JUDGMENT NO. 268 YEAR 2017

In this case, the Court heard a referral order concerning legislation that precluded the payment of an indemnity to individuals harmed by irreversible complications resulting from a vaccination where the vaccine in question (in this case against influenza) was not compulsory but had rather been recommended by the health authorities. Previous rulings by the Court had concerned specific recommended vaccines other than the influenza vaccine. The Court held that, despite the differences between a recommendation and a mandatory requirement, "the key issue for the purpose of deciding on the questions of constitutionality under examination is the essential objective of preventing infectious diseases pursued by both". It thus held that "there is no qualitative difference between an obligation and a recommendation" within the specific context of the influenza vaccine, and thus ruled the contested legislation unconstitutional insofar as it did not provide for the payment of an indemnity in relation to impairment caused by the influenza vaccination. The Court finally held that the issue as to whether vaccination was administered free of charge was immaterial for the purposes of eligibility for the indemnity.

[omitted]

THE CONSTITUTIONAL COURT

[omitted]

gives the following

JUDGMENT

in proceedings concerning the constitutionality of Article 1(1) of Law no. 210 of 25 February 1992 (Indemnity for individuals harmed by irreversible complications resulting from compulsory vaccinations, transfusions and the administration of blood derivatives) initiated by the Employment Division of the Milan Court of Appeal by the referral order of 20 July 2016, registered as no. 252 in the Register of Orders 2016 and published in the Official Journal of the Italian Republic no. 50, first special series 2016.

Having heard the Judge Rapporteur Nicolò Zanon in chambers on 22 November 2017.

[omitted]

Conclusions on points of law

1.— The Employment Division of the Milan Court of Appeal has raised, with reference to Articles 2, 3 and 32 of the Constitution, questions concerning the constitutionality of Article 1(1) of Law no. 210 of 25 February 1992 (Indemnity for individuals harmed by irreversible complications resulting from compulsory vaccinations, transfusions and the administration of blood derivatives), insofar as it does not provide that the right to an indemnity established and governed by the said Law also be available under the conditions set forth thereunder to individuals who have suffered injury or illness that has resulted in irreversible damage to their physical and psychological integrity following a non-mandatory but recommended vaccination against influenza".

The referring court considers that, in the event of a permanent impairment of physical and psychological integrity resulting from the recommended influenza vaccination, the failure to provide for an indemnity results in a violation, first and foremost, of Articles 2 and 32 of the Constitution. Such an outcome is claimed to violate the "right-duty of solidarity" because, absent any award of an indemnity, any individual who has suffered harm will be forced to bear the serious negative consequences resulting from healthcare treatment that is recommended not only in order to protect his/her individual health but also that of society at large.

The contested provision is also claimed to violate the principle of equality set forth in Article 3 of the Constitution as it provides for an unreasonable difference in treatment between those who have been vaccinated pursuant to a legal requirement and those who, by contrast, have decided to receive the vaccine on the recommendation of the health authorities. The unreasonableness is purported to result from the grant only to the former of a right to an indemnity in the event of permanent impairment, notwithstanding that a recommendation and an obligation are of identical significance for the purposes of the protection of public health.

2.– The referring Court of Appeal considers that it is not possible to interpret the contested provision in a manner that is consistent with the Constitution in that it recognises a right to an indemnity on the basis of the same principles that led this Court – by Judgment no. 107 of 2012 – to rule unconstitutional Article 1(1) of Law no. 210 of 1992 insofar as it did not provide for such a right following permanent impairment resulting from vaccination against measles, mumps and rubella.

The referring court observes that, even following the adoption of that Judgment, the substantive content of the contested provision has remained unequivocally clear in providing for an indemnity only in cases involving impairment caused by mandatory vaccinations. In fact, the operative part of Judgment no. 107 of 2012, which ruled the contested legislation unconstitutional, refers solely to that specific vaccination, and could not be extended to the present case other than by the substantive disapplication of the contested provision.

For this reason, the referring court finds the literal wording of the provision to preclude an interpretation that is compatible with the constitutional parameters invoked.

This manner of argumentation is correct, as this Court has asserted on various occasions that, when a referring court considers whether interpretation in a manner consistent with the Constitution is possible, but concludes that this option is not viable, the resulting question of constitutionality cannot be ruled inadmissible. By contrast, where the unequivocal literal wording of the provision precludes interpretation in a manner consistent with the Constitution, constitutional review becomes mandatory (see most recently, *inter alia*, Judgments no. 83 and no. 82 of 2017, no. 241 and no. 219 of 2016).

3.– Certain grounds for inadmissibility averred on a preliminary basis by the State Counsel [*Avvocatura generale dello Stato*] pertain to the merits of the questions raised and must therefore be assessed within a consideration of the merits.

This must apply with regard to the insistent argument that the referral order did not take sufficient account of the reasons underlying the choice, by the individual whose circumstances are at issue within the main proceedings, to take the recommended vaccination: this is because, assuming that such reasons are relevant, any reflection on them will evidently entail an assessment as to the nature of the recommendation made by the health authorities and its impact on the scope for self-determination of the individual, which thus requires an assessment concerning the merits of the questions of constitutionality raised.

In the same way, the alleged failure within the remedy sought in the referral order to state the categories of individual that should effectively be entitled to claim an indemnity is not, in this case, a preliminary issue, but rather a question that only arises once it has been decided that, in the event that permanent impairment is caused as a result of a recommended vaccination, the exclusion of an indemnity is unconstitutional. Logically speaking, it is only at that stage that the question arises as to how broad the class of persons eligible to benefit from that extension should be.

4.– The observation made by the State Counsel according to which any individual who has suffered serious detriment to his/her physical and psychological integrity as a result of the influenza vaccination is in any case entitled to take action to seek compensation for damage to health is immaterial for the purposes of resolving the questions brought before this Court.

This observation cannot in fact constitute a basis for a preliminary objection of inadmissibility or support any arguments concerning the merits of the solution to the questions raised.

As regards the former aspect, the referring Court of Appeal has taken specific account of the causal link, within the case under examination, between the influenza vaccination and the physical and psychological impairment, in order to establish that the prerequisites for the applicability of the specific provisions laid down by Law no. 210 of 1992 with regard to an indemnity have been met.

As far as the latter aspect is concerned, this Court has already clarified that the legislation laid down by the law cited above applies on a level different from that on which the provisions governing compensation under tort operate. Specifically, compensation under tort presupposes a causal link between an unlawful act and unjust injury, whilst the right to an indemnity – which is available irrespective of the issue of fault – arises as a result of a mere finding that the irreversible impairment was caused by the vaccine "and results from the inderogable duty of solidarity incumbent upon society at large in such cases", given that society benefits from the vaccination of the individual (Judgment no. 118 of 1996).

Without prejudice, under all circumstances, to the ability of the interested person to bring also an ordinary damages claim (under tort), which may be recognised where the prerequisites laid down by Article 2043 of the Civil Code are met, the legislator has thus established a self-standing measure of financial support having the status of an indemnity awarded in accordance with the dictates of equity (Judgment no. 118 of 1996) in the event of damage to health, the award of which is dependent upon the simple objective fact of having suffered harm. This measure enables interested parties to obtain protection that is certain with regard both to its existence and to the *quantum*, and that is not conditional upon the successful bringing of a damages action under tort, which requires a finding of an unlawful action and the identification of a responsible party (Judgments no. 423 of 2000, no. 27 of 1998 and no. 118 of 1996).

5.– On the merits, in order to arrive at a decision concerning the questions raised, it is necessary, in the first place, to clarify the prerequisites and conditions governing this Court's extension, in previous rulings, of eligibility for the indemnity – which Article 1(1) of Law no. 210 of 1992 explicitly reserves to impairment resulting from mandatory vaccinations – also in cases involving serious and permanent impairment to physical and psychological integrity resulting from certain specifically identified vaccinations that were non-mandatory but nonetheless recommended.

Second, it is necessary to establish whether these same considerations also apply to the non-mandatory influenza vaccination at issue within the main proceedings.

6.– By Judgments no. 107 of 2012 (concerning vaccination against measles, mumps and rubella), no. 423 of 2000 (concerning vaccination, at the time merely recommended, against hepatitis B) and no. 27 of 1998 (concerning vaccination, also at the time merely recommended, against polio), this Court declared unconstitutional – with reference to Articles 2, 3 and 32 of the Constitution – Article 1(1) of Law no. 210 of 1992 insofar as it did not provide for a right to an indemnity – in the event of an irreversible condition

and subject to the establishment of a causal link between this condition and vaccination – for permanent impairments resulting from the vaccines at issue in the respective main proceedings.

With regard to vaccination, the fact as to whether a vaccine is mandatory (prescribed by law or by order of a health authority, as provided for under the contested provision) or recommended (in the manner discussed below) may result from partially diverging conceptions of the relationship between the individual and the public health authorities, as well as from the different healthcare conditions of the reference population, having been duly documented by the competent authorities.

Under the former scenario, the individual's freedom of choice is suppressed through the imposition of an obligation, which is coupled with a sanction. That solution – which may be adopted by decision of the public health authorities on the basis of objective and recognised requirements of prevention – is not incompatible with Article 32 of the Constitution if the mandatory treatment is intended not only to improve or maintain the health of the individual in receipt of the vaccine but also that of others, as it is precisely this latter purpose, which pertains to health as an interest of society at large, that justifies the restriction on individual self-determination (Judgments no. 107 of 2012, no. 226 of 2000, no. 118 of 1996, no. 258 of 1994 and no. 307 of 1990).

Under the latter scenario, rather than imposing an obligation, the health authorities prefer to recommend to individuals that they participate in a public healthcare programme. The recommendation "technique" affords greater attention to individual self-determination (or, in cases involving children, to parental responsibility), and thus to the subjective aspect of the individual right to health, which is protected by Article 32(1) of the Constitution; however, it nonetheless pursues the goal of achieving the best protection for health as (also) a collective interest.

Specifically from this viewpoint, notwithstanding the different focus of the two techniques under discussion here, the key issue for the purpose of deciding on the questions of constitutionality under examination is the essential objective of preventing infectious diseases pursued by both: namely, the common purpose of guaranteeing and protecting (also) public health by achieving the highest possible vaccination coverage.

Within this perspective, which is centred on health as an interest (also) of society as a whole, there is no qualitative difference between an obligation and a recommendation: the classification of a vaccine as mandatory is simply one of the instruments available to the public health authorities in order to achieve public health protection, in the same way as a recommendation. The various actors (public authorities and individuals) end up achieving the objective of the broadest possible immunisation against the risk of contracting a disease irrespective of the existence of any specific intention on their part to cooperate: "it is entirely irrelevant, or indifferent, whether the cooperative effect is attributable in active terms to an obligation, or to persuasion, or by contrast in passive terms to the desire to avoid a sanction, or to take up an invitation" (Judgment no. 107 of 2012).

As regards recommended vaccinations more specifically, in situations involving widespread and repeated awareness-raising campaigns in favour of vaccinations, it is natural that a reliance will develop on the recommendations of the health authorities, which renders the individual choice to abide by the recommendation in itself objectively directed at safeguarding also the collective interest, aside from the individual's own specific motivation for participating.

This Court has consequently acknowledged that, in terms of the interests guaranteed by

Articles 2, 3 and 32 of the Constitution, there is justification for shifting to the collectivity, which also objectively benefits from the individual choices, any harmful effects that may result from those choices.
Thus, the decisive basis for the right to an indemnity does not result from the fact of being subject to mandatory treatment as such, but rather lies in the requirements of social solidarity that are imposed on society at large where an individual suffers negative consequences for his/her physical and psychological integrity as a result of healthcare treatment (whether mandatory or recommended) carried out also in the interest of society at large.
For this reason, the failure to provide for a right to an indemnity in relation to irreversible conditions resulting from particular recommended vaccinations amounts to a breach of Articles 2, 3 and 32 of the Constitution, because the requirements of social solidarity and the protection of the individual's health require that it must be society at large that takes on the burden of the individual harm, whilst it would be unfair to require that the individuals who have been injured should bear the cost of the benefit, which is also collective (Judgment no. 107 of 2012).
Precisely in the light of these considerations, it may be added that the reasons for extending the right to an indemnity that may be inferred from the case law mentioned have never entailed, and do not entail, any negative assessments by this Court as to the level of scientific reliability of the administration of vaccines. On the contrary, the provision for an indemnity, which was originally reserved to cases involving permanent harm resulting from mandatory vaccinations, and its extension (by this Court) to the cases mentioned involving recommended vaccinations – provided in all cases that a causal link has been established between the administration of the vaccine and the permanent impairment – supplement the "contract of solidarity" between the individual and society at large in terms of the protection of health and provide more serious and reliable backing to any healthcare programme that seeks to promote vaccinations in order to obtain the broadest possible cover throughout the population.
7.– There is no reason not to extend to the case under examination here, and to the questions of constitutionality raised within it, the assertions that may be inferred from the case law of this Court cited above.
The influenza vaccine falls squarely within the category of recommended vaccinations.
A verification of this status is an essential step within the reasoning of this Court. The answer provided to the question as to whether, in an analogous manner to the position established in relation to other specific recommended vaccinations, the health authorities have adopted and implemented an effective awareness-raising campaign also in relation to the influenza vaccine, will in fact make it possible to assess the significance of the protection for (also collective) health in such cases.
This Court therefore cannot avoid carrying out a targeted analysis of the specific circumstances of the individual recommendation to which the question relates, as it cannot simply extend – without carrying out a case-by-case examination – the (albeit clear) principles within its case law in a blanket manner to any measure based on a preventive recommendation adopted by the public authorities.
Within this perspective, the status of the influenza vaccination as recommended healthcare treatment may be established with reference to a series of acts, corresponding to those already identified by this Court within its case law: broad and insistent campaigns, including extraordinary campaigns, providing information and recommendations authorised by the highest levels of the public health authorities; the

dissemination of materials concerning information; information available on the official website of the Ministry of Health; ministerial decrees and circulars; national plans for prevention through vaccination; or the law itself (as was the case, for example, in relation to the polio vaccination, which was recommended at the time under Law no. 695 of 30 July 1959 laying down "Measures to achieve comprehensive vaccination against polio") (see also Judgments no. 107 of 2012, no. 423 of 2000 and no. 27 of 1998).

In the specific case of the influenza vaccination at issue within the proceedings before the referring court, the national plans for prevention through vaccination are of particular relevance (most recently, the national plan for prevention through vaccination 2017-2019) as, in classifying the influenza vaccination amongst other types of recommended vaccinations and indicating the respective coverage targets, they define the overall programme of vaccination, as are also the recommendations of the Ministry of Health specifically adopted each season with reference to vaccination against influenza (most recently, "Prevention and control of influenza: recommendations for season 2017-2018") and the official awareness-raising campaigns of the Ministry of Health in addition to the Regions.

7.1.– In the light of these considerations, the public at large must bear the costs of any individual harm, including in the event that the permanent impairment has resulted from the influenza vaccination. It would moreover be unreasonable to treat those who have followed the recommendations of the public health authorities mentioned above less favourably than those who have complied with an obligation (see to the same effect, with reference to the polio vaccination, Judgment no. 27 of 1998). And the shift, to the public at large, of any negative consequences that may result from the influenza vaccination (in all cases subject to the conditions and limits laid down by Law no. 210 of 1992) necessarily ensues from the application of the constitutional principles of solidarity (Article 2 of the Constitution), protection of health, including public health (Article 32 of the Constitution) and reasonableness (Article 3 of the Constitution). Moreover, such an outcome also supplements, in terms that provide more serious and reliable backing to any healthcare programme that seeks to increase vaccination coverage, the "contract of solidarity" between the individual and society at large with the aim of achieving the highest possible vaccination coverage amongst the general public.

Nor is it possible to overlook the fact – again as justification for the imposition, on society at large, of the onus of the indemnity in question – that the broadest dissemination of vaccination as a preventive measure may in particular alleviate the burden which influenza outbreaks usually impose on the national health service and on employment, a burden which is not only financial in nature.

7.2.– The State Counsel observes that, were the question to be accepted as formulated by the referring Court of Appeal, a whole range of questions which could only be resolved through legislative discretion, such as in particular that concerning the recipients of the expanded indemnity, would remain unresolved and uncertain.

The objection is misconstrued.

Recommendations issued by the health authorities in relation to influenza vaccination are directed in the first place at specific categories of persons at risk, for whom vaccination is expressly recommended because of their advanced age or of a particular health condition; second, at particular categories of public servants and workers, for whom vaccination not only safeguards individual health but also serves the twofold

purpose of protecting those who enter into contact with them and avoiding an interruption of services that are essential for the collectivity; third, at those who cohabit with persons at risk, a situation which gives rise to the need for protection that is not only individual. The recent update to the essential levels of assistance (Decree of the President of the Council of Ministers of 12 January 2017 laying down the "Definition and updating of essential levels of assistance, pursuant to Article 1(7) of Legislative Decree no. 502 of 30 December 1992"), the national plan for prevention through vaccination (2017-2019) and ministerial recommendations (2017-2018) stipulate that an influenza vaccination must be offered free of charge to these classes of person. The specific identification of these categories out of the population as a whole thus serves this principal objective, whilst it could not obviously be used as a basis for delineating the scope of the potential recipients of the indemnity.

On the other hand, the information and awareness-raising campaigns that seek to achieve the broadest possible vaccination coverage are inevitably directed at the general public as a whole, irrespective of any prior specific individual condition pertaining to health, age, employment or cohabitation, as also in this case, the application of the treatment enables both individual and collective health to be protected, preventing the potential contagion of persons at risk by those who are not at risk and thereby contributing also to the protection of those who cannot be vaccinated on account of a specific health condition.

7.3.– Ultimately, in the light of the principles identified within the case law of this Court – which often refers to the protection of public health in relation to the recognition of the right to an indemnity – the fact that for certain classes of individual, the recommendation is accompanied by free-of-charge administration of the vaccine, could not establish any limitation of the class of persons eligible for an indemnity.

The specific position of those classes of person does not by any means diminish the collective significance which protection of health takes on also for the general population, as the vaccination of each and all contributes to achieving the objective, pursued by means of recommendation, of achieving the fullest coverage. Besides, whilst financial constraints might justify restrictions on the class of individual to whom vaccination is to be administered free of charge on the grounds that it has been incorporated into the essential levels of assistance, these certainly cannot justify any release from the duty to pay an indemnity where the statutory prerequisites are met.

It is therefore necessary to declare unconstitutional Article 1(1) of Law no. 210 of 1992 insofar as it does not make provision for the right to an indemnity, under the conditions and according to the procedures laid down by the said Law, to any person who has suffered harm or infirmity resulting in a permanent impairment of physical and psychological integrity on account of the influenza vaccination.

ON THESE GROUNDS

THE CONSTITUTIONAL COURT

declares unconstitutional Article 1(1) of Law no. 210 of 25 February 1992 (Indemnity for individuals harmed by irreversible complications resulting from compulsory vaccinations, transfusions and the administration of blood derivatives) insofar as it does not make provision for the right to an indemnity, under the conditions and according to the procedures laid down by the said Law, for those who have received the influenza vaccination.

Decided in Rome at the seat of the Constitutional Court, *Palazzo della Consulta*, on 22 November 2017.