Case C-47/22

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

21 January 2022

Referring court:

Bundesverwaltungsgericht (Austria)

Date of the decision to refer:

20 January 2022

Appellant:

Apotheke B.

Respondent authority:

Bundesamt für Sicherheit im Gesundheitswesen (BASG)

Subject matter of the main proceedings

Interpretation of provisions of EU law on medicinal products for human use; conditions for obtaining distribution authorisation; requirements in respect of the holder of such authorisation

Subject matter and legal basis of the request

Interpretation of EU law, in particular Article 267 TFEU

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 6) as amended by Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 (OJ 2020 L 231, p. 12) ('Directive 2001/83')

Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (OJ 2013 C 343, p. 1) ('GDP Guidelines')

Questions referred for a preliminary ruling

1. (a) Must Article 80(b) of Directive 2001/83 be interpreted as meaning that the requirement deriving from that provision is fulfilled even where, as in the main proceedings, a holder of distribution authorisation obtains medicinal products from other persons who are also authorised or entitled to supply medicinal products to the public under national law but who are not themselves in possession of such distribution authorisation or who are exempt from the obligation to obtain such distribution authorisation under the terms of Article 77(3) of that directive, and only small quantities are supplied?

(b) If Question 1(a) is answered in the negative, is it relevant to compliance with the requirement laid down in Article 80(b) of Directive 2001/83 whether a supply of medicinal products obtained in the manner described in the main proceedings and in Question 1(a) is made only to persons authorised or entitled to supply medicinal products to the public under Article 77(2) of that directive or also to those who are themselves holders of distribution authorisation?

2. (a) Must Articles 79(b) and 80(g) of that directive, in conjunction with point 2.2 of the GDP Guidelines, be interpreted as meaning that the staffing requirements are fulfilled even where, as in the main proceedings, the responsible person is (physically) absent from the premises for a period of four hours but can be contacted by telephone during that time?

(b) Must Directive 2001/83, in particular Articles 79 and 80(g) thereof, in conjunction with the first paragraph of point 2.3 of the GDP Guidelines, be interpreted as meaning that the staffing requirements provided for in those provisions and guidelines are met where, as in the main proceedings, in the event that the responsible person is absent as described in Question 2(a), the staff present on the premises are not able, in particular in the event of an inspection by the competent authority of the Member State, to provide information themselves on the written procedures relating to their respective areas of responsibility?

(c) Must Directive 2001/83, and in particular Articles 79 and 80(g) thereof, in conjunction with point 2.3 of the GDP Guidelines, be interpreted as meaning that, in assessing whether an adequate number of competent personnel is involved in all stages of the wholesale distribution activities, account must also be taken of activities outsourced to third parties (or activities carried out by third parties on behalf of the establishment), as occurred in the case in the main proceedings, and does that directive preclude or even require the obtaining of an expert report for the purposes of that assessment?

3. Must Directive 2001/83, in particular Articles 77(6) and 79 thereof, be interpreted as meaning that the authorisation to engage in activity as a

wholesaler in medicinal products must also be revoked where it is established that a requirement under Article 80 of that directive is not fulfilled – for example, medicinal products are obtained in a manner contrary to Article 80(b) of that directive, as may be the case in the main proceedings – but that requirement is then once more complied with, in any event at the time of the decision by the competent authority of the Member State or the court before which the matter is brought? If not: what other requirements for that assessment exist under EU law, and, in particular, when must the authorisation be (merely) suspended instead of revoked?

Provisions of EU law relied on

Directive 2001/83, in particular recitals 2, 3, 35 and 36 and Articles 1, 77, 79, 80 and 84

GDP Guidelines, in particular subchapters 1.1, 1.2, 2.1, 2.2, 2.3, 4.1, 4.2 and 5.2 thereof, and the annex thereto

TFEU, in particular Articles 114 and 168

TEU, in particular Article 5

Provisions of national law relied on

Bundesgesetz vom 2. März 1983 über die Herstellung und das Inverkehrbringen von Arzneimitteln (Arzneimittelgesetz) [Federal Law of 2 March 1983 on the production and placing on the market of medicinal products (Law on medicinal products)] (BGBl. No 185/1983 in the version published in BGBl. I No 23/2020) ('the AMG'), in particular Paragraphs 1, 2, 57, 62, 63 and 66a

Gesetz vom 18. Dezember 1906, betreffend die Regelung des Apothekenwesens (Apothekengesetz) [Law of 18 December 1906 regulating pharmacies (Law on pharmacies)] (RGBl. No 5/1907 in the version published in BGBl. No 50/2021) ('the ApG'), in particular Paragraphs 1, 4, 7 and 9

Verordnung des Bundesministers für Gesundheit über Betriebe, die Arzneimittel oder Wirkstoffe herstellen, kontrollieren oder in Verkehr bringen und über die Vermittlung von Arzneimitteln (Arzneimittelbetriebsordnung 2009) [Regulation of the Federal Minister for Health on businesses which manufacture, control or place on the market medicinal products or active substances and on the brokering of medicinal products (2009 Regulation on medicinal product businesses)] (BGBl. II No 324/2008 in the version published in BGBl II. No 41/2019 ('the AMBO'), in particular Paragraphs 1, 2, 4, 5, 6 and 10

Verordnung der Bundesministerin für Gesundheit und Frauen über den Betrieb von Apotheken und ärztlichen und tierärztlichen Hausapotheken

(Apothekenbetriebsordnung 2005) [Regulation of the Federal Minister for Health and Women on the operation of pharmacies and doctors' and veterinarians' dispensaries (2005 Regulation on the operation of pharmacies)] (BGBl. II No 65/2005 in the version published in BGBl. No 354/2019) ('the ABO'), in particular Paragraph 1

Facts and procedure

1 The present appeal proceedings concern the lawfulness of the revocation of a licence granted under the provisions of the Austrian AMG by the Bundesamt für Sicherheit im Gesundheitswesen (Federal Office for Safety in Healthcare; 'the authority') to the appellant for the activity of wholesale distribution of medicinal products.

2 The parties are in dispute concerning one of the conditions for such revocation, namely non-compliance with the requirements which are contained in the AMBO –adopted in implementation of the AMG – and which concern wholesale operations. They are also in dispute concerning the lawfulness of the revocation itself.

3 The Republic of Austria has transposed Directive 2001/83 and its provisions on the wholesale distribution of medicinal products by, inter alia, the AMG and the AMBO.

4 On the basis of the investigative work by the authority and its own investigations, the referring court provisionally proceeds on the basis of the following facts:

5 The appellant is a limited partnership established under Austrian law. It operates a public pharmacy in respect of which the general partner of that company holds a licence – granted to her as a person – under the Austrian legislation on pharmacies. The appellant also holds a licence as a wholesaler of medicinal products, which was granted to it in accordance with the AMG, by decision of XXX.

6 The appellant – as the holder of authorisation to engage in the wholesale distribution of medicinal products – purchased medicinal products on several occasions from other public pharmacies, which do not hold wholesale authorisation under the AMG, and subsequently resold them to authorised wholesalers established in Austria. The medicinal products purchased in that manner were transported by carriers, commissioned by the appellant, from the respective pharmacies selling those medicinal products to the appellant or, on the latter's instructions, to a third party.

7 The authority carried out an inspection of the appellant's premises on XXX. The person identified as the 'qualified person' ('VP') in the description for the appellant's establishment was not present on the premises during that inspection.

She was on leave that day and was in XXX, 30 minutes away, to attend a hairdresser's appointment.

8 In the course of several telephone conversations between the authority and VP, the latter offered to send to the premises an employee who was not her deputy but was responsible for the areas of 'personnel', 'marketing' and 'law'. That person was not able to provide all the documents required by the authority, with the result that the inspection was discontinued and then resumed on XXX in the presence of VP.

9 The appellant maintained a business relationship with XXX in the period from XXX to XXX. That company provided logistics services to the appellant under a 'logistics contract' that they had concluded with one another.

10 The services included checking the authenticity of the medicinal products, monitoring expiry dates and batch numbers and ensuring that medicinal products were packaged in the appropriate product packaging. In that context, the appellant's medicinal products were temporarily stored in the storage facilities of XXX for a few days.

11 According to an expert assessment carried out for the referring court, all persons engaged in wholesale distribution must be fully trained and have constant access to standard operating procedures. In the event of the qualified person being absent, supporting documents must be made available to the inspectors to enable them to evaluate whether all aspects of the legal framework have been complied with.

12 Following its inspections and after having received observations from the appellant, the authority, by decision of XXX ('the decision'), revoked the marketing authorisation for medicinal products which was granted to the appellant by decision of XXX.

13 The authority justified the revocation by citing certain failures to fulfil the applicable legal requirements under the AMG and the AMBO. It also stated that the appellant failed to comply with the regulations adopted on the basis of Section VI of the AMG or with the operating licence and failed to operate according to the principles of good distribution practice (see Paragraphs 2 and 4 of the AMBO, in conjunction with the GDP Guidelines). It also revoked the certificate pursuant to Paragraph 68(5) of the AMG.

14 It stated that the suppliers were not qualified in accordance with the legal requirements and the business' internal specifications at the time when the medicinal products were purchased. Moreover, medicinal products were not obtained exclusively from (duly licensed) medicinal product wholesalers, manufacturers or importers fulfilling the requirements under Paragraph 3(9) and (10) of the AMBO, but were also purchased from public pharmacies.

15 The authority found that the appellant was not in a position to comply with and implement the requirements under Paragraph 3(9) and (10) of the AMBO and the

GDP Guidelines in its business. In the appellant's business, there is a risk of potentially falsified medicinal products entering the legal supply chain.

16 Furthermore, the appellant's business did not have a sufficient number of competent and sufficiently qualified staff. The authority stated that, according to the provisions of the AMBO, all areas of the pharmaceutical quality assurance system must be adequately staffed with competent and sufficiently qualified personnel. The 'qualified person' plays a special role in that respect, and is required to ensure that a quality assurance system is introduced and maintained. The authority found that, on the basis of the failures identified and the appellant's observations, it is apparent that the persons working in the business do not have sufficient knowledge and/or understanding of good distribution practice.

17 The appellant brought an appeal against the decision of XXX. The appellant submits that the safety of the medicinal products has not been specifically jeopardised. With regard to staffing, the appellant argued that the AMBO provides for only one qualified person and that that person could not be at his or her workplace continuously. Although the qualified person in question was not present for the first inspection, she was for the second.

18 As a result of the appeal, the Bundesverwaltungsgericht (Federal Administrative Court, Austria) subsequently held hearings and took evidence, the preliminary result of which is presented in the present order.

Reasoning in the request for a preliminary ruling

19 The success of the appeal turns on a decision of the Court of Justice of the European Union ('the Court') on the interpretation of the Treaties.

20 In connection with the legal dispute described above, questions concerning the interpretation of Directive 2001/83 arise on which the Court has, to date, not made a relevant ruling.

21 The answers to the questions referred are relevant to the resolution of the case because, in accordance with Article 77(6) of Directive 2001/83, a Member State which has granted an authorisation must suspend or revoke that authorisation if the conditions of authorisation cease to be met.

Question 1(a)

22 The appellant is a holder of distribution authorisation as provided for in Article 77(1) of Directive 2001/83. Marketing authorisation was granted to it in accordance with Paragraph 63(1) of the AMG, since it is a 'business' as provided for in Paragraph 62(1) of the AMG.

23 In accordance with Article 80(b) of Directive 2001/83, holders of distribution authorisation must fulfil the requirement to obtain their supplies of medicinal products only from persons who are themselves in possession of the distribution authorisation or who are exempt from obtaining such authorisation in accordance with Article 77(3).

24 According to the facts established on a provisional basis, the appellant procured – and also 'obtained' – medicinal products from other public pharmacies, which, however, were not in possession of distribution authorisation or exempt from obtaining such authorisation. Directive 2001/83 does not define the term 'obtaining' [*]. The referring court takes the view that it must be interpreted as defined in the glossary to the GDP Guidelines and as distinct from the concepts of 'transport' and 'supplying' (see subchapter 5.2 of the GDP Guidelines, the first paragraphs of which refers to the requirement under Article 80(b) of Directive 2001/83). According to that glossary, 'procuring' means 'obtaining, acquiring, purchasing or buying' medicinal products from manufacturers, importers or other wholesale distributors. A purchase or acquisition is already apparent from the respective delivery notes that are the subject of the proceedings.

25 In its judgment of 28 June 2012, *Caronna* (C-7/11, EU:C:2012:396), the Court stated that Article 77(2) of Directive 2001/83/EC, as amended by Commission Directive 2009/120/EC of 14 September 2009, must be interpreted as meaning that the requirement to obtain authorisation for the wholesale distribution of medicinal products is applicable to a pharmacist who, as a natural person, is also authorised under domestic law to operate as a wholesaler in medicinal products. The Court also stated that a pharmacist who is also authorised under domestic law to operate as a wholesaler in medicinal products must satisfy all the requirements imposed on applicants for and holders of authorisation for the wholesale distribution of medicinal products in Articles 79 to 82 of Directive 2001/83, as amended by Directive 2009/120 (see paragraph 50 of the judgment).

26 Under the national legislation, a wholesaler in medicinal products may obtain medicinal products only from a wholesaler, manufacturer or importer of medicinal products, in accordance with Paragraph 3(8) of the AMBO. In that respect, it must verify, in accordance with Paragraph 3(9) of the AMBO, whether the supplying wholesaler in medicinal products complies with 'good distribution practice' and

[*] Translator's note: The German source text refers to the term 'beschaffen' which is used consistently in the German language version of Directive 2001/83. This term appears to be important for the questions referred. However, Directive 2001/83 contains no consistent English language equivalent for DE 'beschaffen', which is most often rendered as 'obtain', for example in Article 80(b) of Directive 2001/83, but is also rendered as 'procure' or 'receive' elsewhere in that directive. The German language version of the glossary in the GDP Guidelines defines the term 'Beschaffung', which is rendered in the English language version as 'Procuring'. As noted above, Article 80(b) uses 'obtain' rather than 'procure'. For DE 'beschaffen', this translation uses 'obtain' or 'procure' as used in the Articles of Directive 2001/83 referenced, and where there is no specific reference, 'obtain' is used. This translation uses 'procure' for DE 'besorgen' (which term is not used in the directive itself, nor in the GDP Guidelines).

also whether it is in possession of the relevant authorisation under the AMG or from an authority of another contracting party to the EEA. Possession of an authorisation must also be verified in the case of a supplying manufacturer or importer (see Paragraph 3(10) of the AMBO).

27 Compliance with the AMBO is a condition for granting authorisation under the AMG. An infringement of the AMBO in the course of business may form the basis for an order suspending or even revoking the authorisation.

28 However, the appellant also operates a pharmacy intended for the general public (a 'public pharmacy') pursuant to Paragraph 1 of the ApG. Its general partner holds a licence pursuant to Paragraph 9 of the ApG. Under the provisions of the Austrian legislation on pharmacies, pharmacy businesses may also be operated in the form of a partnership.

29 The tasks of a public pharmacy in connection with the supply of medicinal products to the population also include the 'occasional supply' of medicinal products to other pharmacies, by virtue of the express provision laid down in Paragraph 1(2) of the ABO – which was adopted in implementation of the ApG.

30 In accordance with Paragraph 62(1) of the AMG, 'public pharmacies' are not considered to be 'businesses' within the meaning of that provision where they place medicinal products on the market 'as part of the normal operation of the pharmacy' in accordance with the ABO. However, the first sentence of Paragraph 62(2a) of the AMG stipulates that, where public pharmacies 'supply' medicinal products to other public pharmacies – a form of 'placing on the market' – in a manner going beyond the normal operation of the pharmacy, they require authorisation to that effect pursuant to Paragraph 63(1) of the AMG.

31 The referring court takes the view that the provision of Article 80(b) of Directive 2001/83 must be interpreted as meaning that persons who are in possession of a distribution authorisation under that directive may procure medicinal products exclusively from persons who are in possession of the distribution authorisation or who are exempt from the obligation to obtain such authorisation, failing which they no longer fulfil the requirement laid down in Article 80(b) of that directive, as a result of having obtained them from other persons. However, this also applies if that person is also otherwise authorised to supply medicinal products to the public (at retail level) and – in accordance with the national rules outlined above – obtains medicinal products from other public pharmacies which are not, however, in possession of a distribution authorisation or exempt from the obligation to obtain such authorisation.

32 Nevertheless, the Federal Administrative Court has doubts as to whether that interpretation is correct, for the reasons set out below. There does not appear to be any case-law of the Court relating specifically to Question 1(a), even if its judgment referred to above is taken into account. Nor is there any relevant national case-law.

33 The appellant submits, in essence, that Article 80(b) must be interpreted as not precluding supply via a public pharmacy as an 'intermediate carrier' (or 'intermediate supplier'). The appellant argues, referring in particular to recitals 2 and 3 of Directive 2001/83, that this applies as long as it can be ensured, in respect of each individual medicinal product (at the level of each individual package), that the product in question comes from a wholesaler or manufacturer of medicinal products which is authorised to supply it, and, in respect of each partial step, all provisions guaranteeing the protection and usability of the medicinal product are complied with. According to the appellant, such pharmacies assume transport and logistics functions, and the quantities of medicinal products involved are extremely small. It claims that the same level of hygiene and protection is provided as in the case where a (pure and simple) transport company is used. The only difference is that the public pharmacy (from which products are obtained) continues to place orders independently. The appellant submits that Articles 28 to 37 TFEU preclude the exclusion of pharmacies from supply chains (including in the form of 'intermediate carriers'). It takes the view that no restrictions on trade and supply chains can be derived from Article 80(b) of the directive, as also follows from the preparatory work relating to Commission Directive 2001/62/EC of 9 August 2001 amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs (OJ 2001 L 221, p. 18).

34 However, taking into account the preparatory work which is relevant in the present case, together with the associated documents, opinions, recitals, etc – which include , on the one hand, Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use (OJ 1992 L 113, p. 1), Directive 2001/83, together with recitals 2, 3 and 35 thereof, and Directive 2001/62 and , on the other hand, the preparatory materials relating to the above directives, Articles 114 and 168(4) TFEU, relating to the level of human health protection to be guaranteed in achieving harmonisation, and the principle of proportionality enshrined in Article 5 TEU – the referring court is unable to share the appellant's view on the interpretation of the requirement under Article 80(b) of Directive 2001/83.

35 Through subparagraphs 2 and 3, which were added to Article 80 of Directive 2001/83, additional protective measures for the distribution chain were also taken in the internal market, with the result that the holder of a distribution authorisation obtaining supplies must (now additionally) verify whether the supplying wholesaler, manufacturer or importer holds a distribution or manufacturing licence.

36 If it is assumed, as the referring court does, that the concepts of 'obtaining'/'procuring' and 'supplying' are to be understood as defined in the glossary ** in the annex to the GDP Guidelines, the appellant's transactions with other public pharmacies in relation to medicinal products in the main proceedings

** As noted above, 'Beschaffung' is rendered in the GDP Guidelines as 'Procuring', despite Article 80(b) using 'obtain' for 'beschaffen' rather than 'procure'.

constitute ‘obtaining’‘ from the point of view of the appellant and ‘supplying’ from the point of view of the respective pharmacies (that is to say, those other pharmacies are to be regarded as ‘suppliers’). They would in any event be mere ‘carriers’ only if the transactions were not to be categorised as ‘obtaining’ or ‘supplying’.

37 However, the interpretation considered to be correct by the referring court might be regarded as being contrary to the principle of proportionality because, despite the objective of ensuring a high level of environmental protection, it would entail an excessive restriction of the supply chain.

Question 1(b)

38 The appellant purchased medicinal products from persons who, although authorised or entitled to supply medicinal products to the public, were not themselves in possession of a distribution authorisation, and the appellant (re)sold the medicinal products thus obtained to persons who were themselves in possession of a distribution authorisation.

39 In view of the wording of Article 80(b) of Directive 2001/83, the referring court proceeds on the assumption that, in the case of a person who holds a distribution authorisation, compliance with the requirement under that provision does not depend on to whom the medicinal products obtained are supplied (or whether they in fact merely enter the retail [pharmacy] business) of the person obtaining them).

40 It is precisely the objective of ensuring a high level of human health protection pursued by the requirements of Article 80 of Directive 2001/83 which precludes an interpretation according to which a person who (also) holds authorisation for the wholesale distribution of medicinal products may also obtain medicinal products from other pharmacies which themselves neither hold such authorisation nor are to be regarded as manufacturers, as long as only the medicinal products obtained in that manner are not supplied to other holders of wholesale distribution authorisations. Accordingly, it is precisely the special requirements for wholesalers – including, in particular, compliance with the principles and guidelines of good distribution practices – which should be extensively applied in the supply chain.

41 However, that interpretation might also contradict the principle of proportionality belonging to the legal order of the European Union.

Questions 2(a) and 2(b)

42 According to Article 79 of Directive 2001/83, in order to obtain the distribution authorisation, applicants must have staff, and in particular, a qualified person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned. They must undertake to comply with the obligations incumbent on them under the terms of Article 80 of that directive,

which include compliance with the GDP Guidelines published by the European Commission in accordance with the procedure laid down in Article 84 of Directive 2001/83.

43 Chapter 2 of the GDP Guidelines concerns the staffing of wholesale establishments with suitable personnel. Subchapter 2.1 of the GDP Guidelines states, as a principle, that the correct distribution of medicinal products relies upon people, and there must be sufficient trained personnel to carry out all the tasks for which the wholesale distributor is responsible. As a concrete guideline, subchapter 2.2 of the GDP Guidelines states that the responsible person should fulfil their responsibilities personally and should be continuously contactable, which also includes duties relating to a fully documented quality system.

44 According to subchapter 2.3 of the GDP Guidelines, there should be an adequate number of competent personnel involved in all stages of the wholesale distribution activities of medicinal products. In accordance with subchapter 4.2 of the GDP Guidelines, documentation comprises all written procedures or instructions, in paper or in electronic form. In addition, the documentation should also be readily available/retrievable, and each employee should have ready access to all documentation necessary for his or her duties.

45 In the present case, the staff who were present at the establishment were not able to produce the requested documents during the first inspection. As regards the details in that respect, reference is made to the above findings of fact. On the basis of those circumstances, the authority took the view that the appellant's staffing was not sufficient.

46 The referring court takes the view that Question 2(a) must be answered to the effect that the requirements of Articles 79(b) and 80(g) of the directive, in conjunction with the GDP Guidelines, continue to be met even where the responsible person is absent for a period of time, as was the case in the main proceedings, and even where that absence lasts for a period of approximately four hours. This is the case, in particular, where it is ensured that the responsible person can be reached by telephone at any time.

47 With regard to the answer to Question 2(b), the referring court takes the view that Articles 79(b) and 80(g) of Directive 2001/83, in conjunction with the GDP Guidelines, must be interpreted as meaning that the requirements deriving from those provisions, in particular the adequate provision of competent staff, are no longer fulfilled where the ('other') staff present during day-to-day operations are not able to provide access, at all times, to the standard operating procedures which are applicable to them and have been established for them on the basis of their responsibilities. That is not altered by the fact that the responsible person can be reached by telephone. Conversely, however, the rules are complied with by virtue of the availability of the responsible person by telephone where, as in the case in the main proceedings, the staff present at the premises are not responsible for the area in respect of which the standard operating procedures are to be provided.

48 Nevertheless, the referring court continues to have doubts as to whether that interpretation is correct in the light of the facts established (see, regarding the assessment of the application to the facts of the present case, judgment of the Court of 8 November 2016, *Lesoochranárske zoskupenie VLK*, C-243/15, EU:C:2016:838, paragraph 64). In accordance with subchapter 2.2 of the GDP Guidelines, the responsible person should fulfil their responsibilities personally and should be continuously contactable, and may delegate duties but not responsibilities.

Question 2(c)

49 There should be an adequate number of competent personnel involved in all stages of the wholesale distribution activities of medicinal products. In accordance with the second sentence of the first paragraph of subchapter 2.3 of the GDP Guidelines, the number of personnel required will depend on the volume and scope of activities. The GDP Guidelines also contain guidelines and a principle on outsourced activities (see, inter alia, Chapter 7 of the GDP Guidelines).

50 In the absence of further rules in the EU legal order on the determination of the required number of employees (and also the determination of whether that number is adequate and the employees are competent), the principle of procedural autonomy of the Member States must be observed. Accordingly, they must determine the respective procedural arrangements in such a manner that (at the least) they are not less favourable than those governing similar domestic situations and do not render impossible in practice or excessively difficult the exercise of rights conferred by the EU legal order (see, inter alia, judgment of the Court of 7 November 2019, *Flausch and Others*, C-280/18, EU:C:2019:928, paragraph 27). Those arrangements also include arrangements of the competent authority (and, above all, of a court subsequently before which an appeal against a decision of that authority is brought) for the ways in which evidence is to be elicited, what evidence is to be admissible, or the principles governing the assessment of the probative value of evidence adduced and also the level of proof required (see judgment of the Court of 21 June 2017, *W and Others*, C-621/15, EU:C:2017:484, paragraph 25).

51 The referring court proceeds on the assumption that, in determining the number of employees required in wholesale distribution activities, account can (or must) also be taken of whether, and if so to what extent, the holder of distribution authorisation outsources activities to a third party. When assessing the required number of employees, a report from a suitable expert can or must be obtained, where necessary.

52 However, the referring court continues to have doubts as to whether what it considers to be the appropriate answer to Question 2(c) is also correct with regard to the facts established in the main proceedings.

Question 3

53 According to Article 77(6) of Directive 2001/83, the Member State which granted the authorisation referred to in paragraph 1 of that provision is to suspend or revoke that authorisation if the conditions of authorisation cease to be met.

54 The minimum requirements to be fulfilled in order for a Member State to grant an authorisation for the wholesale distribution of medicinal products are set out in Article 79(a) to (c) of Directive 2001/83. They include, in particular, the obligations set out in Article 80 of the directive, which in turn include, for example, the requirement that wholesalers in medicinal products must obtain their supplies of medicinal products only from persons who are themselves in possession of the distribution authorisation or who are exempt from obtaining such authorisation under the terms of Article 77(3) of Directive 2001/83 (as provided for in Article 80(b)).

55 It is unclear in which cases authorisation must merely be suspended and when it must (even) be revoked.

56 Austrian law provides, in the first sentence of Paragraph 66a of the AMG, that the authorisation granted is to be revoked if the requirements are no longer met. According to the second sentence of that provision, instead of revocation, the total or partial suspension of the authorisation may also be ordered where the holder of the operating authorisation may be able to eliminate the reason for the revocation within a reasonable period of time. In accordance with the preparatory work, the decision as to whether to order revocation or suspension is left to the discretion of the authority. There does not appear to be any national case-law on that provision.

57 In the main proceedings, the authority took the view – in connection with the obligation under Article 80(c) and the second paragraph of Article 80of the directive – that the extent to which the holder of the authorisation has an understanding of the necessity and importance of compliance with the legal requirements, in particular in relation to the supply chain as a whole and to full documentation of such compliance, must also be taken into account in assessing whether a distribution authorisation may be revoked. According to the authority, if an authorisation holder ceases to be non-compliant only after repeated instances of non-compliance, it must be concluded that it is not capable of complying with its legal obligations.

58 Against that background, the referring court proceeds on the assumption that the authorisation must be revoked only if, at the time of the decision, there are indications in the individual case that compliance with all the obligations and requirements under Article 80 of the directive continues not to be expected. Such indications may arise from the nature and duration of the infringement of such an obligation, or from the fact of whether the authorisation holder has taken appropriate measures at the time of the decision by a competent authority.

59 The referring court also proceeds on the assumption that the nature and gravity of the infringement determines whether the authority will decide to suspend the authorisation instead of revoking it. Furthermore, the competent authority must observe the principle of proportionality when taking such action, that is to say, revocation is lawful only if it is appropriate and necessary in order to achieve the objectives legitimately pursued by the legislation. When there is a choice between several measures, recourse must be had to the least onerous.

60 The referring court continues to have doubts also as regards whether that interpretation of the directive is correct in the light of the facts established.