



Reports of Cases

JUDGMENT OF THE COURT (Second Chamber)

13 July 2023*

(Reference for a preliminary ruling – Public health – National legislation imposing a vaccination obligation on health professionals – Suspension from duty without pay for personnel refusing the vaccine – Regulation (EC) No 726/2004 – Medicinal products for human use – Vaccines against COVID-19 – Regulation (EC) No 507/2006 – Validity of conditional marketing authorisations – Regulation (EU) 2021/953 – Prohibition of discrimination between vaccinated and unvaccinated persons – Inadmissibility)

In Case C-765/21,

REQUEST for a preliminary ruling under Article 267 TFEU from the Tribunale ordinario di Padova (District Court, Padua, Italy), by decision of 7 December 2021, received at the Court on 13 December 2021, in the proceedings

D.M.

v

Azienda Ospedale-Università di Padova,

in the presence of:

C.S.,

THE COURT (Second Chamber),

composed of A. Prechal (Rapporteur), President of the Chamber, M.L. Arastey Sahún, F. Biltgen, N. Wahl and J. Passer, Judges,

Advocate General: M. Szpunar,

Registrar: D. Dittert, Head of Unit,

having regard to the written procedure and further to the hearing on 18 January 2023,

after considering the observations submitted on behalf of:

– D.M., by R. Martina, L. Minisci, A. Sinagra and A. Veneziano, avvocati,

* Language of the case: Italian.

- Azienda Ospedale-Università di Padova, by C. Cester, I. Giancesini, M.L. Miazzi, A. Rampazzo and C. Tomiola, avvocati,
- C.S., by P. Piva and F. Rossi Dal Pozzo, avvocati,
- the Italian Government, by G. Palmieri, acting as Agent, G. De Bellis and F. Urbani Neri, avvocati dello Stato,
- the European Commission, by G. Gattinara and A. Sipos, 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 4 of Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisations for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ 2006 L 92, p. 6), Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic (OJ 2021 L 211, p. 1), and Articles 3, 35 and 41 of the Charter of Fundamental Rights of the European Union ('the Charter').
- 2 The request has been made in proceedings between D.M. and Azienda Ospedale-Università di Padova (University Hospital of Padua, Italy) ('the university hospital') concerning the suspension of D.M. from her duties as a professional nurse at the university hospital, without entitlement to remuneration during her suspension, on account of her failure to comply with national legislation imposing compulsory vaccination for healthcare staff.

The legal framework

European Union law

Regulation No 507/2006

- 3 Article 1 of Regulation No 507/2006 states:

'This Regulation lays down rules on the granting of a marketing authorisation subject to specific obligations in accordance with Article 14(7) of Regulation (EC) No 726/2004 [of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1)], hereinafter "conditional marketing authorisation".'

4 Article 4 of Regulation No 507/2006 is worded as follows:

‘1. A conditional marketing authorisation may be granted where the Committee [for medicinal products for human use] finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- (a) the risk-benefit balance of the medicinal product, as defined in Article 1(28a) of 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. 67)], is positive;
- (b) it is likely that the applicant will be in a position to provide the comprehensive clinical data;
- (c) unmet medical needs will be fulfilled;
- (d) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

In emergency situations as referred to in Article 2(2), a conditional marketing authorisation may be granted, subject to the requirements set out in points (a) to (d) of this paragraph, also where comprehensive pre-clinical or pharmaceutical data have not been supplied.

2. For the purposes of paragraph 1(c), “unmet medical needs” means a condition for which there exists no satisfactory method of diagnosis, prevention or treatment authorised in the Community or, even if such a method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected.’

Regulation 2021/953

5 Recitals 6, 12 to 14 and 36 of Regulation 2021/953 state:

‘(6) Member States may, in accordance with Union law, limit the fundamental right of free movement on grounds of public health. Any restrictions to the free movement of persons within the [European] Union that are put in place to limit the spread of SARS-CoV-2 should be based on specific and limited public interest grounds, namely the safeguarding of public health as emphasised by [Council] Recommendation (EU) 2020/1475 [of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic (OJ 2020 L 337, p. 3)]. It is necessary for such limitations to be applied in accordance with the general principles of Union law, in particular proportionality and non-discrimination. Any measures taken should therefore be strictly limited in scope and time, in line with the efforts to restore free movement within the Union, and should not extend beyond what is strictly necessary to safeguard public health. ...

...

- (12) To facilitate the exercise of the right to move and reside freely within the territory of the Member States, a common framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) should be established. ...
- (13) Although this Regulation is without prejudice to Member States' competence to impose restrictions to free movement, in accordance with Union law, to limit the spread of SARS-CoV-2, it should contribute to facilitating the gradual lifting of such restrictions in a coordinated manner whenever possible, in accordance with Recommendation (EU) 2020/1475. Such restrictions could be waived in particular for vaccinated persons, in line with the precautionary principle, to the extent that scientific evidence on the effects of COVID-19 vaccination becomes increasingly available and more consistently conclusive with regard to the breaking of the transmission chain.
- (14) This Regulation is intended to facilitate the application of the principles of proportionality and non-discrimination with regard to restrictions to free movement during the COVID-19 pandemic, while pursuing a high level of public health protection. It should not be understood as facilitating or encouraging the adoption of restrictions to free movement, or restrictions to other fundamental rights, in response to the COVID-19 pandemic, given their detrimental effects on Union citizens and businesses. ...

...

- (36) It is necessary to prevent direct or indirect discrimination against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the COVID-19 vaccine is currently administered or allowed, such as children, or because they have not yet had the opportunity or chose not to be vaccinated. Therefore, possession of a vaccination certificate, or the possession of a vaccination certificate indicating a COVID-19 vaccine, should not be a pre-condition for the exercise of the right to free movement or for the use of cross-border passenger transport services such as airlines, trains, coaches or ferries or any other means of transport. In addition, this Regulation cannot be interpreted as establishing a right or obligation to be vaccinated.'

6 Under Article 1 of Regulation 2021/953:

'This Regulation lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. This Regulation shall also contribute to facilitating the gradual lifting of restrictions to free movement put in place by the Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

...'

7 Article 3(1) of that regulation provides:

'The EU Digital COVID Certificate framework shall allow for the issuance, cross-border verification and acceptance of any of the following certificates:

- (a) a certificate confirming that the holder has received a COVID-19 vaccine in the Member State issuing the certificate (vaccination certificate);

...

- (c) a certificate confirming that, following a positive result of a NAAT test carried out by health professionals or by skilled testing personnel the holder has recovered from a SARS-CoV-2 infection (certificate of recovery).

...'

- 8 Article 5 of that regulation states:

'(1) Each Member State shall, automatically or upon request by the persons concerned, issue the vaccination certificates referred to in point (a) of Article 3(1) to persons to whom a COVID-19 vaccine has been administered. Those persons shall be informed of their right to a vaccination certificate.

...'

- 9 Article 7 of that regulation states:

'(1) Each Member State shall issue, upon request, the certificates of recovery referred to in point (c) of Article 3(1).

...'

Italian law

- 10 Article 4 of Decree-Law No 44 – Misure urgenti per il contenimento dell'epidemia da COVID-19, in materia di vaccinazioni anti SARS-CoV-2, di giustizia e di concorsi pubblici (Decree-Law No 44 on urgent measures to combat the COVID-19 pandemic, vaccination against SARS-CoV-2, justice and public aid) of 1 April 2021 (GURI No 79 of 1 April 2021, p. 1), converted by Law no. 76 of 28 May 2021 ('Legislative Decree No 44/2021'), provides, in paragraph 1:

'In view of the epidemiological emergency linked to SARS-CoV-2, in order to protect public health and maintain appropriate conditions of safety in the provision of care and assistance, until the full implementation of the plan referred to in Article 1, paragraph 457, of Law No 178 of 30 December 2020, but in no case later than 31 December 2021, health professionals and public health workers ..., who work in public and private healthcare, assistance and social care establishments, pharmacies, parapharmacies and professional practices must undergo free vaccination to prevent infection by SARS-CoV-2. Vaccination is an essential condition for the exercise of the profession and the performance of professional services by persons subject to the obligation. ...'

- 11 Article 4(2) thereof states that 'only in the case of a proven danger to health, linked to specific pathologies certified by a general practitioner, shall the vaccination referred to in paragraph 1 not be compulsory and may be omitted or deferred'.

- 12 Under the terms of Article 4(6) thereof:

'After expiry of the time limits for certifying compliance with the vaccination requirement ..., the competent local health authority shall record non-compliance with the vaccination requirement and, after obtaining any additional information from the competent authorities, shall immediately

communicate it in writing to the person concerned, to the employer and to the professional body to which the person concerned belongs. Adoption of the report by the local health authority entails suspension of the right to perform services or tasks involving interpersonal contact or involving, in any other form, a risk of spreading the SARS-CoV-2 virus’.

13 Article 4(7) thereof provides that ‘the professional body to which he or she belongs shall immediately inform the person concerned of the suspension referred to in paragraph 6’.

14 Under Article 4(8) of Decree-Law No 44/2021:

‘On receipt of the communication referred to in paragraph 6, the employer shall, as far as possible, assign the worker to tasks, even inferior ones, other than those referred to in paragraph 6, with remuneration corresponding to the duties performed and which, in any event, do not entail any risk of spreading the virus. Where assignment to other duties is not possible, no remuneration or other emoluments of any kind shall be payable during the [suspension]’.

15 Article 4(10) thereof provides that, ‘for the period during which the vaccination referred to in paragraph 1 is omitted or postponed, but in no case beyond 31 December 2021, the employer shall assign the persons referred to in paragraph 2 to tasks, even if they are different, without any reduction in pay, so as to avoid the risk of spreading the SARS-CoV-2 virus’.

16 Article 4(11) thereof provides:

‘For the same period as that referred to in paragraph 10, in order to contain the risk of contagion, in the exercise of the liberal professional activity, the persons referred to in paragraph 2 shall adopt the preventive health and hygiene measures indicated in the specific safety protocol adopted by decree of the Minister for Health, in agreement with the Ministers for Justice and Labour and Social Policies, within twenty days of the date of entry into force of this decree’.

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

17 Since 1 January 2017, D.M. has been employed by the university hospital as a professional nurse in the neurosurgery department.

18 On 16 September 2021, the university hospital informed her that she was being suspended from her duties with immediate effect and without entitlement to remuneration, on the grounds that she had breached the vaccination obligation laid down in Article 4 of Decree-Law No 44/2021 and that it was impossible to assign her to other duties that did not involve a risk of spreading the virus. The suspension was to end on the date on which the vaccination obligation was fulfilled or, failing that, on completion of the vaccination plan, but could under no circumstances be maintained beyond 31 December 2021, although the latter date has been postponed on several occasions.

19 By an application for interim measures lodged on 14 October 2021, D.M. applied to the referring court for her to be reinstated in her department at the university hospital, arguing, in particular, first, that Article 4 of Decree-Law No 44/2021 was contrary, in several respects, to the Italian Constitution and to EU law and, secondly, that she had a natural immunity acquired as a result of having recovered from an infection with SARS-CoV-2.

- 20 The referring court notes that the marketing authorisations for the COVID-19 vaccines are conditional within the meaning of Regulation No 507/2006. According to that court, in the light of new therapeutic advances and new acquisitions in terms of available medicinal products, it is not unreasonable to question the validity, in the light of Article 4 of that regulation, of those authorisations granted by the European Commission after obtaining the opinion of the European Medicines Agency (EMA), having regard in particular to the fundamental rights at stake, namely physical integrity and health, protected in particular by Articles 3 and 35 of the Charter.
- 21 Furthermore, although the parties to the main proceedings have not relied on Regulation 2021/953, the referring court considers that it is nevertheless relevant for the purposes of those proceedings. That court points out that that regulation states, inter alia, that ‘restrictions on freedom of movement of persons relating to the COVID-19 pandemic must be applied in accordance with the general EU law principles of proportionality and non-discrimination’. Particularly problematic in that regard is the fact that Article 4(11) of Decree-Law No 44/2021 allows only healthcare professionals who are exempt from the vaccination requirement to continue to exercise their profession without having been vaccinated, provided that they comply with the safety rules, whereas healthcare staff who are not covered by that provision can no longer exercise their profession, whether as employees or self-employed, even though they are prepared to follow exactly the same safety rules.
- 22 Finally, in the light of the Court’s case-law resulting from the judgment of 14 November 2018, *Memoria and Dall’Antonia* (C-342/17, EU:C:2018:906), the referring court wishes to know whether the compulsory vaccination measure, in the event that the host Member State also intends to impose it on a health professional from another EU Member State who is in the first Member State for professional reasons, is compatible with the principle of proportionality expressly referred to by Regulation 2021/953.
- 23 In those circumstances, the Tribunale ordinario di Padova (District Court, Padua, Italy) decided to stay proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:
- ‘(1) Can the conditional authorisations of the Commission, issued following a favourable opinion of the EMA, for vaccines currently on the market be considered still valid for the purposes of Article 4 of Regulation No 507/2006, in the light of the fact that in several Member States (for example in Italy, AIFA (Agenzia italiana del farmaco; Italian Medicines Agency) approval of the method of treatment with monoclonal and/or antiviral antibodies) effective alternative SARS-CoV-2 treatments have been approved, which, the applicant argues, are less hazardous for human health, and also in the light of Articles 3 and 35 of the [Charter]?’
- (2) In the case of healthcare workers on whom the law of the Member State in question has imposed compulsory vaccination, can vaccines approved by the Commission conditionally within the meaning of Regulation No 507/2006 be used for the purposes of compulsory vaccination even if the healthcare workers in question have already been infected and thus have already acquired natural immunity and can therefore apply for a derogation from the obligation?
- (3) In the case of healthcare workers on whom the law of the Member State in question has imposed compulsory vaccination, can vaccines approved by the Commission conditionally within the meaning of Regulation No 507/2006 be used for the purposes of compulsory vaccination, without any procedure for precautionary purposes, or may those healthcare

workers oppose inoculation, in view of the conditionality of the authorisation, at least until the deciding health authority has ruled out, in the circumstances concerned and with reasonable certainty, that, on the one hand, there are no contraindications to that effect and, on the other, that the benefits to be gained from them outweigh those gained from other medicinal products currently available? In that case, must the deciding health authority act in accordance with Article 41 of the Charter?

- (4) In the case of a vaccine authorised conditionally by the Commission, can a failure by healthcare personnel to comply with the obligation under the law of the State to be vaccinated automatically entail suspension from work without pay or must provision be made for a graduated scale of penalties in accordance with the fundamental principle of proportionality?
- (5) Where national law permits forms of *dépeçage* [attribution of different tasks to a worker], must the possibility of alternative deployment of the worker concerned be examined in accordance with the principle of *audi alteram partem* laid down in Article 41 of the Charter, with a consequent right to compensation in the event of failure to do so?
- (6) Is national legislation, such as that laid down in Article 4(11) of Decree-Law No 44/2021, which allows healthcare personnel who have been declared exempt from the obligation to be vaccinated to carry on their activities in contact with patients, albeit in compliance with the safety measures imposed by the legislation in force, whereas a healthcare worker who, like the applicant – being naturally immune following infection – does not wish to be vaccinated without thorough medical examinations, is automatically suspended from all professional activity and without pay, lawful in the light of Regulation 2021/953, which prohibits any discrimination between those who have taken the vaccine and those who have been unwilling or unable to take it for medical reasons?
- (7) Is legislation of a Member State which provides for a compulsory [COVID-19] vaccine – conditionally authorised by the Commission – for all healthcare personnel, even if they come from another Member State and are in Italy for the purposes of exercising the freedom to provide services and freedom of establishment, compatible with Regulation 2021/953 and with the principles of proportionality and non-discrimination contained therein?

The procedure before the Court

- 24 On 13 December 2021, the referring court requested that the present reference for a preliminary ruling be made under an expedited procedure pursuant to Article 105 of the Rules of Procedure of the Court. In support of that request, that court submitted that, pending the outcome of the reference for a preliminary ruling, D.M. remained suspended and deprived of her remuneration, so that she was deprived of any means of subsistence.
- 25 Article 105(1) of the Rules of Procedure provides that, at the request of the referring court or, exceptionally, of its own motion, the President of the Court may decide, after hearing the Judge-Rapporteur and the Advocate General, to submit a reference for a preliminary ruling to an expedited procedure where the nature of the case requires it to be dealt with within a short time.

- 26 It should be borne in mind that such an accelerated procedure is a procedural instrument intended to respond to a situation of extraordinary urgency (judgment of 16 June 2022, *Port de Bruxelles and Région de Bruxelles-Capitale*, C-229/21, EU:C:2022:471, paragraph 40 and the case-law cited).
- 27 In the present case, on 1 February 2022, the President of the Court decided, after hearing the Judge-Rapporteur and the Advocate General, that there was no need to grant the application referred to in paragraph 24 of the present judgment.
- 28 The referring court did not provide all the information necessary to assess the extent of the risk which the suspension of D.M. represented for her financial subsistence, nor did it set out the reasons why the application of the expedited procedure to the present case made it possible to avoid such a risk, having regard in particular to the in principle limited duration of that suspension. Consequently, those elements do not make it possible to characterise a situation of extraordinary urgency justifying that an expedited procedure be applied to the present case.

Admissibility of the questions referred

The first question

- 29 By its first question, the referring court asks, in essence, whether the conditional marketing authorisations granted for vaccines intended to prevent infection with and the spread of COVID-19 and the severity of the symptoms of that pathology are valid, in the light of Article 4 of Regulation No 507/2006, read in the light of Articles 3 and 35 of the Charter, available at the date of the reference for a preliminary ruling, on the ground that alternative treatments which were effective against COVID-19 and less harmful to health had, at that date, already been approved in several Member States.
- 30 In that regard, it should be borne in mind that, according to the Court's settled case-law, in the context of cooperation between the Court and the national courts, the need to arrive at an interpretation or assessment of the validity of EU law which is of use to the national court requires that the latter comply scrupulously with the requirements concerning the content of a reference for a preliminary ruling and which are set out explicitly in Article 94 of the Rules of Procedure, of which the referring court is deemed to be aware. Those requirements are, moreover, set out in the Court's recommendations to the national courts concerning the bringing of proceedings for a preliminary ruling (OJ 2019 C 380, p. 1) (see, to that effect, judgment of 6 October 2021, *Consorzio Italian Management and Catania Multiservizi*, C-561/19, EU:C:2021:799, paragraph 68 and the case-law cited).
- 31 Thus, it is essential, as set out in Article 94(c) of the Rules of Procedure, that the order for reference contain a statement of the reasons which led the referring court to question the interpretation or validity of certain provisions of EU law, as well as the link which it establishes between those provisions and the national legislation applicable to the main proceedings (judgment of 6 October 2021, *Consorzio Italian Management and Catania Multiservizi*, C-561/19, EU:C:2021:799, paragraph 69 and the case-law cited).

- 32 In the present case, according to the referring court, it is called upon, in the main proceedings, to rule on the validity of the decision of the university hospital to suspend D.M. from her duties without entitlement to remuneration, a decision taken on the ground that she had refused to undergo the compulsory vaccination against COVID-19 provided for in Article 4 of Decree-Law No 44/2021.
- 33 In the first place, even supposing that the ‘therapeutic advances’ and ‘new acquisitions in terms of available medicinal products’ referred to by the referring court are capable of calling into question the validity of the conditional marketing authorisations relating to vaccines intended to prevent infection by and the spread of COVID-19 and the severity of the symptoms of that pathology, it should nevertheless be noted that that court neither specifically identified those authorisations nor addressed their content in the light of the validity requirements deriving from Article 4 of Regulation No 507/2006, where appropriate read in the light of Articles 3 and 35 of the Charter.
- 34 The referring court confined itself to stating its general assessment that, in the light of the developments referred to in the preceding paragraph, it is not ‘unreasonable’ to entertain doubts as to the validity of those authorisations, without going into the specific nature of those doubts in any way whatsoever. The order for reference thus does not enable the Court to identify the authorisations at issue and the precise elements of those authorisations which give rise to those doubts or, consequently, to ascertain in what way those authorisations might, in that court’s view, no longer be valid in the light of the requirements arising from Article 4 of Regulation No 507/2006 or Articles 3 and 35 of the Charter, nor did that court set out in the order for reference the possible impact, in that context, of the latter two provisions.
- 35 In the second place, neither the order for reference nor the documents before the Court make it possible to understand how a challenge to the validity of the conditional authorisations could affect the outcome of the main proceedings, which appears to depend not on the validity of those authorisations but on the legality – contested by D.M. – of the vaccination requirement laid down in Article 4 of Decree-Law No 44/2021 and the penalties which that provision imposes for failure to comply with it.
- 36 In that context, it must be emphasised that, while the grant of such authorisations is a precondition for the right of their holders to place the vaccines concerned on the market in each Member State (see, to that effect, judgment of 16 March 2023, *Commission and Others v Pharmaceutical Works Polpharma*, C-438/21 P to C-440/21 P, EU:C:2023:213, paragraph 81), the issue of those conditional authorisations does not, as such, entail any obligation on the part of the potential recipients of those vaccines to have them administered, particularly since the referring court did not clarify whether persons subject to the obligation to vaccinate laid down in Article 4 of Decree-Law No 44/2021 were obliged to use only the vaccines which were the subject of those conditional authorisations.
- 37 Thus, in the absence of any explanation from the referring court as to why it is questioning the validity of the conditional marketing authorisations and those relating to the possible link between, first, the validity of those authorisations and, secondly, the obligation to vaccinate against COVID-19 laid down in Article 4 of Decree-Law No 44/2021, it must be held that the present reference for a preliminary ruling does not satisfy the requirements set out in paragraph 31 of the present judgment as regards the first question.
- 38 It follows that that question is inadmissible.

The second to fifth questions

- 39 By its second to fifth questions, which must be considered together, the referring court asks, in essence, first, whether Regulation No 507/2006 must be interpreted as precluding the use, for the purposes of satisfying an obligation to vaccinate health professionals against COVID-19 imposed by national legislation, of vaccines which have been the subject of a conditional authorisation granted under Article 4 of that regulation, even in a situation where those professionals have developed immunity to the virus causing that disease and the health authority has not specifically established that there are no contraindications to that vaccination. Secondly, it wishes to ascertain whether the penalty incurred by those professionals in the event of non-compliance with that obligation may, in view of Article 41 of the Charter, consist of suspension from their duties without remuneration rather than a graduated scale of penalties in accordance with the principle of proportionality and the adversarial principle.
- 40 In that regard, it should be emphasised, as a preliminary point, that Article 168(7) TFEU does not lay down any requirement for the Member States concerning the compulsory vaccination of certain categories of persons, since, by virtue of Article 168(7), EU law does not affect the competence of the Member States to adopt provisions to define their health policy. However, in exercising that competence, Member States must comply with EU law (see, by analogy, judgment of 28 April 2022, *Gerencia Regional de Salud de Castilla y León*, C-86/21, EU:C:2022:310, paragraph 18 and the case-law cited, and order of 17 July 2014, *Široká*, C-459/13, EU:C:2014:2120, paragraph 19).
- 41 It appears that the second to fifth questions are based on the premiss according to which Regulation No 507/2006 or the conditional authorisations granted under that regulation are such as to govern, first, the conditions governing the imposition, under domestic law, of an obligation to vaccinate, such as that laid down in Article 4 of Decree-Law No 44/2021, where that law provides for the use for that purpose of vaccines which have been the subject of such conditional authorisation, and, secondly, the consequences which may follow, under that domestic law, from non-compliance with that obligation, including the procedure to be followed for that purpose.
- 42 However, as pointed out in paragraph 36 of the present judgment, the grant of such authorisations does not have the effect of imposing on the potential recipients of the vaccines concerned an obligation to take them. Furthermore, the referring court does not explain, in its order for reference, the link which it establishes between, on the one hand, the content or purpose of those authorisations, granted in accordance with Article 4 of Regulation No 507/2006 and, on the other hand, the arrangement, in its domestic law, of the conditions and procedures for the obligation to vaccinate referred to in its second to fifth questions, as applicable to the dispute in the main proceedings.
- 43 Furthermore, as regards Article 41 of the Charter, which enshrines the right to good administration, invoked by the referring court in its third and fifth questions, it should be borne in mind that that article is addressed not to the Member States but solely to the institutions, bodies, offices and agencies of the European Union and is therefore not relevant to the resolution of the dispute in the main proceedings. By contrast, that article reflects a general principle of EU law which is intended to apply to the Member States when they implement that law (see, to that effect, judgment of 10 February 2022, *Bezirkshauptmannschaft Hartberg-Fürstenfeld (Limitation period)*, C-219/20, EU:C:2022:89, paragraphs 36 and 37).

- 44 In the present case, the referring court has not explained how the general principle of EU law relating to the right to good administration relates to the implementation of the obligation to vaccinate laid down in Article 4 of Decree-Law No 44/2021, in the absence of a finding by that court that the latter provision constitutes an implementation of EU law.
- 45 It follows that the present reference for a preliminary ruling does not, as regards the second to fifth questions, satisfy the requirements set out in Article 94(c) of the Rules of Procedure and noted in paragraph 31 of the present judgment.
- 46 In the light of the foregoing, the second to fifth questions are inadmissible.

The sixth and seventh questions

- 47 By its sixth and seventh questions, which should be examined together, the referring court asks, in essence, whether Regulation 2021/953, read in conjunction with the principles of proportionality and non-discrimination, must be interpreted as precluding national legislation which imposes an obligation on health professionals to be vaccinated against COVID-19, although, first, it allows a category of professionals who are exempt from that requirement on medical grounds to continue to carry on their activities subject to compliance with the precautionary measures provided for by that legislation without, however, giving professionals who do not wish to be vaccinated the same opportunity, and, secondly, it is also capable of applying to nationals of other Member States carrying on a professional activity in Italy.
- 48 It should be noted at the outset that the referring court does not identify, either in the wording of its questions or, more generally, in the order for reference itself, the provisions of Regulation 2021/953 whose interpretation it is seeking. It refers only to the principles of proportionality and non-discrimination ‘that [that regulation] provides’ and to recital 6 of that regulation in so far as it specifies that ‘it is necessary for [limitations on the free movement of persons] to be applied in accordance with the general principles of Union law, in particular proportionality and non-discrimination’.
- 49 In that regard, first, even though the recitals form an integral part of the regulation concerned, setting out the objectives which it pursues, they are not in themselves binding (see, to that effect, judgment of 24 February 2022, *Glavna direktsia ‘Pozharna bezopasnost i zashtita na naselenieto’*, C-262/20, EU:C:2022:117, paragraph 34). The reference to recital 6 of Regulation 2021/953 cannot therefore, in itself, suffice to establish the connecting link between that regulation and the national legislation applicable to the dispute in the main proceedings.
- 50 Secondly, as regards the principles of proportionality and non-discrimination invoked by the referring court, it should be noted that it follows from recitals 12 to 14 of Regulation 2021/953 and from Article 1 thereof that, if that regulation seeks to implement those principles, it is with the aim of facilitating the exercise of the right to free movement by the holders of that right by establishing a framework for the issue, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates.
- 51 Thus, in application of those principles, that regulation is not intended, in particular, to define criteria for assessing the appropriateness of the health measures adopted by the Member States to deal with the COVID-19 pandemic where those measures are of such a kind as to restrict freedom of movement, such as the obligation to vaccinate laid down in Article 4 of Decree-Law

No 44/2021 at issue in the main proceedings, or to facilitate or encourage their adoption, since recital 36 of that regulation states that it ‘cannot be interpreted as establishing a right or obligation to be vaccinated’.

- 52 Consequently, neither the details contained in the order for reference nor, moreover, the other information in the case file before the Court make it possible to determine with any accuracy the provisions of Regulation 2021/953, read in conjunction with the principles of proportionality and non-discrimination, the interpretation of which is sought and which are necessary for the resolution of the dispute in the main proceedings.
- 53 It follows that the present reference for a preliminary ruling does not, as regards the sixth and seventh questions, satisfy the requirements set out in Article 94(c) of the Rules of Procedure and noted in paragraph 31 of the present judgment.
- 54 It should be added that, in any event, there must be a connecting link between the dispute in the main proceedings and the provisions of EU law whose interpretation is sought, such that that interpretation meets an objective need for the decision which the referring court is required to give (judgment of 26 March 2020, *Miasto Łowicz and Prokurator Generalny*, C-558/18 and C-563/18, EU:C:2020:234, paragraph 48).
- 55 The dispute in the main proceedings concerns D.M.’s request, based on the allegedly unlawful nature of the vaccination requirement laid down in Article 4 of Decree-Law No 44/2021, for reinstatement in the neurosurgery department of the university hospital. That dispute does not therefore concern the application of the provisions of Regulation 2021/953, in particular Article 5(1) thereof, which confers on vaccinated persons the right to be issued with a vaccination certificate, or Article 7(1) thereof, which confers on persons who have recovered from an infection with SARS-CoV-2 the right to be issued with a certificate of recovery.
- 56 As regards the possibility, raised by the referring court, that the vaccination requirement laid down in Article 4 of Decree-Law No 44/2021 might also apply to persons who have exercised their right to freedom of movement, it must be observed, first, that the referring court did not state that the dispute pending before it concerned a cross-border situation, since the university hospital indicated that D.M. is not a national of another Member State who had come to Italy to work.
- 57 Secondly, the referring court has not explained why such a possibility would be relevant for the purposes of applying Regulation 2021/953 in the circumstances of the main proceedings.
- 58 Thirdly, if, by its reference to the judgment of 14 November 2018, *Memoria and Dall’Antonia* (C-342/17, EU:C:2018:906), that court wished to state that national law requires it, as regards the right to freedom of establishment and the right to freedom to provide services under Articles 49 and 56 TFEU, to give D.M. the same rights as those enjoyed, under EU law, by nationals of other Member States in the same situation, it should be borne in mind that the sixth and seventh questions concern the interpretation of Regulation 2021/953 and not, as the Italian Government also emphasised at the hearing, the interpretation of those fundamental freedoms.
- 59 In any event, the Court cannot consider, without any indication from the referring court other than the fact that the national legislation at issue is applicable without distinction to nationals of the Member State concerned and to nationals of other Member States, that an interpretation of

the provisions of the TFEU relating to fundamental freedoms is necessary for it to resolve the dispute pending before it (see, to that effect, judgment of 15 November 2016, *Ullens de Schooten*, C-268/15, EU:C:2016:874, paragraph 54).

- 60 In those circumstances, it is not apparent from the order for reference that there is a connecting link within the meaning of paragraph 54 of the present judgment between Regulation 2021/953 and the dispute in the main proceedings.
- 61 In the light of the foregoing considerations, the sixth and seventh questions are inadmissible.
- 62 It follows from all the foregoing that the reference for a preliminary ruling made by the referring court is inadmissible.

Costs

- 63 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring 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 (Second Chamber) hereby rules:

The reference for a preliminary ruling made by the Tribunale ordinario di Padova (District Court, Padua, Italy) by decision of 7 December 2021 is inadmissible.

[Signatures]