Reports of Cases

JUDGMENT OF THE COURT (Eighth Chamber)

10 March 2021 *

(Reference for a preliminary ruling – Public health – Article 168 TFEU – Directive 2002/98/EC – Standards of quality and safety of human blood and of blood components – Objective of ensuring a high level of protection of human health – Article 4(2) and Article 9(2) – Blood establishments – Responsible person – Minimum conditions of qualification – Option for a Member State to provide for a more stringent regime – Discretion afforded to the Member States)

In Case C-96/20,

REQUEST for a preliminary ruling under Article 267 TFEU from the Corte suprema di cassazione (Court of Cassation, Italy), made by decision of 7 November 2019, received at the Court on 24 February 2020, in the proceedings

Ordine Nazionale dei Biologi,

MX,

NY,

OZ

v

Presidenza del Consiglio dei Ministri,

intervening parties:

Sds Snabi,

Agenzia Regionale Protezione Ambiente (ARPA),

THE COURT (Eighth Chamber),

composed of N. Wahl, President of the Chamber, A. Prechal (Rapporteur), President of the Third Chamber, and L. S. Rossi, Judge,

Advocate General: H. Saugmandsgaard Øe,

* Language of the case: Italian.

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Ordine Nazionale dei Biologi, MX, NY and OZ, by G. Sciacca and R. Arbib, avvocati,

– the Italian Government, by G. Palmieri, acting as Agent, and by C. Colelli, avvocato dello Stato,

– the European Commission, by C. Sjödin and A. Szmytkowska, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 9(2) of Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ 2003 L 33, p. 30).

2 The request has been made in proceedings between the Ordine Nazionale dei Biologi (National Association of Biologists, Italy) and MX, NY and OZ, three individuals holding a degree in biological sciences, and the Presidenza del Consiglio dei Ministri (Presidency of the Council of Ministers, Italy) concerning the validity of a provision of Italian law which provides that only individuals holding a degree in medicine and in surgery who also fulfil certain conditions in terms of post-graduate experience can be designated as the responsible person of a blood establishment.

Legal context

European Union law

3 Recitals 15 and 33 of Directive 2002/98 state:

‘(15) Personnel directly involved in the collection, testing, processing, storage and distribution of blood and blood components need to be appropriately qualified and provided with timely and relevant training, without prejudice to existing Community legislation on the recognition of professional qualifications and on the protection of workers;

…

(33) Responsibility for the organisation of health services and the provision of medical care should remain the responsibility of each Member State’.

4 Article 1 of that directive, entitled ‘Objectives’, provides:

‘This Directive lays down standards of quality and safety of human blood and of blood components, in order to ensure a high level of human health protection.’

5 Article 2(1) of that directive defines the scope of that directive as follows:

‘This Directive shall apply to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for transfusion.’

6 Article 3 of Directive 2002/98, entitled ‘Definitions’, provides:

‘For the purposes of this Directive:

…

(e) “blood establishment” shall mean any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks;

…’

7 Under Article 4(2) of Directive 2002/98:

‘This directive shall not prevent a Member State from maintaining or introducing in its territory more stringent protective measures which comply with the provisions of the Treaty.

In particular, a Member State may introduce requirements for voluntary and unpaid donations, which include the prohibition or restriction of imports of blood and blood components, to ensure a high level of health protection and to achieve the objective set out in Article 20(1), provided that the conditions of the Treaty are met.’

8 Article 5 of that directive, entitled ‘Designation, authorisation, accreditation or licensing of blood establishments’, provides in paragraph 1 thereof:

‘Member States shall ensure that activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution when intended for transfusion, are undertaken only by the blood establishments which have been designated, authorised, accredited or licensed by the competent authority for that purpose.’

9 Article 9 of the directive, ‘Responsible person’, lays down:

‘1. Blood establishments shall designate a person (responsible person), responsible for:

– ensuring that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force in the Member State,

– providing information to the competent authority in the designation, authorisation, accreditation or licensing procedures as required in Article 5,

– the implementation of the requirements of Articles 10, 11, 12, 13, 14 and 15 in the blood establishment.

2. The responsible person shall fulfil the following minimum conditions of qualification:

(a) he/she shall possess a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;

(b) he/she shall have practical post-graduate experience in relevant areas for at least two years, in one or more establishments which are authorised to undertake activities related to collection and/or testing of human blood and blood components, or to their preparation, storage, and distribution.

…'

10 Article 10 of the directive, headed 'Personnel', provides:

'Personnel directly involved in collection, testing, processing, storage, and distribution of human blood and blood components shall be qualified to perform those tasks and be provided with timely, relevant and regularly updated training.'

11 According to Article 20(1) of Directive 2002/98:

'Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations.'

Italian law

12 Article 6 of the decreto legislativo del 20 dicembre 2007 n. 261, recante revisione del decreto legislativo 19 agosto 2005, n. 191, recante attuazione della direttiva 2002/98/CE che stabilisce norme di qualità e di sicurezza per la raccolta, il controllo, la lavorazione, la conservazione e la distribuzione del sangue umano e dei suoi componenti (Legislative Decree No 261 of 20 December2007, amending Legislative Decree No 191 of 19 August 2005, transposing Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components) (GURI No 19 of 23 January 2008) ('Legislative Decree No 261/2007'), provides:

'1. The entity of which the blood establishment is part shall designate the person responsible for it and who, as such, is required to perform the following tasks:

(a) ensure that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, distributed and allocated, when intended for transfusion, in compliance with the provisions in force;

(b) provide the information required in the context of authorisation and accreditation procedures;

(c) ensure that blood establishments meet the requirements set out in Articles 7 to 11.

2. The person responsible under paragraph 1 holds a degree in medicine and [in] surgery, and satisfies the conditions laid down by the rules in force concerning appointment to the management of a complex structure operating in the field of transfusion medicine.'

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

13 On 10 June 2008, the applicants in the main proceedings brought an action before the Tribunale di Roma (Rome District Court, Italy) in which they sought a declaration that Article 6(2) of Legislative Decree No 261/2007, in so far as it restricts appointment to the position of responsible person of a blood establishment to graduates in medicine and in surgery only, is contrary to Article 9(2) of Directive 2002/98, since that provision, in that it lays down, as a condition for appointment to that position, the possession of a university diploma in medical or biological sciences, confers a right on individuals holding a degree in biological sciences to be eligible for appointment to that position, from which it follows that that provision of national law is contrary to EU law and must be disapplied.

14 That court dismissed that action principally on the ground that Directive 2002/98 is not 'self-executing' since it lays down only general rules and principles with regard to blood establishments, leaving it to national law to regulate their creation and functioning. Article 9(2) of that directive allows the Member States to choose, in a discretionary manner, whether appointment to the position of responsible person of blood establishments must be reserved to graduates in medicine only, to graduates in biological sciences only or to both of those categories of graduates.

15 The applicants in the main proceedings brought an appeal against the judgment of the Tribunale di Roma (Rome District Court) before the Corte d'appello di Roma (Rome Court of Appeal, Italy) which, by judgment of 19 June 2015, dismissed that appeal and upheld that judgment in its entirety.

16 Hearing an appeal on a point of law brought by the applicants in the main proceedings, the referring court asks whether Article 9(2) of Directive 2002/98 must be interpreted as conferring on graduates in biological sciences a right to be designated as the responsible person for blood establishments, or whether, in the light of the fact that that directive lays down only minimum requirements in that field, that provision must rather be understood as allowing the Member States the freedom to choose to restrict appointment to that position to graduates in medical sciences only, to graduates in biological sciences only or to both of those categories of graduates.

17 In those circumstances, the Corte suprema di cassazione (Supreme Court of Cassation, Italy) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is Article 9(2) of Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components to be interpreted as meaning that, by identifying as minimum conditions of qualification for appointment to the position of responsible person of a blood establishment the possession of an academic qualification "in the field of medical or biological sciences", it confers directly on graduates in either discipline the right to carry out the duties of responsible person within a blood establishment?

(2) Does European Union law accordingly permit national law to exclude graduates in biological sciences from carrying out the duties of responsible person within a blood establishment or preclude it from doing so?'

Consideration of the questions referred

18 By its two questions, which it is appropriate to examine together, the referring court asks, in essence, whether Article 9(2)(a) of Directive 2002/98, read in conjunction with Article 4(2) thereof, must be interpreted as precluding national legislation which provides that only persons holding a degree in medicine and in surgery may be designated as the responsible person of a blood establishment.

19 Article 9(2) of Directive 2002/98 provides that the responsible person designated by a blood establishment must fulfil the 'minimum conditions of qualification' listed therein, including that set out in subparagraph (a) of that provision, of being in 'possess[ion of] a diploma, [a] certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned'.

20 The Italian legislature's intention was to transpose that provision into national law by adopting Article 6(2) of Legislative Decree No 261/2007 which restricts appointment to the position of responsible person of a blood establishment solely to persons with a 'degree in medicine and [in] surgery'.

21 Before the referring court, the applicants in the main proceedings challenge the validity of that national provision principally on the ground that Article 9(2) of Directive 2002/98 confers a 'right' on graduates in biological sciences to be designated as the responsible person of a blood establishment and, consequently, that national provision, in so far as it restricts appointment to that position to graduates in medicine and in surgery and thus excludes graduates in biological sciences, constitutes a transposition of Article 9(2) which is contrary to EU law and which must therefore be disapplied.

22 In that regard, it must be noted that Directive 2002/98, the objective of which is the protection of public health, is based on Article 168 TFEU, paragraph 1 of which provides that a high level of human health protection is to be ensured in the definition and implementation of all European Union policies and activities. Article 1 of that directive states that it lays down standards of quality and safety of human blood and of blood components, in order to ensure a high level of human health protection. Moreover, Article 168(4)(a) TFEU provide that the Member States cannot be prevented from maintaining or introducing more stringent protective measures, since that provision is expressly reproduced in Article 4(2) of Directive 2002/98 (see, to that effect, judgment of 13 March 2014, *Octapharma France*, C-512/12, EU:C:2014:149, paragraph 43).

23 In the present case, the question arises as to whether the national provision at issue in the main proceedings, in so far as it allows only graduates in medicine and in surgery to be appointed to the position of responsible person of a blood establishment, may be considered a 'more stringent protective measure', within the meaning of the first subparagraph of Article 4(2) of Directive 2002/98, as compared with that laid down in Article 9(2) of that directive.

24 That question must be answered in the affirmative.

25 It is apparent from the very wording of Article 9(2) of Directive 2002/98 that that provision merely imposes 'minimum conditions of qualification' relating both to having a university diploma and to minimum practical post-graduate experience which a person must fulfil in order to be able to be designated as the responsible person of a blood establishment.

26 As regards, in particular, the qualification condition laid down in Article 9(2)(a) of Directive 2002/98, it is also apparent from the legislative history of that provision that, whereas the initial proposal of the European Commission referred to the condition of possessing a diploma falling within a wide range of scientific disciplines, that proposal was subsequently amended to a condition requiring possession of a diploma in medicine, preferably with a specialisation in haematology, and, in the final text of that provision, graduates in biological sciences were added.

27 Thus, the legislative history of Article 9(2)(a) of Directive 2002/98 shows that, although the EU legislature reduced the number of university diplomas which may give access to the position of responsible person of a blood establishment, it nevertheless intended to grant Member States a certain flexibility in the choice of the qualifications required in order to be appointed to that position.

28 Furthermore, it cannot be inferred from the stricter protective measure mentioned, for purely illustrative purposes, in the second subparagraph of Article 4(2) of Directive 2002/98, concerning voluntary and unpaid blood donations, or indeed from any other provision of that directive, that only national provisions which include a more stringent regime than that laid down by the provisions of that directive which directly govern the collection, testing, processing, storage or distribution of blood and blood components by blood establishments and which do not include Article 9(2) of that directive may constitute stricter protection measures.

29 The minimum qualification conditions laid down in Article 9(2) of Directive 2002/98 seek to ensure that the person responsible for a blood establishment has sufficient theoretical and practical skills to carry out the duties entrusted to him or her in accordance with Article 9(1) of that directive.

30 In so far as those duties include, in particular, the task of ensuring that every unit of blood or of blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force in the Member State concerned or that of implementing in blood establishments the requirements in Articles 10 to 15 of Directive 2002/98, contribute fully to the Directive's objective of ensuring a high level of protection of human health as regards quality and safety standards for human blood and blood components which it sets.

31 In that context, the Italian Government states that the choice of requiring possession of a degree in medicine and in surgery in order to be designated as the responsible person of a blood establishment was dictated by the fact that, in Italy, blood establishments constitute services forming part of the national health system which carry out numerous and delicate activities, including purely medical and diagnostic activities, which are not limited to the activities of those establishments referred to in Article 3(e) of Directive 2002/98 and, accordingly, the possession of such a diploma is indispensable.

32 In that regard, it is true that the tasks of blood establishments, even those of an allegedly 'purely medical' nature which are entrusted to them under Italian law, are, as such, carried out not by the person responsible for those establishments, but by their 'personnel' referred to in Article 10

of Directive 2002/98, namely 'personnel directly involved in collection, testing, processing, storage, and distribution of human blood and blood components' who are 'qualified to perform those tasks and [who are] provided with timely, relevant and regularly updated training'. According to recital 15 of that directive, this is personnel 'directly' involved in those tasks.

33 The distinction between 'personnel' and 'responsible person' made in Directive 2002/98 is also reflected in the last indent of Article 9(1) of that directive which provides that the responsible person is to be responsible for the implementation in blood establishments of the requirements set out, inter alia, in Article 10 of that directive, which implies that that person must ensure, inter alia, that the personnel possess the qualifications necessary to carry out the tasks of those establishments, which may require the personnel concerned to possess a diploma in medicine in the case of tasks of a medical nature.

34 However, according to the Italian Government and subject to verification by the referring court, the fact remains that the objective pursued by the national provision at issue in the main proceedings, relating to the fact that qualification as a doctor is likely to further enable the responsible person to perform his or her duties fully and effectively so far as concerns all the activities of blood establishments, including those of a purely medical nature, is consistent with the objective of Directive 2002/98 which consists, in accordance with Article 1 thereof, in setting quality and safety standards for human blood and blood components in order to ensure a high level of protection of human health and the national provision at issue in the main proceedings is thus likely, as a stricter protective measure, to further guarantee that that objective is actually met.

35 This is an assessment in the field of public health for which responsibility lies with Member States pursuant to the identical provisions of Article 168(4)(a) TFEU and Article 4(2) of Directive 2002/98.

36 According to the settled case-law of the Court, since the health and life of humans rank foremost among the assets and interests protected by TFEU, it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved. Since that level may vary from one Member State to another, Member States should be allowed some measure of discretion (see judgment of 8 June 2017, *Medisanus*, C-296/15, EU:C:2017:431, paragraph 82 and the case-law cited). Consequently, the fact that a Member State imposes less strict rules than another Member State does not mean that the latter's rules are disproportionate (judgment of 18 September 2019, *VIPA*, C-222/18, EU:C:2019:751, paragraph 71 and the case-law cited).

37 In the present case, in the light of the documents provided to the Court and subject to verification by the referring court, it does not appear, having regard also to the discretion granted to the Member States, referred to in the preceding paragraph, that the national provision at issue in the main proceedings may be considered an inappropriate measure to achieve the objective of enhanced protection of the protection of human health which it pursues in the field of quality and safety standards for human blood and blood components.

38 Moreover, the compatibility of the national provision at issue in the main proceedings with EU law seems to be supported by the fact, noted by the Italian Government and which is also for the referring court to ascertain, that blood establishments constitute, in Italy, services forming part of the national health system, from which it follows that that provision falls under the responsibilities incumbent on the Member States pursuant to Article 168(7) TFEU so far as concerns the

definition of their health policy and the organisation and provision of health services and medical care, which include the management of such services and the allocation of the resources assigned to them.

39 This is furthermore referred to in recital 33 of Directive 2002/98 which states that responsibility for the organisation of health services and the provision of medical care should remain the responsibility of each Member State.

40 In the context of the implementation of that responsibility, Member States must also be allowed some discretion as to the choice of appropriate measures, in particular as regards the qualifications of persons providing health services.

41 Therefore, a Member State has, under Article 168(4)(a) TFEU and Article 4(2) of Directive 2002/98, the ability to make the qualification conditions which a person responsible for a blood establishment must satisfy subject to a more stringent regime than that provided for in Article 9(2)(a) of that directive, in so far as that Member State considers, without exceeding the discretion conferred on it to decide on the high level of protection which it wishes to afford to public health and the way in which that level has to be achieved, that that more stringent regime makes it possible to further ensure that the person responsible for such an establishment will be fully and effectively able to perform the tasks incumbent upon him or her and that, therefore, the objective of protection of human health which that directive seeks to achieve is met.

42 Finally, it must be stated that, although Article 4(2) of Directive 2002/98 provides that a more stringent measure for the purposes of that provision may be maintained or introduced by a Member State only if it 'compl[ies] with the provisions of the Treaty' and although the applicants in the main proceedings rely on a series of provisions and principles of EU law which are allegedly infringed by the national provision at issue in the main proceedings, the referring court does not ask the Court whether any of those are complied with.

43 In that regard, it may nevertheless be observed, as regards the argument put forward by the applicants in the main proceedings concerning the alleged failure to comply with the requirement of mutual recognition imposed by Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255, p. 22), as amended by Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 (OJ 2013 L 354, p. 132), which harms migrant biologists wishing to carry out the duties of a responsible person of a blood establishment in Italy, that that argument, which may be admissible even if raised in a request for a preliminary ruling, regardless of the fact that it arises in a purely internal situation (see, by analogy, judgment of 21 February 2013, *Ordine degli Ingegneri di Verona e Provincia and Others*, C-111/12, EU:C:2013:100, paragraphs 33 to 35), must in any event be rejected on the substance.

44 It is for the national legislation of the host Member State to define the field of activities covered by the profession of biologist and it is only if, under that legislation, an activity is regarded by that Member State as falling within that field that the requirement of mutual recognition means that migrant biologists must also be able to pursue that activity (see, by analogy, judgment of 21 February 2013, *Ordine degli Ingegneri di Verona e Provincia and Others*, C-111/12, EU:C:2013:100, paragraph 48).

45 In the present case, the Italian legislation does not consider that the duties of a person responsible for a blood establishment fall within the field of activity of the profession of biologist.

46 In the light of the foregoing, the answer to the questions referred is that Article 9(2)(a) of Directive 2002/98, read in conjunction with Article 4(2) thereof, must be interpreted as not precluding national legislation which provides that only individuals holding a degree in medicine and in surgery may be designated as the responsible person of a blood establishment, provided that that legislation complies with EU law in all aspects.

Costs

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

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

Article 9(2)(a) of Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, read in conjunction with Article 4(2) thereof, must be interpreted as not precluding national legislation which provides that only individuals holding a degree in medicine and in surgery may be designated as the responsible person of a blood establishment, provided that that legislation complies with EU law in all aspects.

[Signatures]