JUDGMENT No 14 YEAR 2023

In this case, the Court considered various questions referred by the Council of Administrative Justice of Sicily Region concerning rules applicable in relation to vaccination against COVID-19. The referring court questioned the constitutionality of the requirement of mandatory vaccination for healthcare workers, as well as provisions requiring the suspension of the right to practise the medical profession in the event of non-compliance. It also objected that the legislation did not expressly dispense with the requirement to obtain signed, informed consent in situations involving compulsory medical treatment and mandatory vaccination. Citing the previous case law of the Constitutional Court, the referring court objected that the adverse effects caused by the vaccines were not "normal and tolerable", and indeed were "higher by several orders of magnitude" than adverse events associated with previous vaccines. It also objected that no provision was made for pre-vaccination triage, which – by its assertion – would identify persons at risk of adverse reactions.

The Court rejected the questions, holding that the risk of a serious adverse event does not in itself render unconstitutional the requirement of mandatory vaccination and that Article 32 of the Constitution requires that a balance be struck between the individual right to health and overall public health in accordance with the principle of solidarity. Moreover, in keeping with its existing case law, the Court reiterated that medical treatments – including mandatory vaccination – that may entail a risk of undesirable consequences, detrimental beyond normally tolerable limits, must be deemed to be lawful if their goal is to protect public health. The balance that the legislator must strike between individual health and public health is a discretionary one, although it must be based on scientific evidence. The Court may review whether the legislation is reasonable and proportionate and is consistent with the underlying scientific facts. After reviewing the scientific basis, the Court held in this case that the scientific authorities all attest that vaccines against SARS-CoV-2 are safe and effective. It also upheld the legislation as reasonable and proportionate, as it was necessary and appropriate to achieve legitimately pursued objectives, and that the consequences were nuanced as regards their duration and severity. Finally, the Court held that no issue of informed consent was raised in this case, as individuals were free to choose whether or not to comply with the requirement, although in the latter eventuality they would have to accept in a responsible manner the consequences provided for by law.

[omitted]

THE CONSTITUTIONAL COURT

[omitted]

gives the following

JUDGMENT

[omitted]

The facts of the case

[omitted]

Conclusions on points of law

1.– By a referral order of 22 March 2022, registered as No 38 of the 2022 Register of Referral Orders, the Council of Administrative Justice of Sicily Region (*Consiglio di giustizia amministrativa per la Regione Siciliana*) raised questions concerning the

constitutionality of Article 4(1) and (2) of Decree-Law No 44 of 2021, as converted into law, with reference to Articles 3, 4, 32, 33, 34 and 97 of the Constitution, insofar as it provides, on the one hand, for mandatory vaccination against SARS-CoV-2 for healthcare workers, and, on the other hand, for the suspension of the right to practise the medical profession in the event that this requirement is not complied with.

The Council of Administrative Justice also raised questions concerning the constitutionality of Article 1 of Law No 219/2017 and Article 4 of Decree-Law No 44/2021, as converted into law, with reference to Articles 3 and 21 of the Constitution, insofar as those provisions do not expressly dispense with the requirement to obtain signed, informed consent in situations involving, respectively, compulsory medical treatment and mandatory vaccination.

2.– As a preliminary matter, it must be confirmed that the interventions *ad adiuvandum* filed within these proceedings are inadmissible for the reasons mentioned in the order read out at the hearing of 30 November 2022, which is annexed to this judgment.

Moreover, it cannot be argued, as some of the interveners seek to do, that an inadmissible intervention can be somehow converted into a statement of opinion by an *amicus curiae*, albeit "on a subordinate basis". The significant differences between the two institutes, as regards both the applicable prerequisites and the procedural arrangements, do not enable them to apply simultaneously to the same act, on an alternative or subordinate basis.

3.– When setting out the first class of questions of constitutionality, which concern the requirement of mandatory vaccination against SARS-CoV-2 for healthcare workers, associated with suspension of the right to practise the medical profession in the event that this requirement is not complied with, the referring court starts by examining the case law of this Court on mandatory vaccination. It notes that, for the purposes of Article 32 of the Constitution, compulsory medical treatment ordered by law is admissible subject to the following preconditions: a) if the treatment is intended not only to improve or safeguard the health of the person who receives it, but also to preserve the health of others; b) if it is anticipated that it will not have any adverse effects on the health of the person who is obliged to receive it, except exclusively such consequences "that appear to be normal and hence tolerable"; and c) if, in the event of any further harm, provision is made under all circumstances for the payment of fair compensation to the injured party, irrespective of any parallel compensatory relief (*inter alia* Judgments No 258/1994 and No 307/1990).

The referring court acknowledges that it is engaging "with principles asserted by the Court concerning […] situations that are so to speak ordinary, and that no precedents deal with emergency situations brought about by a serious pandemic". Rejecting the objections made by the appellant, it agrees as a matter of fact and in the light of the investigation ordered within the main proceedings that the methodology used for counting deaths and the related official mortality figures, as well as the seriousness of the disease SARS-CoV-2, cannot be disputed; it endorses the conclusion reached following its investigation that vaccines against SARS-CoV-2 are not experimental, having been granted conditional marketing authorisation.

3.1.– Turning now to the substance of the challenges, whilst recognising that preconditions a) and c) above as elaborated within the constitutional case law referred to have been met, the referring court takes the view that insuperable critical issues apply in relation to precondition b) as regards the consequences for the health of a person who is obliged to take the vaccine that extend beyond normal tolerability (known as "adverse events").

Starting from the consideration that, based on the most recent data, it is apparent that the number of adverse events associated with vaccines against SARS-CoV-2 is higher than the "average number […] of adverse events previously recorded for mandatory vaccinations that have been in use for years" and moreover "that it is higher by several orders of magnitude", the referring court considers that it is necessary to "review the case law previously adopted on the basis of data that have in the meantime been superseded", in the sense that the vaccine purportedly has a negative effect on the health of a person who is obliged to undergo vaccination in excess of consequences "that appear to be normal and hence tolerable".

The Council of Administrative Justice voices doubts in this regard "concerning the adequacy of the monitoring system operated until now", which as things currently stand is limited merely to passive pharmacovigilance, and objects that adverse events associated with vaccination against SARS-CoV-2 have been underestimated (and in any case that their scale is uncertain). It then goes on to assert, as will be discussed in greater detail below, that constitutional case law contains a line of judgments that negate "the legitimacy of mandatory vaccination using preparations where the effects on the health of persons receiving the vaccine exceed the threshold of normal tolerability, which does not appear to leave scope for the acceptance of serious and fatal adverse events".

3.2.– Finally, the referring court objects that pre-vaccination triage is inadequate.

Whilst acknowledging that mass screening would be logistically and financially unsustainable within the context of mass vaccination, the referring court essentially took account of three aspects in reaching that conclusion: 1) the failure to involve family doctors – who normally have in-depth knowledge of their patients – within pre-vaccination triage, which is left to the healthcare workers who administer the vaccination; these healthcare workers must in turn rely on the ability (which will inevitably vary) of individuals presenting for vaccination to describe relevant facts and circumstances concerning their general health (within the limited period of time available for this); 2) the failure to require the presentation of laboratory examinations, as diagnostic procedures to be carried out prior to vaccination, or tests (including genetic tests) with a view to excluding from vaccination or subjecting to appropriate pharmacological treatment prior to vaccination those persons who feature specific risk profiles; 3) the failure to provide for SARS-CoV-2 testing in order to identify any infection in progress which – according to the referring court – would render the administration of the vaccine inadvisable, taking account of the risk of an anomalous response from the immune system.

4.– In view of the above, it is first necessary to examine the objections raised by the President of the Council of Ministers concerning the admissibility of the first group of questions.

4.1.– The objection of *aberratio ictus* is unfounded.

The State Counsel (*Avvocatura generale dello Stato*) asserts first and foremost that the provisions objected to when referring the questions were incorrectly identified. This is because Article 4 of Decree-Law No 44/2021, as converted into law, is contested with regard to paragraphs 1 and 2 only insofar as – according to the referring court – it provides, on the one hand, for mandatory vaccination for healthcare workers "and, on the other hand, for the suspension of the right to practise the medical profession in the event that the requirement of mandatory vaccination is not complied with". In actual fact, the suspension of the right to practise the medical profession is provided for – so it is argued – as a consequence of the breach of the requirement of mandatory vaccination under paragraph 4 (or rather, within the version objected to by the referring court, which

is applicable *ratione temporis*, paragraph 6, which was renumbered as paragraph 4 within the later version as applicable following the amendments made to Article 4 by Decree-Law No 172/2021, as converted into law), although this provision is not otherwise objected to within the referral order.

This argument cannot be endorsed since the violation objected to by the referring court – which was identified as consisting in the requirement of mandatory vaccination, as is clearly apparent from the reasons provided and the manner in which the question of constitutionality is framed – is a direct result of the contested provisions. Indeed, paragraph 1 expressly provides that vaccination against SARS-CoV-2 is an "essential prerequisite for the practice of the profession and for the performance of work by obliged persons". The remaining paragraphs of Article 4 are limited to regulating operational arrangements for establishing instances of non-compliance, and finally provide that the "making of a finding [concerning non-compliance] by the local health authority will result in the suspension of the right to perform certain duties or tasks involving interpersonal contact or that otherwise entail any risk of the spread of SARS-CoV-2" (paragraph 6) as well as the operational consequences, that is stipulating the consequences, i.e. suspension and not for example the termination of the employment relationship.

The objection must therefore be rejected.

4.2.– On the other hand, the objection that certain questions are inadmissible due to the absolute failure to provide reasons with reference to Articles 3, 4, 33 and 34 of the Constitution must be accepted.

This shortcoming can be identified in relation to all provisions other than Article 32 of the Constitution.

Specifically, they are invoked exclusively in section 19.b.6) of the referral order, where the Council of Administrative Justice of Sicily Region however does nothing more than mention the Articles and state the rights granted by them, whilst referring to all of the reasons "set out above". These reasons are those illustrated in section 18 of the referral order, which however exclusively concern the review of the constitutionality of the requirement of mandatory vaccination for healthcare professionals and healthcare sector workers under Article 1(2) of Law No 43 of 1 February 2006 (Provisions on the nursing, obstetric, rehabilitation, healthcare support and preventive medicine healthcare professions and delegation of authority to the Government to establish their respective professional regulatory bodies), with reference (exclusively) to Article 32 of the Constitution, having regard to the constitutional case law concerning this provision.

Accordingly, the challenges relating to provisions other than Article 32 of the Constitution must be declared manifestly inadmissible due to the failure to state reasons.

4.3.– Other grounds for inadmissibility averred by the State Council concern the merits of the questions raised and must therefore be examined in that part of the judgment.

The State Counsel asserts first of all that – when assessing the part of this Court's Judgment No 307/1990 that refers to "precautions or conduct in the manner that current scientific knowledge and the state of the art prescribe as regards its nature" – the referring court "mistakenly elevated to status as a prerequisite for the constitutionality of the law imposing the requirement of mandatory vaccination certain aspects that are legally relevant on a different level", i.e. the consideration of the prerequisites for compensatory relief. However, these aspects are not relevant for the issue of admissibility.

Similarly, the objection that the questions are inadmissible due to the failure to object to the general provisions governing the system of pharmacovigilance, and the

specific system of vaccination, must also be rejected insofar as irrelevant for the issue of admissibility.

Indeed, the doubts and critical issues raised by the referring court as regards the system for pharmacovigilance and the system for collecting data concerning the consequences of vaccination amount to nothing more than arguments provided in support of the objections, whereas the only provision the constitutionality of which is questioned is that requiring mandatory vaccination (along with the attendant suspension of the right to practise the medical profession). The contested provision is the provision imposing mandatory vaccination, which has been correctly identified.

4.4.− There are no doubts concerning the jurisdiction of the administrative courts as the measure challenged within the proceedings before the referring court was a decision taken by the Rector and the Director General of the University of Palermo to render the continuation of medical and healthcare traineeships within healthcare facilities conditional upon taking the COVID-19 vaccine.

5.– On the merits, in order to consider the first question raised with reference to Article 32 of the Constitution, it is necessary to start by considering the criteria (recalled by the referring court) in the light of which this Court has assessed the compatibility with Article 32 of the Constitution of a law providing for compulsory medical treatment.

These criteria, which were previously listed in Judgment No 258/1994, are the following: "a) 'whether the treatment is intended not only to improve or safeguard the health of the person who receives it, but also to preserve the health of others, with the result that it is precisely this additional purpose pertaining to the interest of society at large that justifies the interference with each individual's self-determination, which is inherent to each person's right to health as a fundamental right' (cf. Judgment No 307/1990); b) whether there is any 'stipulation that the treatment must not adversely affect the health of the person who receives it, except exclusively those consequences that, on account of their ephemeral nature and low level of severity, are a normal feature of any medical treatment, and hence tolerable" (ibid.); c) whether in the event of any further harm to the health of the person receiving compulsory treatment – including any infectious disease contracted as a result of prophylactic vaccination – provision has been made under all circumstances for 'fair compensation' to the injured party (cf. Judgment 307 cited above, and now Law No 210/1992)". Based on an overall reading of the criteria set out above, it is apparent that the risk of the occurrence of an adverse event, including a serious adverse event, does not in itself render unconstitutional the requirement of mandatory vaccination, as such an outcome establishes grounds for eligibility for compensation.

This Court has clearly asserted that Article 32 of the Constitution requires that a balance be struck between the individual's right to health (including in its negative manifestation of the right not to be subject to medical treatment that has not been requested or that is not accepted) and the parallel right of other people, and hence the interest of the public at large (Judgments No 5/2018, No 258/1994 and No 307/1990).

As was effectively held in Judgment No 218/1994, the protection of health also implies a "duty for individuals to refrain from harming or putting at risk the health of other people through their own actions, in accordance with the general principle that the right of each person is subject to a limit consisting in reciprocal recognition of and equal protection for the parallel rights of others. These equivalent rights vested in all individuals are further balanced against the essential interests of the community. These interests may require certain individuals to be subjected to compulsory medical treatment, which may also be administered in the interest of individuals themselves, or

may provide for their subjection to particular obligations".

5.1.– As part of this balancing of the right to health between two juxtaposed poles – the individual and the collective – a requirement of compulsory medical treatment may be justified by the principle of solidarity, which constitutes "the basis for social cohabitation, as envisaged under the framework of rules adopted by the Constituent Assembly" (Judgment No 75/1992).

According to the settled case law of the Constitutional Court, this principle is of central importance, above all within the field of healthcare, on account of the "constitutional significance of health as an interest of society at large" (Judgment No 307/1990): "each individual may be obliged to undergo specific medical treatment, even if it entails a specific risk, in the name of this interest and hence of solidarity towards other people, thereby legitimately being subjected to a restriction on their self-determination" (see again Judgment No 307/1990, referred to also by Judgment No 107/2012).

5.2.– With regard to this last aspect, this Court has always based its reasoning on an awareness that there is a risk of adverse events, including serious adverse events, following vaccination or indeed any medical treatment (Judgments No 268/2017, No 118/1996 and No 307/1990). It has therefore held that, until the development of medical science and technology enables this risk to be eliminated entirely, the decision to impose any particular medical treatment falls within the discretion of the legislator, which must be exercised in a manner that is not unreasonable (Judgment No 118/1996).

It has in fact been held that, "since that risk cannot always be avoided, the individual and collective dimensions come into conflict" (Judgment No 118/1996). The risk is "preventable in abstract terms – as it has been statistically identified – although in concrete terms it is not possible to predict which people will be affected by the harmful event. Under these circumstances, the law imposing a requirement of mandatory vaccination […] specifically strikes a balance between the collective and individual interests at stake, up to the limit of what have been referred to as the 'tragic choices' of the law […]" (Judgment No 118/1996).

Moreover, that awareness constitutes the basis for this Court's settled position concerning the absolute right to compensation, which must be available also in relation to recommended vaccinations (see, amongst many, Judgments No 118/2020 and No 268/2017).

5.3.– In the light of the above, it should be pointed out first and foremost that the main argument made by the referring court cannot be accepted.

As mentioned above, the referring court states as follows in the referral order: "[i]t is a settled fact that adverse reactions account for a very small share of the overall adverse events reported; however, the criterion applied by the Constitutional Court to compulsory medical treatment does not appear to leave any scope for quantitative assessment. As such, a requirement of mandatory vaccination involving preparations whose effects on the health of vaccinated persons exceed the threshold of normal tolerability cannot be constitutional. This does not appear to leave any scope for the acceptance of serious or fatal adverse events, even if they are small in number when compared to the vaccinated population, and this criterion would engage delicate ethical issues (for example, who should be responsible for establishing what percentage of citizens were 'expendable'). It therefore appears that, since the possibility of adverse reactions to any type of drug can never be excluded as a general matter, in the light of the criteria set forth in the constitutional case law referred to, the discriminating consideration must be the occurrence of fortuitous events and unforeseeable individual reactions. However, in the case at hand, an examination of data published on the

EudraVigilance website, broken down according to the reporting country, indicates some level of homogeneity in terms of the types of adverse events reported by the various countries (leaving aside the differences in data quantity, which were noted by the expert witnesses for the appellant), which leaves little space for the possibility of fortuitous events/unforeseeable reactions" (section 18.4. of the referral order).

This part of the argument is in actual fact open to some degree of interpretative uncertainty. This is because it is not clearly apparent whether the referring court is arguing that the compulsory medical treatment is unconstitutional simply due to the possibility that adverse events may occur, which would be "intolerable" as such, or that – mindful of the difficulty in "excluding the possibility of adverse reactions to any type of drug" – the only "tolerable" adverse reactions are those attributable to fortuitous events and unforeseeable individual reactions.

However, leaving aside this uncertainty, it must be pointed out that the referring court appears to overlook the fact that the constitutional case law has clearly asserted (on the basis of the criteria referred to above) that the remote disk of adverse events, which may in some cases be serious, cannot as such be deemed to be intolerable, but rather − as mentioned above − establishes grounds for compensation. The referring court's interpretation of the case law of this Court cannot therefore be accepted. The Court has in fact held that medical treatments – including mandatory vaccination – that may entail a risk of "undesirable consequences, detrimental beyond normally tolerable limits" (Judgment No 118/1996), must be deemed to be lawful if their goal is to protect public health (Judgment No 118/1996).

The assertion that adverse reactions are tolerable (exclusively) "in situations involving fortuitous events and unforeseeable individual reactions" also lacks any basis in the case law of this Court. Taking this as its starting point, the referring court concludes that these scenarios do not obtain for the vaccines under examination, owing to "a certain degree of homogeneity in the types of adverse event reported by the various countries". However – leaving aside the fact that this last conclusion is simply asserted, without providing any data in support – when examining laws that have provided for mandatory vaccination, this Court has never created any "filter" of this sort. On the contrary, it has in all instances followed scientific data on vaccine safety, within which it is not in itself homogeneity in terms of the type of adverse event that is relevant, but rather their incidence at general level, taking account also of their severity.

Besides, the possibility that an adverse event might occur is specifically the reason for providing for compensation which, in contrast to compensation for losses due to fault, is also available in the event of a risk that is unforeseeable in terms of the specific person affected (Judgments No 5/2018, No 268/2017, No 107/2012, No 118/1996 and No 307/1990).

It must therefore be reiterated that this conclusion is not affected by the possible identification of the risk of an adverse event, even if this adverse event is serious. As recalled above, this Court has always based its reasoning on an awareness that there is an unavoidable risk of adverse events, including serious adverse events, following vaccination or indeed any medical treatment (Judgments No 5/2018, No 268/2017, No 118/1996 and No 307/1990).

6.– In view of the above, in order to answer the question referred to this Court it is first necessary to frame it correctly, and in particular to establish how the Constitution deals with scenarios in which the two dimensions to health contemplated under Article 32 of the Constitution – namely individual health and public health – enter into conflict.

As mentioned above, where the conflict between the two dimensions may even result in a scenario in which "the pursuit of the interest of public health through the

provision of medical treatment such as mandatory vaccination interferes with the individual right to health, where such treatment entails undesired, adverse consequences beyond the limit of those that should normally be tolerated for those obliged to receive it" (Judgment No 118/1996). It has been expressly held that "[s]uch treatment is lawful, by virtue of the express provision of Article 32(2) of the Constitution, which subjects it to a reservation to primary legislation, which is qualified by a requirement to respect the integrity of each individual and was fleshed out further by this Court in Judgment No 258/1994, which held that the legislator must take all possible precautions in order to avoid the risk of complications. However, since that risk cannot always be avoided, the individual and collective dimensions come into conflict" (again, Judgment No 118/1996).

In the event of an insurmountable conflict, Judgment No 118/1996 held that the law imposing a requirement of mandatory vaccination – as recalled above – "specifically strikes a balance between the collective and individual interests at stake, up to the limit of what have been referred to as the 'tragic choices' of the law: these are choices that a society considers must be made in order to achieve a positive outcome (in our case, the elimination of polio) that however entails the risk of a negative outcome (in our case, the albeit extremely rare infection suffered by some people who receive the vaccine). The tragic aspect lies in the fact that suffering and benefit are not shared equally among all people but are respectively borne or enjoyed entirely by some and not by others. Unless and until every risk of any complication has been entirely eliminated through developments in science and medical technology […], the decision as to whether to require mandatory vaccination will entail this type of public choice".

It is undeniable that this (potential) conflict between the right to health of the individual and the right to collective health has become a highly topical one following the outbreak of "a healthcare emergency with highly specific features" (Judgment No 37/2021). On 30 January 2020, the World Health Organization declared the COVID-19 epidemic a Public Health Emergency of International Concern; subsequently, in view of the extent of its spread and seriousness at global level, it classified it as a "pandemic" on 11 March 2020. For its part, a resolution adopted by the Council of Ministers on 31 January 2020 declared a state of emergency throughout the country for a period of six months with regard to the risk to health associated with the contraction of diseases caused by transmissible viral agents. The state of emergency was subsequently extended on several occasions until it was brought to an end by Decree-Law No 24 of 24 March 2022 (Urgent measures concerning the cessation of measures to combat the spread of the COVID-19 epidemic, as a consequence of the cessation of the state of emergency), converted with amendments into Law No 52 of 19 May 2022.

It falls to this Court to assess whether, when confronted with the conflict ascertained, the legislator exercised its discretion in accordance with Article 32 of the Constitution, i.e. striking a balance between the dimensions to the right to health referred to above in a manner that was not unreasonable or disproportionate having regard to the goals pursued. In other words, this Court must assess whether, under those given circumstances, the decision made by the legislator when exercising its political discretion was compatible with constitutional principles.

Accordingly, since this review pertains to choices made by the legislator, it must feature two core elements: first an assessment of the factual situation (i.e. in this case the pandemic) and secondly appropriate consideration of the scientific data available concerning vaccine efficacy and safety.

7.– As regards the factual situation, it should be pointed out that the specific characteristics of the epidemiological conditions prevailing at the time mandatory

vaccination was introduced – i.e. their severity and the unpredictable nature of epidemiological developments (as is proven by the World Health Organization's declaration of 11 March 2020, mentioned above) – entail several consequences.

First and foremost, the parallel existence of rights and duties – which underpins our Constitution's rooting in solidarity as a general matter during ordinary times – has a tangible manifestation in terms of the right to health under Article 32 of the Constitution: this provision applies to the two dimensions of the "fundamental right of the individual" and the "interest of society at large" and expressly requires that a balance be struck between them. The interest of society at large provided for in Article 32 of the Constitution is a manifestation, within the scope of the right to health, of the duties of solidarity laid down by Article 2 of the Constitution. It follows that, whenever the two dimensions come into conflict, according to the case law referred to above the individual right to health may be limited in the name of the interest of society at large, affording consideration to the (individual) rights of others in the name of the "horizontal" solidarity that ties together each member of the community to their fellow citizens (Judgment No 288/2019). The inderogable duties incumbent upon each person are in actual fact imposed as a safeguard and guarantee for the rights of others, which mirror each individual's own rights: it falls to the legislator to strike a balance between these individual rights, and to this Court to ensure that the balance has been properly struck.

On the other hand, it should be considered more generally that the review to ensure that the choice made by the legislator to encroach upon the fundamental right to health was not unreasonable, including with reference to the issue of self-determination, must be carried out having regard to the specific ongoing medical and epidemiological situation. The case law of the Constitutional Court has clarified that, in the event of a conflict between the rights contemplated under Article 32 of the Constitution, legislative discretion "must be exercised in light of the various health and epidemiological conditions, as ascertained by the responsible authorities (Judgment No 268/2017)" (Judgment No 5/2018).

8.– It should be added – as mentioned above – that this discretion must be exercised by the legislator in the light "of constantly changing progress in medical research, which must guide the legislator when making its choices in this area (according to the settled case law of this Court since the leading Judgment No 282/2002)" (Judgment No 5/2018).

Specifically, any intervention in these areas "cannot result from decisions made by the legislator on the basis of pure political discretion but must rather provide for the consideration of approaches based on a review of the state of scientific knowledge and experimental evidence acquired by institutions and bodies – normally national or supranational – charged with obtaining such knowledge and evidence, given the 'essential significance' that 'technical-scientific bodies' take on in this regard (cf. Judgment No 185/1998); alternatively, it should in any case constitute the result of such a review" (Judgment No 282/2002). Therefore, this operation still amounts to an exercise of political discretion, albeit based (of necessity) on scientific evidence.

8.1.– It must not be forgotten that the medical-scientific nature of the elements upon which the legislator must base its choices does not render them immune to review by this Court (Judgment No 282/2002). However, in such cases, the review will concern the consistency of the legislation with the scientific data underlying the provision, whilst also verifying that the legislation is not unreasonable or disproportionate.

8.2.− This Court considers first and foremost whether, when exercising its legislative discretion, the legislator remained within the bounds of scientific credibility,

having regard to the state of the art at the given moment in time, as defined by the competent medical and scientific authorities.

As such, the Court can and must verify, first of all, whether or not the choice made by the legislator to impose mandatory vaccination against SARS-CoV-2 for healthcare professionals and healthcare sector workers under Article 1(2) of Law No 43/2006, in the light also of the prevailing circumstances in relation to the pandemic, was supported by, and whether or not it was consistent with, medical and scientific knowledge available at the relevant moment in time (Judgment No 5/2018), as identified by the national and supranational bodies competent in this field.

As has already been asserted by this Court, when making this choice "the timely nature of the response to the development of the epidemiological curve is decisive in ensuring its efficacy" (Judgment No 37/2021). A timely choice must necessarily be made on the basis of scientific knowledge at the relevant point in time, and in an awareness that it is inherently provisional. Moreover, whenever a decision entails technical and scientific assessments, the legislator chooses between the possible options offered to it by science at that point in time. This choice is one among various possible options – the respective intensities of which inevitably differ, and which hence entail differing levels of restrictions on rights – and amounts to an exercise of political discretion which, within the bounds of its reasonableness and proportionality, cannot be replaced by a different choice imposed by this Court.

On the other hand, it cannot be denied that any law drafted on the basis of medical and scientific knowledge is by its very nature transitory, having been adopted on the basis of knowledge at the time of its enactment and being destined to become obsolete in the wake of medical and scientific developments.

However, it is precisely because the legislator must exercise its own discretion on the basis of medical and scientific knowledge provided by sectoral authorities at the time the decision is made that it is fundamentally important to give full consideration to the "evolutionary dynamic inherent to medical and scientific knowledge, which must underpin legislative choices in relation to medical matters" (Judgment No 5/2018). As this Court has clarified in the past, if any action taken was not unreasonable in the light of the epidemiological conditions and scientific knowledge prevailing at the relevant point in time, this does not mean that the choice may not (and should not) be reassessed and reconsidered in the event of a change in circumstances: indeed, such reconsideration is mandatory.

Accordingly, the rules may and must change in line with the developing health situation as well as scientific knowledge accumulated.

When assessing the constitutionality of the legislation, consideration must be given to the fact that the legislation was, at the outset, inherently transitory. It is also important to take account of the incorporation of flexibility and provision for monitoring, which enabled measures to be adapted in line with a changing factual situation (Judgment No 5/2018).

Regarding this matter, it should be pointed out at this stage that Article 4 of Decree-Law No 44/2021, as converted into law, has been amended on several occasions over time in terms of both the legal consequences associated with the failure to comply with the requirement of mandatory vaccination as well as, above all, the stipulation as to the duration of the requirement.

Indeed, the overall body of rules concerning the handling of the pandemic has been continuously modified in response to changes in the health situation and in medical knowledge. It is sufficient to consider the restrictions imposed on freedom of movement, the right to an education, the exercise of business activity and the

performance of work, which have been amended over time and ultimately revoked, in each instance on the basis of changes in the epidemiological and health situation as well as improvements in the tools offered by medical science to deal with this situation.

In particular, insofar as is of most interest for the purposes of this judgment, the contested provision as originally enacted (and to which the question of constitutionality relates) stipulated a precise expiry date of 31 December 2021 for the requirement of mandatory vaccination. That deadline was altered on various occasions, taking account specifically of infection trends and the evolution of the pandemic, and was subjected to various extensions until 31 December 2022, until it was finally brought forward from 31 December 2022 to 1 November 2022.

This deadline was brought forward by Decree-Law No 162/2022, as converted into law, in consideration (as stated in its preamble) "of changes in the epidemiological situation that has seen a reduction in the levels of infection with COVID-19 and a stabilisation in transmissibility, albeit still higher than the threshold for an epidemic, [and also in consideration of the] need to embark upon a progressive return to normality during the current post-pandemic phase, in which the objective to be pursued is effective control of the endemic virus".

It should be added, as specifically regards the system for monitoring reactions to vaccination against SARS-CoV-2, that, on the one hand, specific systems for monitoring epidemiological trends have been put in place by the Ministry of Health (under the terms of the Decree of the President of the Council of Ministers of 26 April 2020 laying down "Further provisions implementing Decree-Law No 6 of 23 February 2020 laying down urgent measures for the containment and handling of the COVID-19 epidemiological emergency, applicable throughout the national territory", which include in particular the Decree of the Minister of Health of 30 April 2020 on the "Adoption of criteria for the monitoring of medical risk in accordance with Schedule 10 to the Decree of the President of the Council of Ministers of 26 April 2020"), and, on the other hand, that the respective oversight has been conducted by the Italian Medicines Agency (*Agenzia Italiana del Farmaco* – AIFA) at quarterly intervals, the results of which are incorporated into reports featuring all data concerning reactions caused by the administration of vaccines.

9.– Thus, in view of the considerations set out above regarding the constant updating of the legislation under examination in line with changes in the epidemiological and medical situation as well as evolving medical and scientific knowledge, it is now appropriate to carry out an analysis – albeit in summary terms – of that knowledge.

Indeed, as mentioned above, the review that this Court must perform involves verifying whether – using the medical and scientific data made available by the sectoral authorities – the legislator remained within the bounds of "scientific credibility" and whether it reached a decision that was not unreasonable and that was not inappropriate and disproportionate, having regard to the goal pursued.

10.– In order to do so it is necessary to engage first and foremost with the memoranda drawn up by the AIFA, the Italian National Institute of Health (*Istituto Superiore di Sanità* – ISS), the General Secretariat of the Ministry of Health, the General Directorate for Medical Planning of the Ministry of Health and the General Directorate for Medical Prevention, all of which have been filed by the State Counsel as annexes to the intervention by the President of the Council of Ministers.

10.1.– Since the time the contested provision was adopted until the present day, the principal medical and scientific fact guaranteed by the national and European authorities competent in this sector has been that the vaccine is not experimental and

that it is effective and safe.

10.2.– The conclusions of the AIFA, the ISS and the General Secretariat of the Ministry of Health agree regarding the first two aspects, which the referring court itself does not substantially dispute.

It has been attested first of all that "vaccines against COVID-19 cannot in any way be regarded as experimental", as "[the] vaccines currently being used in the vaccination campaign in Italy […] are vaccines that have been duly granted marketing authorisation having completed the process for establishing their quality, safety and efficacy" (citing from the AIFA memorandum referred to above, page 2).

As attested in greater detail by the AIFA, these vaccines were granted conditional marketing authorisation (CMA) in accordance with a pre-existing protocol that had previously been used at European level for a variety of medicines intended to satisfy a high demand for treatment that was not being met (see the AIFA memorandum referred to above, page 9).

In view of the above, the European Union thus concluded that, in the face of the serious threat to public health, which a pandemic certainly represents, the technical choice to obtain CMA was the best choice in order to guarantee protection for health. This is because "this authorisation certifies that the safety, efficacy and quality of the medicines authorised, in this specific case the vaccine, have been established and that the benefits exceed the risks" (page 8 of the AIFA memorandum). Again according to the AIFA memorandum, none of the pre-clinical or clinical development phases (quality testing, assessments of efficacy and safety profile) for the vaccines was omitted, and the number of patients involved in clinical trials was identical to the number involved in vaccines developed according to standard timescales. It was indeed possible to "temporarily operate in parallel the various phases of clinical development and enrol a very high number of participants in phase 3 trials (tens of thousands)" (page 10 of the AIFA memorandum).

The ISS focuses on the efficacy of the vaccine againstSARS-CoV-2, asserting that "[t]he vaccine against COVID-19 is a fundamental preventive instrument in containing the spread of SARS-CoV-2. A considerable body of international scientific evidence has demonstrated the high efficacy of the currently available vaccines against COVID-19, both amongst the general population and within specific at-risk groups, including healthcare workers" (pages 2 and 3 of the ISS memorandum). Aside from the inherent differences in immune responses by individuals and the greater capacity of the Omicron variant to evade immunity compared to previous variants, it is attested that "protection remains high, especially against severe illness or death" (page 3 of the ISS memorandum). The ISS also clarifies that, "even if vaccine efficacy is not l00%, although no vaccine has that level of efficacy, the high rates of circulation of the SARS-CoV-2 virus in any case mean that a significant number of cases can be prevented" (page 5 of the ISS memorandum).

10.3.– As far as the safety profile is concerned, as mentioned above the AIFA clearly states that the CMA "certifies that the safety, efficacy and quality of the medicines authorised, in this specific case the vaccine, have been established and that the benefits exceed the risks".

Moreover – as regards specifically the critical issues raised by the referring court – the AIFA attests that the system for collecting data based on passive pharmacovigilance is absolutely reliable (pages 16 to 23 of the AIFA memorandum), and above all highlights the difference between "reports concerning adverse events following vaccination against COVID-19" and "signal analysis" (pages 23 to 25 of the AIFA memorandum). Specifically, adverse events are reported solely on the basis of the

time when they occurred; however, whilst the temporal criterion is a necessary condition it is not sufficient in order to establish a causal link between vaccination and the adverse event (pages 23 to 25 of the AIFA memorandum).

According to the conclusions reached, "most adverse reactions to vaccines are not serious and end up resolving in full. The most serious adverse reactions are rare to extremely rare and do not constitute a risk that is such as to outweigh the benefits of vaccination. In addition, no excess deaths following vaccination have been observed, and the number of cases in which vaccination may have contributed to a death as a result of an adverse event are extremely limited and in any case not such as to impair the benefit of these medicines" (pages 26 to 27 of the AIFA memorandum).

Again on the issue of safety, the ISS in turn states that "[t]o date billions of people around the world have been vaccinated against COVID-19. Approved vaccines against SARS-CoV-2 have been carefully tested and continue to be monitored constantly. A copious body of international scientific evidence has confirmed the safety of vaccines against COVID-19" (page 6 of the ISS memorandum). Finally, it is important to note the considerable volume of safety data relating to people who have received a vaccine against SARS-CoV-2 given that, according to the EMA, by the start of April 2022 more than 868 million doses of vaccine had been administered to individuals in the EU and the European Economic Area (EEA), with the ISS concluding that "[a]ccording to the data, the vast majority of side effects of vaccines against COVID-19 are minor and last for a short period of time. Safety problems that can be classified as serious are extremely rare" (page 8 of the ISS memorandum).

11.– In the light of the data considered above, it must be concluded that the scientific authorities all attest that vaccines against SARS-CoV-2 for which CMA has been granted are safe and that they are effective in reducing the virus in circulation (as is apparent from the reduction in the number of infections, as well as the number of people admitted to hospital, either in a general ward or in intensive care, and the number of deaths attributable to SARS-CoV-2 over the period since the start of the mass vaccination campaign in March-April 2021).

It is on the basis of these scientific data, which were provided by sectoral authorities and hence cannot be replaced by data obtained from a different origin, even if those data originate from sectoral "experts", that the legislator made its political choice. It is not indicated according to what criteria the legislator should otherwise have relied on "experts" rather than on institutional authorities.

It is therefore evident – in keeping with the medical and scientific data that attest the full efficacy of the vaccine and the suitability of mandatory vaccination vis-a-vis the aim of reducing the spread of the virus – that recourse to mandatory vaccination was not unreasonable "[w]hen confronted with 'a highly contagious respiratory virus, spreading throughout the world, which could be contracted by any person' (Judgment No 127/2022)" (Judgment No 171/2022) and which was characterised by the rapidity and unforeseeable nature of infections.

12.– This conclusion that mandatory vaccination was not unreasonable and was suitable for the intended purpose applies in particular in relation to healthcare professionals and healthcare sector workers under Article 1(2) of Law No 43/2006.

Indeed, the requirement of mandatory vaccination for these persons not only protects the health of one of the categories of people most exposed to infection, but also makes it possible to pursue "the twofold objective of protecting those who enter into contact with them and avoiding any interruption in essential services for the public at large" (Judgment No 268/2017).

12.1.– This last-mentioned aim was particularly keenly felt at a time when, on the

one hand, the healthcare system overall was being placed under massive strain (having to deal not only with growing demand for assistance at home, but also an enormous and incessant increase in hospital admissions of patients suffering from SARS-CoV-2, thereby clogging hospitals and intensive care units), whilst, on the other hand, infections amongst healthcare workers were continuing to rise.

With regard to this last-mentioned aspect, it is sufficient to recall that, in the memorandum mentioned above, the ISS expressly states that "healthcare workers are amongst the categories at high risk of infection with SARS-CoV-2, as they may be more easily infected whilst providing care to patients and/or interacting with other healthcare workers" (page 5 of the ISS memorandum).

On the other hand, the General Secretariat of the Ministry of Health succinctly attests the significant impact of the vaccine campaign on the spread of SARS-CoV-2 amongst healthcare workers: "since the vaccination campaign was launched there has been a clear reduction in the percentage of cases amongst healthcare workers compared to the rest of the population: at the end of December 2020 the case incidence rate amongst healthcare workers was around 6%, whereas at the end of February 2021, after a vaccination course had been completed, resulting in the development of immunity, the case incidence rate was slightly above 1.5%" (page 28 of the memorandum of the General Secretariat of the Ministry of Health).

However, the massive influx of patients into hospitals was even more alarming since, within the context of a healthcare system that was predominantly focused on handling the pandemic, it was becoming extremely difficult to arrange treatment and hospital admission for patients not suffering from SARS-CoV-2. As regards this aspect it is sufficient to note the observations of the General Directorate for Medical Planning of the Ministry of Health which, based on a comparative analysis of hospital admission numbers in 2019-2020, found a clear change in overall admissions in 2020 compared to the previous year, with a loss in terms of volume of around 1.5 million admissions (page 2 of the memorandum of the General Directorate for Medical Planning of the Ministry of Health). This change "in all likelihood made it impossible to care for patients suffering from diseases other than COVID-19" (page 3 of the memorandum).

12.2.– As regards specifically the – different yet complementary – purpose of protecting those persons who enter into contact with healthcare professionals and healthcare sector workers under Article 1(2) of Law No 43/2006, it is important to recall that in the past – when examining a regional law that granted power to a Regional Council to designate specific wards, access to which was permitted only to workers who had complied with the requirements laid down in the National Vaccine Prevention Plan applicable to persons at risk of occupational exposure – this Court was able to assess, with reference to the vaccination of healthcare workers, the "purpose of preventing and protecting the health of persons attending healthcare facilities: first and foremost that of patients, who are often infirm and are exposed to serious danger of infection, as well as that of their family members, other workers, and only by extension society at large. That purpose […] has moreover been considered with particular attention by medical and scientific professional associations, which report the urgent need to put in place procedures that are capable of preventing hospital outbreaks, calling in particular for appropriate conduct on the part of healthcare workers in order to guarantee safe care for patients" (Judgment No 137/2019).

Moreover, as is also pointed out by the ISS in the memorandum cited above, "[i]nfections amongst healthcare workers have a negative impact on individual and collective health, both directly and indirectly. Specifically, the healthcare worker may pass on the infection more readily to patients, who may include infirm persons at high

risk of contracting serious forms of the disease. In addition, the isolation and quarantine procedures that may prove to be necessary following any infection may cause harm to the national health system indirectly in terms of the guarantee of and continuity in the provision of care" (page 5 of the ISS memorandum). This highlights once again the possible ramifications in terms of the risk of interruptions to the health service.

12.3.– The fact that these multiple considerations all apply to healthcare professionals and healthcare sector workers under Article 1(2) of Law No 43/2006 − which justify a difference in treatment for these persons − is also apparent within the Illustrative Report concerning Decree-Law No 44/2021: "The imposition of this obligation on the categories of workers concerned results from the finding that the vaccination of healthcare workers, in conjunction with other individual and collective protective measures to prevent the spread of infectious agents within healthcare facilities and professional studios, has a multiple effect: it enables the worker to be safeguarded against the risk of occupational infection; it helps to protect patients from infection whilst receiving care; it helps to maintain the operational status of healthcare services by guaranteeing the quality of the care provided; and it helps to pursue public health objectives".

12.4.– Finally, from a comparative law perspective, the general homogeneity with the solution adopted in other countries of rendering vaccination mandatory for certain professions, including in particular the healthcare professions – albeit with some degree of variation compared to the other classes affected, and despite the differences in approach apparent from a comparison between the various legal systems – is highly significant.

In particular, it should be pointed out that mandatory vaccination for healthcare workers has been introduced, *inter alia*, in France and Germany, as well as in the United Kingdom and the United State of America. Moreover, as will be set out in greater detail below, courts (including constitutional courts) in some countries have held that mandatory vaccination is lawful, arguing with reference to the principles of reasonableness and proportionality, which have been deployed in a manner not dissimilar to how they are construed under Italian law.

13.– Thus, having verified (in keeping with the medical and scientific data establishing the full efficacy of the vaccine in the manner examined above) the suitability of mandatory vaccination for healthcare professionals and healthcare sector workers under Article 1(2) of Law No 43/2006 vis-a-vis the aim of reducing the spread of the virus – which pursues the twofold purpose recalled above of protecting persons who enter into contact with such workers and avoiding interruptions in services that are essential for society at large – and having hence established that this requirement is not unreasonable, it is now necessary to consider whether the proportionality principle has been complied with as regards the aims pursued.

As this Court has previously held, in cases involving balancing between two rights, "the assessment as to the reasonableness of legislative choices is made according to the proportionality test, which 'requires an assessment as to whether the contested provision, having regard to the scope and manner of application provided for, is necessary and appropriate in order to achieve legitimately pursued objectives in that, out of the various appropriate measures, it requires the one that entails the least restriction on rights and imposes burdens that are not disproportionate having regard to the pursuit of those objectives' (Judgment No 1/2014, recently cited in Judgments No 137/2018, No 10/2016, No 272/2015, No 23/2015 and No 162/2014)" (Judgment No 20/2019).

13.1.– As regards this aspect, it must be concluded that the measure is not disproportionate, first of all because at the relevant time no alternative measures were

available that were equally appropriate for the purpose set by the legislator of combatting the pandemic. This is the case in particular for the alternative feasible solution (which was used on a more general level in order to gain access to public spaces by persons who did not belong to a category subject to mandatory vaccination) of regular diagnostic testing to detect infection with SARS-CoV-2. This is first and foremost because, since such tests would have to be carried out at particularly frequent intervals (i.e. every two or three days), they would have entailed unsustainable costs and would have resulted in an intolerable burden for a healthcare system already committed to handling the pandemic, both at a logistical and organisational level and also in terms of the staff deployment. Moreover, a test result is not immediately available at the time the test is carried out: it is therefore already "obsolete" at the time it is issued, as the person may have been infected during the intervening period, resulting in an inherent risk of asymptomatic or pre-symptomatic infected persons being present in healthcare facilities.

13.2.– Again as regards compliance with the proportionality principle, it must also be pointed out that the consequence of the failure to comply with the requirement is suspension of the right to practise the medical profession, followed by reinstatement once the obligation no longer applies, or in any case once the epidemiological crisis has passed.

This choice – which does not entail a sanction as such – has been made in accordance with the responsibility of the legislator to identify a nuanced consequence in terms of the encroachment on the rights of the healthcare worker that is strictly conducive to the aim of reducing the spread of the virus.

The solution is nuanced in terms of its duration given that, as pointed out above, from the outset the legislator stipulated a specified period for mandatory vaccination, which it altered on various occasions in line with changes in the health situation, and eventually even brought forward its expiry as soon as the epidemiological circumstances permitted. It is also nuanced as regards its intensity, as it involves suspension from work without any disciplinary consequences, and not dismissal.

13.3.– It is interesting to note the position taken in other legal systems, specifically in France. In a ruling rejecting a petition seeking the referral of an application for a priority preliminary ruling on the issue of constitutionality (*question prioritaire de constitutionnalité*) concerning Articles 12 and 14 of Law No 1040 of 5 August 2021, the Council of State (*Conseil d'État*) held that the fact that Article 14 – on the consequences of the failure to comply with the requirement of mandatory vaccination – did not provide for the termination of the employment contract or the removal from office of the persons concerned, but rather the suspension of the relationship. This is an indication of the fact that "the constitutional requirements resulting from the right to work and the right to protection of health were reconciled in a manner that was not manifestly imbalanced" (*Conseil d'État*, joint Vth and VIth divisions, Judgment No 457879 of 28 January 2022, para. 12).

In contrast, other legal systems such as Germany, the United Kingdom and the United States of America have provided for the possibility of dismissal (leaving aside the prevalence of this outcome in practice).

In Germany in particular, the Federal Constitutional Court has held that, whilst the freedom to practise a profession also protects the desire of individuals to keep their jobs, thereby prohibiting all measures that have the effect of obliging people to give up their jobs (para. 246), the provision for mandatory vaccination was however justified, having been imposed in order to protect the most vulnerable (para. 254). Specifically: a) the goal pursued was legitimate (para. 256); b) the mechanism chosen for achieving it was

appropriate, as no alternative measures entailing a lower sacrifice were apparent (para. 257, although also para. 189ff); c) an appropriate balance was struck between the goal pursued and the severity of the sacrifice required (para. 258-266) (Federal Constitutional Court, Order of 27 April 2022, 1 BvR 2649/21).

14.– Finally, the objections – which however need to be carefully considered also by the legislature – raised by the referring court concerning the failure to adopt "mitigatory measures" and "precautionary measures" in parallel with mandatory vaccination (which in its view could be identified in certain shortcomings within pre-vaccination triage, such as the failure to involve general practitioners and the lack of adequate pre-vaccination checks, analyses and diagnostic tests, as well as an antibody test) are misconstrued.

14.1.– As regards the aspect of mitigatory measures, as a general rule vaccination practice in Italy does not entail any triage by a family doctor or paediatrician. As is stated in the memorandum referred to above of the General Secretariat of the Ministry of Health, vaccinations provided for under regional vaccination schedules are generally administered – other than in a few exceptional cases, which are not relevant here – by public health officials (public health doctors, healthcare assistants, nurses) within the vaccination services of local or provincial health authorities of the various regions.

Thus, as a general rule family doctors do not perform a primary role in assessing the eligibility of their patients for vaccination, including in relation to vaccinations ordinarily included within the National Vaccine Prevention Plan. As a matter of fact, this assessment falls to the doctors administering the vaccine, who have been specifically trained for this purpose and who decide whether or not to administer the vaccine to any given person.

This does not detract from the fact that, in accordance with the express provision of Article 4(2) of Decree-Law No 44/2021, as converted into law, family doctors have assisted doctors administering the vaccine in checking for the presence of grounds for exemption from vaccination. Accordingly, they have de facto performed a role that has been far from secondary in the provision of assistance to their respective patients within the ambit of the vaccination campaign, precisely in view of their knowledge of those patients and their respective clinical histories.

14.2.– Likewise, the assertion made by the referring court that adequate "precautionary measures" have not been put in place in parallel with mandatory vaccination, such as adequate checks during pre-vaccination triage, cannot be accepted.

In practice, pre-vaccination screening is a standardised practice, which is used in order to establish whether there are any contraindications or whether any precautions should be taken in relation to vaccination. It involves a series of clear and simple questions, which may and must if appropriate be followed up by more detailed consideration, including in rare situations diagnostic tests or clinical examinations with the family doctor or specialist doctor assisting the individual. According to a consolidated protocol, any healthcare worker administering a vaccine must indeed establish whether there are any contraindications and/or whether any precautions should be taken for each person before administering any vaccine.

As regards the significance afforded by the referring court to the failure to carry out pre-vaccination tests, it should be considered that, under normal circumstances, no provision is made for the conduct of such tests prior to vaccination in order to establish the vaccine's safety in relation to a specific individual. No laboratory examinations or other diagnostic tests are required on a routine basis prior to vaccination, as there is no evidence to support the utility of their widespread usage, on an *ex ante* basis, for all people eligible for vaccination: no tests, including genetic tests, are recommended as

pre-vaccination tests (page 28 of the memorandum by the General Secretariat of the Ministry of Health).

Besides, as the President of the Council of Ministers recalls in his intervention, none of the main international health authorities, including the World Health Organization and the Centers for Disease Prevention and Control in the USA, has recommended any tests prior to vaccination against SARS-CoV-2.

The consideration that no provision is normally made for the conduct of tests for the relevant disease prior to vaccination also applies to the failure to carry out an antibody test.

14.3.– Finally, it is also necessary to consider the more general issue of the precautions or conduct required according to the scientific state of the art in relation to the provision and material administration of healthcare treatment.

Without prejudice to the right to obtain compensation for any adverse events attributable in any manner to the vaccine, which pertain to that unavoidable risk referred to above, it is also possible to bring a liability action pursuant to Article 2043 of the Civil Code in the event that "any additional harm is attributable to negligent conduct pertaining to the specific provision […] or even the material administration of the treatment" (Judgment No 307/1990).

Indeed, referring to the "need for the candidate for vaccination to be protected as far as possible from the risks of vaccine-related complications", this Court has stressed that these "precautionary requirements […] are already addressed in the first instance by the duty, when providing and administering mandatory treatment, to comply with those 'precautions or […] procedures prescribed by the scientific state of the art in relation to its nature', the violation of which may give rise to […] an action pursuant to Article 2043" (Judgment No 258/1994; however see also, with regard to the specific facts of the case, Judgment No 307/1990).

15.– In the light of all of the considerations set out above, it must therefore be declared that the question raised concerning the constitutionality, with reference to Article 32 of the Constitution, of Article 4(1) and (2) of Decree-Law No 44/2021, as converted into law, insofar as it provides, on the one hand, for mandatory vaccination for healthcare workers, and, on the other hand, the suspension of the right to practise the medical profession in the event that this requirement is not complied with, is unfounded.

16.– The requestions raised, with reference to Articles 3 and 21 of the Constitution, concerning the constitutionality of Article 1 of Law No 219/2017, insofar as it does not provide for an express dispensation from the requirement to obtain signed, informed consent in situations involving compulsory medical treatment, and of Article 4 of Decree-Law No 44/2021, as converted into law, insofar as it does not dispense with the requirement to obtain signed, informed consent in situations involving mandatory vaccination, are likewise unfounded.

16.1.– Informed consent, as a precondition for the lawfulness of any healthcare treatment, is grounded on the principle of self-determination with regard to choices pertaining to one's own health, understood as the freedom to exercise control over one's own body, which are the fundamental human rights enshrined in Articles 2, 13 and 32 of the Constitution and in Articles 1, 2 and 3 of the Charter of Fundamental Rights of the European Union. According to Article 1 of Law No 219/2017, "no healthcare treatment may be started or continued without the free and informed consent of the individual concerned, except under the circumstances expressly provided for by law". More specifically, the patient's consent must be free and informed, and may only be provided after full, up-to-date and understandable information has been provided with regard to the diagnosis, prognosis, benefits and risks associated with diagnostic tests

and medical treatment advised, potential alternatives and the consequences of any refusal of medical treatment or diagnostic tests, or any decision not to continue with them.

However – taking account of the importance of obtaining informed consent also with the aim of ensuring the adequate recording of essential data for the purpose of full and complete pre-vaccination screening, which as recalled above is intended, *inter alia*, to assess the relevant person's eligibility for vaccination – the mandatory nature of the vaccine under examination does not preclude the need to obtain informed consent, and this requirement is only dispensed with under the circumstances expressly provided for by law, under the terms of Article 1(1) of Law No 219/2017.

The mandatory nature of vaccination in any case leaves each individual the option of choosing whether to comply with or disregard the obligation; in the latter case, the person must accept in a responsible manner the consequences provided for by law.

If, on the contrary, the person undergoes mandatory vaccination, that person's consent, albeit provided in response to an obligation, constitutes authorisation for the physical injection of the vaccine, in accordance with the principle that the individual's right not to be interfered with without consent must be respected.

17.– In conclusion, the questions of constitutionality raised must be declared in part manifestly inadmissible and in part unfounded.

ON THESE GROUNDS

THE CONSTITUTIONAL COURT

1) *declares* that the questions concerning the constitutionality of Article 4(1) and (2) of Decree-Law No 44 of 1 April 2021 (Urgent measures to contain the COVID-19 epidemic, on vaccination against SARS-CoV-2, on the administration of justice and on public competitions), converted with amendments into Law No 76 of 28 May 2021, insofar as it provides, on the one hand, for mandatory vaccination for healthcare workers, and, on the other hand, the suspension of the right to practise the medical profession in the event that this requirement is not complied with, raised with reference to Articles 3, 4, 33, 34 and 97 of the Constitution by the Council of Administrative Justice of Sicily Region by the referral order mentioned in the headnote, are manifestly inadmissible;

2) *declares* that the question concerning the constitutionality of Article 4(1) and (2) of Decree-Law No 44/2021, as converted into law, raised with reference to Article 32 of the Constitution by the Council of Administrative Justice of Sicily Region by the referral order mentioned in the headnote, is unfounded;

3) *declares* that the questions concerning the constitutionality of Article 1 of Law No 219 of 22 December 2017 (Provisions on informed consent and advance healthcare directives), insofar as it does not provide for an express dispensation from the requirement to obtain signed, informed consent in situations involving compulsory medical treatment, and of Article 4 of Decree-Law No 44/2021, as converted into law, insofar as it does not dispense with the requirement to obtain signed, informed consent in situations involving mandatory vaccination, raised with reference to Articles 3 and 21 of the Constitution by the Council of Administrative Justice of Sicily Region by the referral order mentioned in the headnote, are unfounded.

Decided in Rome at the seat of the Constitutional Court, *Palazzo della Consulta*, on 1 December 2022.

Signed:

Silvana SCIARRA, President

Filippo PATRONI GRIFFI, Author of the Judgment