Reports of Cases

OPINION OF ADVOCATE GENERAL
WAHL
delivered on 21 September 2017 [1]

Case C-297/16

Colegiul Medicilor Veterinari din România
v
Autoritatea Națională Sanitară Veterinară şi pentru Siguranța Alimentelor
Intervening party:
Asociația Națională a Distribuitorilor de Produse de Uz Veterinar din România

(Request for a preliminary ruling from the Curtea de Apel Bucureşti (Court of Appeal, Bucharest, Romania))

(Article 49 TFEU — Directive 2001/82/EC — Veterinary medicinal products — Directive 2005/36/EC — Training of veterinary practitioners — Directive 2006/123/EC — Services in the internal market — National rules limiting the right to retail, use and administer veterinary medicinal, anti-parasitic and organic products to veterinary practitioners — Requirement that the capital of veterinary pharmaceutical establishments be held entirely or mainly by veterinary practitioners — Protection of health and life of humans and animals)

1. By its request for a preliminary ruling, the Curtea de Apel Bucureşti (Court of Appeal, Bucharest, Romania) asks whether it is permissible, under EU law, for the retail, use and administering of veterinary organic products, special purpose anti-parasitic products and veterinary medicinal products in Romania ('the products at issue') to be limited to veterinary practitioners. It also requests guidance on the interpretation of EU law in relation to national rules regulating the economic structure of the veterinary pharmaceutical establishments through which the sale of such products takes place.

2. The request has been made in the context of proceedings between, on the one hand, the Colegiul Medicilor Veterinari din România (College of Veterinary Physicians of Romania; 'the College') and, on the other, the Autoritatea Națională Sanitară Veterinară şi pentru Siguranța Alimentelor (National Veterinary Health and Food Safety Authority, Romania; 'the 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 Distributors') — regarding the lawfulness of an order issued by the Authority amending its Veterinary Health Rules ('the VHR'). That order abolished a duty to present a copy of the certificate of entry in the single Register of veterinary practices of Romania ('the Register') for the purpose of issuing a veterinary health permit for the operation of veterinary pharmacies and veterinary pharmaceutical outlets.

3. The questions referred centre on the limits of the Member States' regulatory autonomy as regards the prerogatives of the profession as veterinary practitioner. In what follows, I shall explain why I consider the Romanian rules at issue, as they have been put to the Court, to be incompatible with Directive 2006/123/EC. [2]

1 Original language: English.

2 Directive of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ 2006 L 376, p. 36).

I. Legal framework

A. EU law

(a) Directive 2001/82/EC[3]

4. Under Article 1(2) of Directive 2001/82, included in Title I thereof ('Definitions'), a 'veterinary medicinal product' denotes, for the purpose of that directive, any substance or combination of substances (a) presented as having properties for treating or preventing disease in animals, or (b) which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

5. Article 66(1) of Directive 2001/82, which forms part of Title VI of that directive ('Possession, distribution and dispensing of veterinary medicinal products'), requires Member States to 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.

6. Article 67 of Directive 2001/82 states that without prejudice to stricter EU or national rules relating to dispensing veterinary medicinal products and serving to protect human and animal health, a veterinary prescription is required for dispensing to the public the veterinary medicinal products listed in that provision. Moreover, under that provision, Member States shall take all necessary measures to ensure that, in the case of medicinal products supplied only on prescription, the quantity prescribed and supplied shall be restricted to the minimum amount required for the treatment or therapy concerned.

7. Article 68(1) of Directive 2001/82 provides:

'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.'

(b) Directive 2005/36/EC[4]

8. Under Article 38(3) of Directive 2005/36 ('The training of veterinary [practitioners]'[5]), training as a veterinary practitioner is to provide an assurance that the professional in question has acquired the knowledge and skills listed in that provision including, in point (f) of that provision, 'the knowledge, skills and competences required for the responsible and sensible use of veterinary medicinal products, in order to treat the animals and to ensure the safety of the food chain and the protection of the environment'.

3 Directive 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.

4 Directive of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255, p. 22), as amended.

5 In its English version, Directive 2005/36 uses the term 'veterinary surgeon' — the term traditionally preferred in British English — over other terms, such as 'veterinarian' (the term preferred in US English). That latter term is, however, used in Directive 2001/82. For reasons of style I shall employ the term 'veterinary practitioner' throughout this Opinion. No difference is intended thereby.

(c) Directive 2006/123

9. Directive 2006/123 applies, under Article 2(1) thereof ('Scope'), 'to services supplied by providers established in a Member State'.[6] However, healthcare services are excluded from its scope under Article 2(2)(f).

10. Article 3(3) of Directive 2006/123 ('Relationship with other provisions of [EU] law') provides that Member States are to apply the provisions of the directive in compliance with the rules on the right of establishment and the free movement of services.

11. Article 15 of Directive 2006/123 ('Requirements to be evaluated') provides:

'1. Member States shall examine whether, under their legal system, any of the requirements [7] 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] or provided for in other [EU] 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.

…'

6 Under Article 4(1) and (2) of Directive 2006/123 ('Definitions'), a 'service' means any self-employed economic activity, normally provided for remuneration, as referred to in Article 57 TFEU, and a 'provider' means any natural person who is a national of a Member State, or any legal person as referred to in Article 54 TFEU and established in a Member State, who offers or provides a service.

7 Under Article 4(7) of Directive 2006/123 ('Definitions'), a 'requirement' means 'any obligation, prohibition, condition or limit provided for in the laws, regulations or administrative provisions of the Member States or in consequence of case-law, administrative practice, the rules of professional bodies, or the collective rules of professional associations or other professional organisations, adopted in the exercise of their legal autonomy; rules laid down in collective agreements negotiated by the social partners shall not as such be seen as requirements within the meaning of this Directive'.

B. Romanian law

(a) Law No 160/1998

12. Under Article 2 of 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, in its republished version; 'Law No 160/1998'): [8]

'1. The profession of veterinary practitioner shall be practised in Romania by any person who is a Romanian citizen and holds a diploma in veterinary medicine or its equivalent under the law, and by citizens of a Member State of the European Union, the European Economic Area, or Switzerland who hold diplomas in veterinary medicine, certificates, or other qualifications provided for by law and issued by an educational establishment of the State concerned.

…

5. Veterinary practitioners who are Romanian citizens living abroad and veterinary practitioners who are citizens of a Member State of the European Union, the European Economic Area, or Switzerland who practise the profession of veterinary practitioner in Romania shall have the same rights and be subject to the same obligations established by the [College] in respect of veterinary practitioners.'

13. Article 4(i) of Law No 160/1998 provides that veterinary practitioners have an exclusive right in relation to the retailing and use of organic products, special purpose anti-parasitic products and veterinary medicinal products.

14. Under Article 9(b) of Law No 160/1998, the College is to draw up, inter alia, the Charter of veterinary practitioners ('the CVP'), the provisions of which are binding in the practice of the profession of veterinary practitioner.

15. Article 16 of Law No 160/1998 states that membership of the College may be awarded to any veterinary practitioner who is a citizen of Romania or of a Member State of the European Union who (i) lawfully exercises the profession of veterinary practitioner in Romania under Article 2 of that law, (ii) does not find himself in a situation of disgrace as provided by law, and (iii) is medically fit to exercise the profession of veterinary practitioner. However, under Article 17 of Law No 160/1998, the requirements of Article 16 do not apply to the exercise of the profession by citizens of the Member States of the European Union, of the European Economic Area and of Switzerland which takes place in the form of provision of services. In such a situation, the citizens of those States are added to the Register, without acquiring the status of member.

16. Under Article 28(1) of Law No 160/1998:

'In the practice of his profession, a registered veterinary practitioner shall organise himself and operate within the framework of:

(a) a veterinary practice, in one of the following forms:

    1. an individual veterinary practice;

    2. a group of associated veterinary practices;

(b) a company … primarily engaged in veterinary activities.'

8 *Monitorul Oficial al României*, Part I, No 289, of 6 August 1998.

17. Under Article 32 of Law No 160/1998:

‘1. The instrument of establishment of veterinary practices is the certificate of entry in the [Register] … The certificate of entry in the Register is required in order to receive the authorisation to operate the practice; a copy of the said certificate is delivered to the holder.

2. The [Register] shall be held by the [College].’

18. Article 37 of Law No 160/1998 states:

‘1. Veterinary medicinal products and anti-parasitic products shall be sold only in legally authorised warehouses, pharmaceutical outlets, and veterinary pharmacies.

2. Organic veterinary products shall be sold only in authorised veterinary warehouses and shall be used only by veterinary practitioners or authorised natural or legal persons, in the context of veterinary treatment.’

(b) The CVP

19. Article 1(m) of the CVP, adopted by the College by Decision No 3/2013,[9] contains the following definition:

‘[Register] — official and public document managed by the Bureau of the [College] which includes the following:

– all veterinary care establishments whether or not having legal personality authorised to practise in Romania;

– 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 …’

20. Article 37 of the CVP provides:

‘1. In the retailing of veterinary medicinal products, registered veterinary practitioners shall be organised exclusively as legal persons, in accordance with the conditions set out in [Law No 160/1998] and shall perform their activities within the following authorised veterinary structures: (a) veterinary pharmaceutical outlets; (b) veterinary pharmacies.

…

3. Veterinary practitioners who are citizens of a Member State of the European Union, the European Economic Area, or Switzerland and who hold a diploma, certificate or other qualification issued by a veterinary educational establishment of that State or a third State and confirming that they are qualified veterinary practitioners, or their equivalent under the law, may be shareholders of veterinary structures without being obliged to be members of the [College] or to apply for authorisation to practise that profession.

…’

9 *Monitorul Oficial al României*, Part I, No 676, of 16 September 2014.

21. Under Article 38 of the CVP:

‘1. Veterinary medicinal products and anti-parasitic products shall be sold, under the conditions provided for by law, only in warehouses, pharmaceutical outlets and veterinary pharmacies in possession of a veterinary health permit.

2. Organic veterinary products shall be sold only in authorised veterinary warehouses.

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 …’

22. Article 39 of the CVP states:

‘The certificate for the practice of the profession of veterinary practitioner … is a document issued via the Bureau of the District Council — or of the municipality of Bucharest — of the [College], following an application made by a veterinary practitioner for authorisation to exercise the profession of veterinary practitioner within the framework of the veterinary care structures and veterinary pharmaceutical structures which carry out the retailing of veterinary medicinal products.’

(c) The VHR

23. By Order No 83/2014 of 22 July 2014,[10] the Authority adopted the VHR, which govern the conditions for the organisation and management of veterinary pharmaceutical structures and the veterinary health registration procedure/veterinary health authorisation of structures and activities of the veterinary pharmaceutical sector.

24. Under Article 3(a) of the VHR, a ‘veterinary pharmacy’ is defined as a veterinary pharmaceutical establishment which possesses and retails veterinary medicine, animal feed, medicinal feed and other veterinary products, medical instruments and appliances, medical devices and accessories for animals, in accordance with the law. Under Article 3(h) of those rules, a ‘veterinary pharmaceutical outlet’ is defined as a veterinary pharmaceutical establishment the activity of which consists of retail trade limited to prescription-free veterinary medicine, other veterinary products, medical instruments and appliances, medical devices, accessories and food for animals.

25. Article 11 of the VHR provides:

‘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.’

26. Under Article 12 of the VHR:

‘1. It is not mandatory to employ staff with specialised secondary education in a veterinary pharmacy.

10 *Monitorul Oficial al României*, Part I, No 541A, of 22 July 2014.

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 [College].

3. The placing on the market of veterinary medicinal products of a veterinary pharmacy shall be carried out, only through retailing, by the staff referred to in Article 11(a) and (b).'

27. Article 14 of the VHR requires the staff mentioned in Article 11(b) to carry out its business only in the presence and under the supervision of a veterinary practitioner, and to have knowledge of the applicable veterinary health legislation.

28. Article 23(1) and (2) of the VHR mirrors, as regards the staff of veterinary pharmaceutical outlets, the rules set out in Article 11(a) to (c) and Article 12(1). In addition, Article 23(3) specifies that a veterinary pharmaceutical outlet may not operate without the presence of the staff mentioned in Article 11(b).

29. According to Article 24 of the VHR, only non-prescription veterinary medicinal products, other veterinary products and food and accessories for animals may be sold in veterinary pharmaceutical outlets. Moreover, under Article 25 of those rules, it is forbidden to sell immunological veterinary medicine, veterinary medicine delivered on prescription and medicinal feed in veterinary pharmaceutical outlets.

30. Article 43(j) of the VHR provides:

'In order to be issued with a veterinary health permit for the operation of veterinary pharmacies, the legal representative of the structure concerned must file with the competent national veterinary health and food safety authority an application containing the following documents:

…

(j) a copy of the certificate of entry in the [Register].'

31. Article 51(g) of the VHR imposes an identical obligation on veterinary pharmaceutical outlets as that laid down in Article 43(j).

32. By Order No 31/2015 of 26 March 2015 ('the contested Order'),[11] the Authority revoked Article 43(j) and Article 51(g) of the VHR.

II. Facts, procedure and the questions referred

33. Following the adoption of the contested Order, the College brought an action before the referring court seeking its annulment claiming, inter alia, that it infringes Article 4(i) of Law No 160/1998.

34. In that action, the College argues that, in accordance with Article 4(i) of Law No 160/1998, true exclusivity in retail trade in veterinary medicine requires veterinary practitioners to have decision-making powers and does not arise if they have only minority partner status. Accordingly, it submits that shares in companies that apply for registration or authorisation as veterinary pharmacies and pharmaceutical outlets ought to be held exclusively or at least mostly by registered veterinary practitioners. In reference to Article 1(m) of the CVP, the College argues that as holder of the Register, it knows best the situation of Romanian veterinary practitioners, which is why it has been

11 *Monitorul Oficial al României*, Part I, No 235, of 7 April 2015.

given tools to ensure compliance with Article 4(i) of Law No 160/1998. The College states that the requirement of exclusivity is not observed in practice, as the competent veterinary health authorities now issue authorisations to companies in which the veterinary practitioner is not only not the sole shareholder, but not even the main shareholder.

35. The Authority counters by arguing that the Ministerul Afacerilor Externe (Ministry of Foreign Affairs, Romania) had issued reservations when consulted during the process leading to the adoption of the VHR. That ministry referred, in particular, to an exchange of views with the European Commission regarding the compatibility of the Romanian rules at issue with Directive 2006/123, notably a requirement that veterinary practitioners own 100% of the shares in companies which manage veterinary pharmacies in Romania. The Authority also referred to the view of the Consiliul Concurenței (Competition Council, Romania), which mentioned a possible restriction of competition on the market for the retailing of veterinary products through veterinary pharmacies arising from Article 43(j) of the VHR. In light of the observations it received, the Authority considers that the exclusivity referred to in Article 4(i) of Law No 160/1998 concerns the activity as veterinary practitioner, and not the activity of the establishment in which a veterinary practitioner works. Law No 160/1998 does not require companies to be held exclusively by veterinary practitioners, as a veterinary practitioner may work for such a company and thus ensure compliance with the rules on exclusivity in retail trade, usage and administering of the products at issue.

36. Intervening in support of the Authority, the Distributors argue, inter alia, that the Romanian rules at issue give rise to exclusive rights which restrict the conditions under which veterinary practices may be established and held as well as the terms of trade in veterinary products. The Distributors claim that this amounts to a distortion of competition as those rules breach the freedoms guaranteed unto traders under the Treaties; Articles 67 and 69 [12] of Directive 2001/82, as well as a number of other provisions.

37. In view of the above, the referring court decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

‘(1) Does EU law preclude national legislation which provides that veterinary practitioners 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 practitioners?’

38. Written observations have been submitted by the College, the Distributors, the Romanian Government, and by the Commission. Except for the College, those parties presented oral argument at the hearing held on 28 June 2017.

12 Under Article 69(1) of Directive 2001/82: ‘Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products to such animals for five years after their administration, including when the animal is slaughtered during the five-year period.’

III. Analysis

A. Issues of form

1. Alleged deficiencies of the order for reference

39. In their written submissions, the Distributors argue that the present request for a preliminary ruling is inadmissible, as the questions referred presuppose that the Court must select the rule of EU law that must be interpreted. The parties do not have the possibility of gaining knowledge of that choice or of submitting observations in that regard.

40. The Distributors also consider that the order for reference does not contain the necessary elements of fact or of law, leading them to suggest reformulating and completing it.

41. However, those objections must be dismissed.

42. The referring court does specify, in the body of the order for reference, the provisions of EU law which it considers relevant.[13] The order for reference therefore complies with Article 94(c) of the Rules of Procedure of the Court of Justice. Furthermore, the fact that the Court will likely have to identify the exact provisions of EU law applicable in the main proceedings does not render the order for reference inadmissible. The Distributors have had the opportunity to give their views on which rules they consider to be applicable.[14]

43. As for the need to reformulate or complete the questions referred, I shall revert to that matter below at point 55.

2. The presence of a cross-border element

44. In its observations, the Commission raises the point as to whether the main proceedings concern a purely internal situation, which it considers not to be the case. In any event, it takes the view that Directive 2006/123 also applies in purely internal situations.

45. In those circumstances, the Court must consider whether it has jurisdiction to rule on the interpretation sought, as it does not have jurisdiction where it is obvious that the provision of EU law referred to it for interpretation cannot apply. That may, as a rule, be the case where all the facts relevant to the case in the main proceedings are confined within a single Member State.[15]

46. I agree with the Commission that the present request for a preliminary ruling does not concern a purely internal situation. In the main proceedings, the College seeks the annulment of the contested order, which eases certain formalities for setting up veterinary practices. The order for reference explains why it is not a purely internal situation. It summarises the exchange of views between Romania and the Commission on the effect that the Romanian rules at issue might have on economic operators from other Member States in the exercise of the activity of veterinary practitioner, in particular through ownership of shares in companies established in Romania set up for that purpose.

13 Apart from citing, inter alia, Articles 49, 54 and 55 TFEU, the referring court mentions Articles 1, 66, 67 and 69 of Directive 2001/82; Article 38 of Directive 2005/36; and Articles 3, 14 and 15 of Directive 2006/123.

14 Compare with judgment of 19 January 1994, *SAT Fluggesellschaft*, C-364/92, EU:C:1994:7, paragraph 9.

15 See judgment of 10 September 2015, *Wojciechowski*, C-408/14, EU:C:2015:591, paragraphs 25 and 26 and the case-law cited.

47. Against that background, I consider that the order for reference contains sufficient indications as to why a decision of the Court interpreting the Treaty rules on freedom of movement is necessary for the referring court in the case pending before it. [16]

48. In view thereof, there is a fortiori no need for the Court to take a position on the Commission's argument, raised in the alternative, that Directive 2006/123 might apply even where a dispute were to be confined in all respects within a single Member State. [17]

B. Substance

1. Applicable provisions

49. As the wording of both questions referred simply mentions 'EU law', it is necessary to determine whether the Romanian rules at issue fall to be considered under the rules on freedom of movement enshrined in the FEU Treaty or rather under Directive 2006/123. [18]

50. In *Rina Services and Others*, [19] the Court did not explicitly state that national rules falling within the scope of both Directive 2006/123 and Articles 49 and 56 TFEU are to be assessed only against the requirements of the former. [20] However, the effect of that judgment seems — perhaps surprisingly — to be precisely that. According to that judgment, irrespective of Article 3(3) of Directive 2006/123, Member States may not rely on the grounds listed in Article 52(1) TFEU to derogate from Directive 2006/123. [21]

51. From that judgment it can thus be inferred that the questions referred should be considered on the basis of Directive 2006/123.

52. Next, although 'healthcare services' are excluded from the scope of Directive 2006/123, under Article 2(2)(f) thereof, as noted by the Commission, according to recital 22 thereof, 'healthcare services' are services provided by health professionals to patients to assess, maintain or restore their state of health. [22] As that is not the case for the provision of veterinarian services, Directive 2006/123 remains applicable in the main proceedings, pursuant to Article 2(1) thereof.

53. I should also point out that it does not follow from the previous points that the concomitant application of Article 63 TFEU is excluded. That provision covers direct investments in the form of participation in an undertaking through the holding of shares which confers the possibility of participating effectively in its management and control, and also portfolio investments. [23] However, if the Romanian rules at issue have restrictive effects on the free movement of capital, those effects

16 Judgment of 15 November 2016, *Ullens de Schooten*, C-268/15, EU:C:2016:874, paragraphs 50, 51 and 54 and the case-law cited. In that case, the Court, considering it had jurisdiction, went on to give an answer on the substance, rather than declaring the case inadmissible.

17 In his Opinion in Joined Cases *Trijber and Harmsen*, C-340/14 and C-341/14, EU:C:2015:505, points 51 to 57, Advocate General Szpunar took the view that Directive 2006/123 applies to situations confined to one Member State. The Court did not address that issue, as it did not consider the facts of that case to be purely internal: see judgment of 1 October 2015, *Trijber and Harmsen*, C-340/14 and C-341/14, EU:C:2015:641, paragraphs 40 to 42. On that issue see also my Opinion in *Grupo Itevelesa and Others*, C-168/14, EU:C:2015:351, point 36.

18 Directive 2006/123 establishes, according to its Article 1(1) ('Subject matter'), 'general provisions facilitating the exercise of the freedom of establishment for service providers and the free movement of services, while maintaining a high quality of services'. It then sets out rules, in its Chapters III and IV, governing the freedom of establishment for providers and the free movement of services.

19 Judgment of 16 June 2015, *Rina Services and Others*, C-593/13, EU:C:2015:399.

20 See however the Opinion of Advocate General Cruz Villalón in *Rina Services and Rina*, C-593/13, EU:C:2015:159, point 23, who considered that to be the case.

21 Judgment of 16 June 2015, *Rina Services and Others*, C-593/13, EU:C:2015:399, paragraphs 23, 24, and 36 to 40.

22 See, in that regard, judgment of 11 July 2013, *Femarbel*, C-57/12, EU:C:2013:517, paragraphs 34 to 39.

23 See judgment of 21 December 2016, *AGET Iraklis*, C-201/15, EU:C:2016:972, paragraph 58 and the case-law cited. Portfolio investments are the acquisition of securities on capital markets solely with the intention of making a financial investment without any intention to influence the management and control of the undertaking.

would be the unavoidable consequence of any restriction on freedom of establishment under Article 49 TFEU and would not warrant independent examination in the light of Article 63 TFEU.[24] It stands to reason that, given the judgment in *Rina Services and Others*,[25] that must also be the case for burdens identified not under Article 49 TFEU directly, but rather under Directive 2006/123.

54. I shall therefore proceed with my analysis solely on the basis of Directive 2006/123.

2. The first question

55. By its first question, the referring court essentially wishes to know whether Directive 2006/123 precludes national rules, such as the rules at issue in the main proceedings, which provide that veterinary practitioners enjoy an exclusive right to retail, use and administer veterinary organic products, special purpose anti-parasitic products and veterinary medicinal products.

(a) The existence of a requirement which must be evaluated: Article 15(2) of Directive 2006/123

56. In limiting the retailing and use of organic products, special purpose anti-parasitic products and veterinary medicinal products to veterinary practitioners, the Romanian rules at issue, in particular Article 4(i) of Law No 160/1998, quite clearly fall under the type of requirement which must be evaluated under Article 15(2)(d) of Directive 2006/123.[26] The Romanian Government does not contest this.

57. Quite simply, those rules confer on veterinary practitioners a legal monopoly to retail, use and administer the products at issue.

58. Does the reference, in Article 15(2)(d) of Directive 2006/123, first, to Directive 2005/36 and, second, to other EU instruments — such as Directive 2001/82 — change that assessment? The College appears to be of that opinion.

59. I, on the other hand, do not consider that to be the case.

60. In the first place, none of the rules of Directive 2005/36 cited in the order for reference justifies exclusive treatment. Article 38(3) of Directive 2005/36 merely harmonises the requirements relating to the training as veterinary practitioner and, in particular, the knowledge that those professionals must possess. It does not however limit the retail, use and administering of the products at issue to veterinary practitioners.

61. In the second place, although Article 66 of Directive 2001/82 requires Member States to 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, that provision does not state that those persons may only be veterinary practitioners.

62. Moreover, the fact that Article 67 of Directive 2001/82 refers to stricter national rules relating to dispensing veterinary medicinal products is of no consequence. Indeed, that provision concerns the acquisition by the end user of such products, and not the power to limit the activity in question to veterinary practitioners.

24 Judgment of 21 December 2016, *AGET Iraklis*, C-201/15, EU:C:2016:972, paragraph 59 and the case-law cited.

25 Judgment of 16 June 2015, *Rina Services and Others*, C-593/13, EU:C:2015:399.

26 See, as regards Article 49 TFEU in respect of similar rules relating to pharmacies, judgments of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 24, and *Commission* v *Italy*, C-531/06, EU:C:2009:315, paragraphs 45 and 47.

63. I therefore conclude that the Romanian rules at issue constitute a requirement to be evaluated under Article 15(2)(d) of Directive 2006/123. It remains to be seen whether that requirement satisfies the conditions listed in Article 15(3) thereof.

(b) Justification: Article 15(3) of Directive 2006/123

64. Under Article 15(3) of Directive 2006/123, Member States are to verify that any requirements referred to in Article 15(2) thereof in their legal systems are (a) non-discriminatory, (b) necessary and (c) proportionate.

65. Although on its face, that provision attempts to codify the *Gebhard* doctrine,[27] it would seem to follow from the wording of Article 15(3)(a) of Directive 2006/123 that requirements which are indirectly discriminatory cannot be justified. That arguably goes beyond the requirements of that doctrine.[28] Be that as it may, citizens of other Member States are entitled to establish themselves in Romania as veterinarians, thereby obtaining the right to retail, use and administer the products at issue. It is, moreover, not alleged in the main proceedings that the Romanian rules at issue, although applicable without distinction, tend to favour Romanian nationals.

66. As for whether the Romanian rules at issue are justified by an overriding reason relating to the public interest, the Romanian Government argues that those rules are necessary in order to protect public health, which constitutes such a reason.[29] Moreover, that government points to recital 2 of Directive 2001/82, which specifies that 'the primary purpose of any rules for the production and distribution of veterinary medicinal products must be the safeguarding of public health'.

67. Yet is it really open to the Romanian Government to rely on the protection of public health, even though the products at issue might not be intended for direct human consumption? That is a salient question, given that the provision of veterinary services is not a 'healthcare service' under Article 2(2)(f) of Directive 2006/123.

68. Still, I would tend to consider that to be the case.

69. Indeed, the question of what services come within the scope of Directive 2006/123 is different from the question of what overriding reasons a Member State may rely on to justify a requirement under Article 15(3) thereof. In addition, Article 15(3)(b) does not limit the overriding reasons a Member State may invoke. Hence, no conflict arises with the dictum of the Court in *Rina Services and Others*.[30]

27 Judgment of 30 November 1995, *Gebhard*, C-55/94, EU:C:1995:411, paragraph 37.

28 On that issue, recital 65 of Directive 2006/123 is inconclusive.

29 See judgment of 16 December 2010, *Commission* v *France*, C-89/09, EU:C:2010:772, paragraph 52 and the case-law cited. The Romanian Government makes an implicit link, at a different part of its observations, between the protection of public health and the protection of the health of animals.

30 Judgment of 16 June 2015, *Rina Services and Others*, C-593/13, EU:C:2015:399, paragraph 40.

70. Moreover, as demonstrated by the Romanian Government, many instruments of EU legislation testify, for reasons which are self-evident, to a link between animal health and/or welfare and public health. That is in particular the case in the field of food safety, where the link between animal and public health is perhaps at its strongest.[31] Ensuring a safe and high-quality supply of veterinary medicinal products throughout a Member State appears to me to be a lawful objective.[32]

71. What remains to be considered is whether those rules (i) are suitable for securing the attainment of the objective of protecting public health, (ii) do not go beyond what is necessary to attain that objective, and (iii) cannot be replaced by other, less restrictive measures which attain the same result.

72. On those points, it is, on the one hand, for the Member States to determine the level of protection they wish to afford to public health and the way in which that level is to be achieved. Since that level may vary from one Member State to another, Member States must be allowed discretion.[33]

73. On the other hand, the Member State concerned must provide the necessary evidence, through statistical or ad hoc data or by other means, from which it may reasonably be concluded that the means chosen are appropriate for the attainment of the objectives pursued and that those objectives cannot be attained by measures which are less restrictive of the fundamental freedom of movement and, by the same token, Directive 2006/123.[34]

74. It seems clear that the Romanian rules at issue, which give effect to Article 66 of Directive 2001/82, are suitable for securing the attainment of the objective of protecting public health. Limiting the right to retail, use and administer the products at issue to veterinary practitioners is one way of ensuring that the quantity of veterinary medicine prescribed and supplied is restricted to the minimum amount required for the treatment or therapy concerned, in accordance with Article 67 of Directive 2001/82. In that connection, as the College essentially argues, overprescription of veterinary medicine for which a prescription is required, such as antibiotics, raises serious concerns for public health.[35] That concern is echoed at the EU level.[36]

75. That does not, however, answer the question whether the Romanian rules at issue go beyond what is necessary in order to protect public health, and whether they can be replaced by other, less restrictive measures which achieve the same result.

76. That question is clearly best answered by the referring court itself.[37]

31 See, for instance, recital 5 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ 2004 L 191, p. 1), which states that 'animal health and animal welfare are important factors that contribute to the quality and safety of food, to the prevention of the spreading of animal diseases and to a humane treatment of animals'. Moreover, under Article 67(aa) of Directive 2001/82, a prescription is required for dispensing to the public veterinary medicinal products for food-producing animals. Indeed, according to recital 17 of Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ 2004 L 136, p. 58), veterinary 'medicinal products should be used only under conditions that guarantee that the foodstuffs produced will be harmless to consumers as regards any residues of medicinal products'.

32 See, regarding medicinal products for human use, judgment of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraph 34.

33 See judgment of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 19 and the case-law cited.

34 See, to that effect, judgment of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraphs 35 and 36 and the case-law cited.

35 See, inter alia, World Economic Forum, *Global Risks 2013*, Eighth Edition, p. 28 et seq., which observes (p. 31) that 'antibiotics are over-used around the world in livestock and fish farming (e.g. as growth promoters). Resistant bacteria can be transferred to humans through contact with livestock, through the food chain, and through wastewater from these operations, as well as wastewater from hospitals and pharmaceutical plants'.

36 See, inter alia, European Parliament resolution of 11 December 2012 on the Microbial Challenge — Rising threats from Antimicrobial Resistance (2012/2041 (INI)) which after having stated, at point K, that 'there is a link between the use of antimicrobials in animals and the spread of resistance in humans', calls on the Commission, at point 19 thereof, 'to examine the condition for prescription and sale of antimicrobials in order to ascertain whether practices in human and animal healthcare may lead to over-prescription, overuse or misuse of antimicrobials'.

37 See, by way of example, judgment of 21 June 2012, *Susisalo and Others*, C-84/11, EU:C:2012:374, paragraph 42.

77. Having said that, I shall presently explain why I consider the legal monopoly at issue in the main proceedings to be disproportionate.

78. At the hearing, the Romanian Government stated that the products at issue require a veterinary medical prescription as a condition for acquisition. It is for the referring court to verify that assertion, bearing in mind that the arguments submitted in the context of the main proceedings do not justify maintaining a legal monopoly in respect of products for which such a prescription is not mandatory. [38]

79. Independently thereof, it is not apparent why it is absolutely necessary for a veterinary practitioner to have the *sole* right to retail the products at issue as well as having the exclusive power to prescribe them. In particular, as the Commission observed at the hearing, it is conceivable that other suitably qualified persons might also be allowed to sell the products at issue, such as pharmacists or other persons with advanced professional training in pharmacy. In reply thereto, the Romanian Government stated at the hearing that the profession of veterinary pharmacist is not regulated in Romania. It observed, moreover, that, pursuant to the study programme which veterinary practitioners are required to follow under Article 38(1) of Directive 2005/36, as specified in point 5.4.1 of Annex V thereto, veterinary practitioners undergo training in pharmacy and therefore have the required set of skills to sell the products at issue. That is true, yet the Romanian Government did not explain how that training sets veterinary practitioners apart from 'regular' pharmacists who have also studied pharmacy. In that regard, although pharmacists would also have a private interest in making a profit in connection with the retail of veterinary medicinal products, allowing an independent party also to retail those products on presentation of a veterinary medical prescription would help to temper that interest. [39]

80. In addition, there is no apparent risk that overconsumption or incorrect use of veterinary medicinal products might lead to a waste of financial resources for the health insurance bodies concerned. [40] Rather, as it is the end users who must normally finance the acquisition of those products (whether by taking out a private animal health insurance or by their own means), those end users ought to be able to freely choose between purchasing those products from a veterinary practitioner or through another appropriate retail channel.

81. Against that backdrop, the Romanian Government has not, in my view, discharged the burden of proof as it must in line with the case-law stated above at point 73.

82. On that basis, I propose that the Court should answer the first question referred to the effect that, on a proper construction of Article 15 of Directive 2006/123, national rules which grant an exclusive right for veterinary practitioners to retail, use and administer veterinary organic products, special purpose anti-parasitic products and veterinary medicinal products do not satisfy the requirement of proportionality set out in Article 15(3)(c) of that directive, insofar as those rules either:

– extend to products for which a veterinary medical prescription is not mandatory; or

– do not allow persons professionally trained in pharmacy, other than veterinary practitioners, the right to retail those products, if need be in accordance with the directions of a veterinary medical prescription issued by a veterinary practitioner if their acquisition is contingent on such a prescription.

It is for the referring court to determine whether that is the case in the main proceedings.

38 See, by analogy, judgment of 11 December 2003, *Deutscher Apothekerverband*, C-322/01, EU:C:2003:664, paragraph 112.

39 Compare with judgment of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 37.

40 Unlike what is the case for prescription-based medicinal products destined for direct human consumption, see judgments of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 33, and *Commission* v *Italy*, C-531/06, EU:C:2009:315, paragraph 57.

3. The second question

83. By its second question, the referring court essentially wishes to know whether Directive 2006/123 precludes national rules, such as the Romanian rules at issue in the main proceedings, which not only provide that veterinary practitioners enjoy an exclusive right to retail, use and administer the products at issue, but also that the structures through which those products are sold must be mainly or exclusively owned by one or more veterinary practitioners.

84. It follows from the wording of that question, which is asked in the alternative, that the Court will have to answer it only if it does not answer the first question referred in the affirmative. In my view, the Romanian rules at issue, as they have been put to the Court, are not compatible with Directive 2006/123. However, for the sake of completeness I shall give my view on the second question, bearing in mind that the observations made above at points 55 to 82 are still of relevance when considering that question.

85. In its observations, the Commission identifies two requirements flowing from the Romanian rules at issue. First, a requirement that veterinary pharmacies and veterinary pharmaceutical outlets may only be legal persons. Second, a requirement that their share capital be held exclusively (not mainly) by veterinary practitioners.

86. However, the second question referred does not centre on the nature of the personality — be it legal or physical — of the structures through which those products are sold. I shall therefore not address that issue, as it lies outwith the scope of that question.[41]

87. On substance, a requirement that the products at issue must be sold at veterinary pharmacies or veterinary pharmaceutical outlets mainly or exclusively owned by veterinary practitioners[42] relates to the shareholding of the 'companies' or, in this case, the retail establishments. That is a questionable requirement under Article 15(2)(c) of Directive 2006/123.

88. As to whether that requirement satisfies the conditions laid down in Article 15(3) of Directive 2006/123, my observations in respect of the first question referred go some way in answering that question — chiefly as to whether there exists an overriding reason in the public interest.

89. That said, as I have concluded elsewhere, case-law shows that the Court is, rightly, wary of Member States interfering with the freedom of establishment by regulating in detail a given market structure or competitive situation, inter alia under the pretext of ensuring a high quality of service for customers and consumers.[43] It seems to me that restrictions on the ownership and/or economic structure of any establishment fall within the same category and ought to be met with a healthy dose of suspicion.

90. In its observations, the Commission takes the principled view that protection of the health and life of animals cannot justify the contested ownership requirement to the same extent as the protection of the health and life of human beings.

41 See, for example, judgment of 18 July 2013, *Consiglio Nazionale dei Geologi and Autorità garante della concorrenza e del mercato*, C-136/12, EU:C:2013:489, paragraph 31.

42 Such as appears to follow from a combined reading of Article 32 and Article 37(1) of Law No 160/1998; Article 1(m) and Article 37(1) of the CVP; and Article 43(j) and Article 51(g) of the VHR before they were repealed by the contested order.

43 See my Opinion in *Grupo Itevelesa and Others*, C-168/14, EU:C:2015:351, points 73 and 74 and the case-law cited.

91. That claim seems to have more philosophical than practical relevance. To be sure, the Court has consistently recognised that the health and life of humans rank foremost among the interests protected by the Treaties.[44] Still, I see no need for the Court to specify to what extent the health and life of humans 'outrank' the health and life of animals. That suggestion also appears somewhat perplexing in the light of the Commission's own recent policy statement.[45]

92. Indeed, first, as stated in points 70 and 74 above, there is a link between the protection of the health and life of humans and of animals.

93. Second, in stating that the therapeutic effects of veterinary medicinal products are 'primarily' targeted at animals, and that their incorrect or unnecessary use does 'not directly' harm humans, the Commission does recognise that there are secondary and indirect effects on humans. In other words, it is common ground that the protection of public (human) health is still of relevance.

94. Third, where there is uncertainty as to the existence or extent of risks to human health, the precautionary principle may allow Member States to take protective measures in respect of veterinary medicinal practices without having to wait until the reality of the risks for humans becomes fully apparent.

95. Accordingly, instead of addressing that rather theoretical question, the focus of the Court ought simply to be on whether the end invoked justifies the means, that is to say, whether the protection of public health justifies a restriction on the ownership of the establishments which retail the products at issue.

96. Now, without stating clearly the applicable threshold, the order for reference indicates that the Commission and the Romanian Government have discussed the possibility of lowering the proportion of the capital of a veterinary pharmacy or a veterinary pharmaceutical outlet which must be owned by veterinary practitioners under the Romanian rules at issue.[46] However, I must confess that the hearing made it particularly unclear what that threshold actually is, inasmuch as the parties diverged on how the national law ought to be interpreted. That is obviously a matter for the national court to determine. The observations which follow must therefore be read with that in mind.

97. The parties were invited to state their views on the judgment in *Commission* v *France*, where the Court partly dismissed an action seeking a declaration that, by maintaining in force rules limiting to a maximum of 25% of the shares, hence the voting rights, that may be held by non-biologists in a limited liability company or firm formed by persons practising a profession operating biomedical analysis laboratories, the French Republic had infringed (now) Article 49 TFEU. In particular, the Court held that the restrictive nature of those rules was justified for reasons of public health and satisfied the requirements of proportionality.[47] Pivotal for the Court's assessment was the fact that the 25% share possession ceiling for non-biologists allowed biologists to exercise a decisive influence of the most important decisions taken in the company — in other words, to retain control.[48]

44 See judgment of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraph 30 and the case-law cited.

45 See the Communication from the Commission to the Council and the European Parliament of 29 June 2017 on a European One Health Action Plan against Antimicrobial Resistance (AMR) (COM(2017) 339 final), where the Commission states (p. 3) that the 'One Health' approach 'is a term used to describe a principle which recognises that human and animal health are interconnected, that diseases are transmitted from humans to animals and vice versa and must therefore be tackled in both. The One Health approach also encompasses the environment, another link between humans and animals and likewise a potential source of new resistant microorganisms. This term is globally recognised, having been widely used in the EU and in the 2016 United Nations Political Declaration on AMR'.

46 That eventuality is also hinted at in Article 1(m) of the CVP, which requires veterinary pharmacies and veterinary pharmaceutical outlets to specify 'if their capital is exclusively held by veterinary practitioners *or if it is otherwise amassed in the wake of subsequent legislative amendments*' (emphasis added).

47 Judgment of 16 December 2010, *Commission* v *France*, C-89/09, EU:C:2010:772. It also emerges from paragraph 78 of that judgment that non-biologists were permitted to hold in excess of 25% of the capital in limited partnerships operating biomedical analysis laboratories.

48 Ibid., paragraphs 68 and 78.

98. That being so, it seems to me that in that judgment, the Court exercised an inordinate degree of restraint in not finding a breach of Article 49 TFEU. Perhaps that might be explained by the apparently unique and central role which biologists play in the French healthcare sector.[49] I am not convinced that the same can be said for veterinary practitioners. Indeed, not even the Romanian Government supports such a strict interpretation of its own law.[50]

99. As it is, I consider that the Romanian rules at issue go beyond what is necessary even if the ownership requirement is interpreted as requiring only a majority ownership by veterinary practitioners of veterinary pharmacies and veterinary pharmaceutical outlets.

100. That is, firstly, because the need to safeguard the professional independence of veterinary practitioners cannot justify it.[51] To be sure, the Court has recognised that there is a genuine risk that persons who are not members of a given health sector profession may take corporate control, as they might be tempted to refuse to carry out less profitable or more complicated tasks and/or to cut down on the advice they provide.[52] However, in addition to what I have stated above at point 79, in the case under consideration nothing prevents veterinary practitioners from doing the same, given that they have the sole power to prescribe veterinary medicinal products. The mere prospect of professional disciplinary proceedings, although undeniably some sort of safeguard, does not remove that risk.

101. Secondly, an obligation for veterinary practitioners to own all or most of the shares of veterinary pharmacies and veterinary medicinal outlets does not allow the conclusion to be drawn that, among other things, less and more effective veterinary medicine might be prescribed, or that customers and patients might receive better advice. In that respect, it already follows from a combined reading of Article 12(2), Article 24 and Article 25 of the VHR that veterinary pharmaceutical products for which a prescription is required may be sold only in veterinary pharmacies, in the presence of and under the supervision of a veterinary practitioner. As for the veterinary products for which such a prescription is not required — which may also be sold in veterinary pharmaceutical outlets — Article 23(3) of the VHR requires, as a minimum, the presence of staff with specialised secondary education. Nothing therefore leads me to believe that the contested ownership requirement adds any value to the rules otherwise applicable.

102. Accordingly, I propose answering the second question referred to the effect that, on a proper construction, Article 15(3) of Directive 2006/123 precludes the rules of a Member State which not only provide that veterinary practitioners enjoy the right to prescribe products for which a veterinary medical prescription is required and the exclusive right to retail, use and administer those products, but also that the structures through which those products are sold must be owned exclusively or mostly by one or more veterinary practitioners. It is for the referring court to determine whether that is the case in the main proceedings.

49 Ibid., paragraphs 29 and 56. Opticians do not enjoy that same status, see judgment of 21 April 2005, *Commission* v *Greece*, C-140/03, EU:C:2005:242, paragraphs 35 and 36.

50 I should add that, when pressed on that issue, the Romanian Government stated that its views on the second question referred were premised on an affirmative answer to the first question referred. However, it did not explain why the possibility of forgoing the ownership requirement is linked to the maintenance of the exclusive right for veterinary practitioners to retail, use and administer the products at issue.

51 The College simply mentions that, in 2014, the Authority checked 543 veterinary pharmacies and imposed a penalty on 112 of those for breach of the rules, without explaining what risk multidisciplinary ownership rules would have for the independence of veterinary practitioners. The lack of relevance of that circumstance appears corroborated by the fact that the College goes on to state that none of those 112 cases gave rise to disciplinary proceedings.

52 Judgment of 16 December 2010, *Commission* v *France*, C-89/09, EU:C:2010:772, paragraph 82.

IV. Conclusion

103. In the light of the foregoing considerations, I propose that the Court answer the questions referred in Case C-297/16 by the Curtea de Apel București (Court of Appeal, Bucharest, Romania) to the effect that:

(1) On a proper construction, Article 15(3) of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market precludes national rules which grant an exclusive right for veterinary practitioners to retail, use and administer veterinary organic products, special purpose anti-parasitic products and veterinary medicinal products, insofar as those rules either:

– extend to products for which a veterinary medical prescription is not mandatory; or

– do not allow persons professionally trained in pharmacy, other than veterinary practitioners, the right to retail those products, if need be in accordance with the directions of a veterinary medical prescription issued by a veterinary practitioner if their acquisition is contingent on such a prescription.

It is for the national court to determine whether that is the case in the main proceedings.

(2) On a proper construction, Article 15(3) of Directive 2006/123 precludes rules of a Member State which not only provide that veterinary practitioners enjoy the right to prescribe products for which a veterinary medical prescription is required and the exclusive right to retail, use and administer those products, but also that the structures through which those products are sold must be owned exclusively or mostly by one or more veterinary practitioners. It is for the national court to determine whether that is the case in the main proceedings.