question is conducted in such a way that veterinary practitioners hold all the shares in such establishments, legislation such as that at issue in the main proceedings is appropriate for the purpose of minimising such a risk and thus ensuring that the objective pursued by the legislation is attained.
- Veterinary practitioners who are shareholders in an establishment that retails veterinary medicinal products are, unlike economic operators who are not veterinary practitioners, subject to rules of professional conduct designed to moderate the pursuit of profit, so that their interest connected with the making of a profit is tempered by the responsibility which they have in this area, given that any breach of the rules of law or professional conduct undermines not only the value of their investment but also their own professional existence (see, by analogy, judgment of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 37).
- In the second and third place, if the requirement that the share capital of an establishment retailing veterinary medicinal products be held only by veterinary practitioners is to be regarded as proportionate, it must not go beyond what is necessary to attain the objective pursued and it should not be possible for it to be replaced by other, less restrictive, measures by which the same result may be achieved.
- While, as is clear from the Court's case-law cited in paragraph 82 above, a Member State may lawfully prevent economic operators who are not veterinary practitioners from being in a position to exert decisive influence over the operation of establishments retailing veterinary medicinal products, the objective referred to in that paragraph cannot justify a provision that totally precludes such operators from holding shares in such establishments, as it is perfectly plausible that veterinary practitioners will be able to monitor such establishments effectively even if they do not hold all the shares in those establishments, given that the fact that a limited number of those shares are held by persons who are not veterinary practitioners will not necessarily make such monitoring impossible. Accordingly, national legislation such as that at issue in the main proceedings goes beyond what is necessary to attain the objective pursued by the legislation.

- That view cannot be called into question by the case-law established by the judgment of 19 May 2009, *Commission v Italy*, (C-531/06, EU:2009:315), in which the Court found to be compatible with freedom of establishment and free movement of capital national legislation which prevented not only non-pharmacists from holding, in companies or firms operating pharmacies, significant stakes giving them definite influence over their management but also investors from other Member States who are not pharmacists from acquiring, in those companies or firms, smaller stakes which do not confer such influence.
- Whilst, as is apparent from paragraph 62 above, the primary considerations to be taken into account in the field of medicinal products for human use may, in principle, be transposed to the field of trade in veterinary medicinal products, the discretion enjoyed by Member States in order to ensure that the provision of veterinary products is of good quality and that veterinary practitioners operating in establishments selling such products are independent is more restricted than the discretion conferred on Member States in certain other sectors more closely connected with the protection of human health and does not, therefore, extend to excluding persons who are not veterinary practitioners from holding any shares in such establishments.
- Accordingly, the answer to the second question is that Article 15 of Directive 2006/123 is to be interpreted as precluding national legislation, such as that at issue in the main proceedings, under which shares in establishments retailing veterinary medicinal products must be owned exclusively by one or more veterinary practitioners.

Costs

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

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

- 1. Article 15 of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market is to be interpreted as not precluding national legislation, such as that at issue in the main proceedings, under which veterinary practitioners have an exclusive right to retail and use organic products, special purpose anti-parasitic products and veterinary medicinal products.
- 2. Article 15 of Directive 2006/123 is to be interpreted as precluding national legislation, such as that at issue in the main proceedings, under which shares in establishments retailing veterinary medicinal products must be owned exclusively by one or more veterinary practitioners.

[Signatures]