

JUDGMENT NO. 118 YEAR 2020

In this case, the Court considered a referral order concerning legislation that precluded the payment of compensation for harm caused by the vaccine against hepatitis A, which was not mandatory but had been recommended by the health service. Drawing on previous judgments concerning other vaccines, the Court ruled the legislation unconstitutional insofar as it did not provide for the payment of compensation under such circumstances. Whilst the fact that a vaccine was recommended left scope for individual decisions, the fact that it pursued a public health goal engaged solidarity considerations under the Constitution, and hence a duty of the State to pay compensation.

[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 Supreme Court of Cassation within the proceedings pending between the Ministry of Health and A.O. and others, with referral order of 11 October 2019, registered as No. 6 in the Register of Orders 2020 and published in the Official Journal of the Italian Republic No. 5, first special series 2020.

after hearing Judge Rapporteur Nicolò Zanon in chambers on 26 May 2020, a session held in accordance with the Decree issued by the President of the Court of 20 April 2020, item 1), letter *a*);

after deliberating in chambers on 26 May 2020.

[omitted]

Conclusions on points of law

1.— The Employment Division of the Court of Cassation 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, should also be available under the conditions set forth thereunder to individuals who have suffered injury or illness that has resulted in irreversible impairment of their physical and psychological integrity as a result of a non-mandatory but recommended vaccination against infection by the hepatitis A virus.

As regards the relevance of the questions raised, the referring court has taken specific account of the finding concerning a causal link, within the case that gave rise to the main proceedings, between the illness and the administration of the vaccine against hepatitis A, in order to establish that the further prerequisites for the applicability of the provisions enacted by Law No. 210 of 1992 in relation to compensation are met. It has thereby been clarified, according to the referring court, that the provisions on compensation could only be applied for the interested party in the event that the question raised were considered to be well founded.

As regards the non-manifest unfoundedness of the questions, the referring court considers that, in the event that irreversible complications were to result from vaccination, the difference in treatment arising from the contested provision as regards the payment of compensation – between persons suffering injury or impairment due to mandatory vaccinations and persons in whom the same illnesses arise following a vaccination that is not mandatory but has been recommended by the health authorities, such as the vaccine against hepatitis A – would violate the constitutional provisions invoked. As recommended vaccinations also pursue the goal of protecting public health, in addition to individual health, also in such cases Articles 2, 3 and 32 of the Constitution require the negative consequences that the vaccine has caused for the individual to be transferred to society as a whole, in the same way as the position that has already been established by various judgments of this Court (including in particular Judgments Nos. 268 of 2017, 107 of 2012, 423 of 2000 and 27 of 1998) in relation to diseases resulting from the administration of vaccinations that were not mandatory, but nonetheless recommended, against infectious diseases other than hepatitis A.

2.– The referring court observes, as a preliminary matter, that it would not be practicable to interpret the contested provision in a manner consistent with the Constitution, in that in this case, it is intended specifically to recognise a right to compensation on the basis of the same principles that have led this Court, in the judgments cited above, to rule the same provision unconstitutional insofar as it did not provide for compensation following permanent impairment caused by other specific vaccines that were not mandatory, but nonetheless recommended. This, so it is argued, is not possible both due to the literal wording of the provision and – in the case at issue in the proceedings – because it is impossible to discern any “administrative documents that essentially impose an obligation” within the regional recommendations in favour of vaccination against hepatitis A. Indeed, the extension to this case of the principles already set out in the case law of the Constitutional Court concerning other vaccines should result, in the opinion of the referring court, in the “substantive disapplication by the courts of the contested provision”. Ultimately, it is argued that the violation of the Constitution identified could only be rectified if this Court held the questions raised to be well founded.

The reasoning of the referring court is correct.

The case law of the Constitutional Court has asserted on various occasions that the unequivocal wording of the provision marks out the boundary beyond which an attempt at a constitutionally compatible interpretation must be replaced by constitutional review (see in particular Judgment No. 232 of 2013 and, more recently, Judgments Nos. 221 of 2019, and 83 and 82 of 2017). On the other hand, again according to constitutional case law that is now settled, once the referring court has specifically established that the wording of the contested provision requires one particular interpretation and precludes others, all of which may be constitutional, the review of the respective interpretative solutions is not a matter of admissibility but is rather an assessment that pertains to the merits of the question (see, *inter alia*, Judgments Nos. 50 of 2020 and 133 of 2019).

Finally, with specific reference to the case now before the Court, a mere finding that a vaccine – for the harmful consequences of which compensation is sought – has been recommended does not allow ordinary courts to extend automatically to such cases the (albeit shared) rationale underlying the previous rulings declaring Article 1(1) of Law No. 210 of 1992 partially unconstitutional (see by analogy, albeit in relation to a different matter, Judgment No. 110 of 2012). In fact, in case of complications resulting

from vaccination, the right to compensation is not a consequence of the public authorities' generic goal of preventing the disease to which the vaccine relates, but rather solely of specific awareness-raising campaigns conducted by the health authorities with the aim of protecting health on not only an individual, but also a collective, level. Therefore, the finding that the usage of the vaccine under examination was recommended (which is without doubt a matter for the ordinary courts) must necessarily be followed – for the purposes of constitutional review – by a verification by this Court as to whether those recommendations had those specific characteristics that, according to the settled case law of the Constitutional Court, subject the healthcare treatment recommended for individuals to the broader goal of protecting health as a public interest, and thus require the normative scope of the contested provision to be extended (Judgment No. 268 of 2017).

3.– This review has concluded that the treatment did have this broader goal, and the questions are hence well founded.

3.1.– First of all, the referral order acknowledges the existence within Puglia Region of a vaccination campaign against hepatitis A specifically during the period in which the individual – who has claimed to be entitled to compensation – was administered that vaccine, following moreover a specific summons from the health authorities.

The vaccination campaign had in fact been launched in 1997 following a specific regional epidemic, which moreover continued also during the following years, in the wake of detailed indications by the Regional Epidemiological Observatory. The campaign had also resulted, precisely during the periods of relevance for proceedings before the referring court, in the issuance of detailed resolutions adopted by the Regional Council and Executive.

In particular, by a resolution of 2 July 1996, the Council of Puglia Region had approved a regional programme of mandatory and optional vaccinations, which included the offer of the vaccine against hepatitis A to certain categories of at-risk persons free of charge. In line with that programme, by Resolution No. 4272 of 18 July 1996, the Regional Executive had decided *inter alia* (on the basis of the studies by the Epidemiological Observatory mentioned above) to promote a vaccination campaign against hepatitis A directed in particular at newborn babies and twelve year-old children, stipulating that it should be administered free of charge and on a voluntary basis and that an awareness-raising programme should be conducted amongst the population both prior to and in parallel with it.

After these decisions were taken, over the next few years, vaccine coverage amongst the interested groups of the population grew exponentially, and was accompanied by a fall in infections. Nevertheless, again according to the information provided by the Regional Epidemiological Observatory, by Resolution No. 2087 of 27 December 2001 approving the regional healthcare plan for 2002-2004, the Executive had reiterated the objective of “implementing the programme of vaccination against hepatitis A and restating its free and voluntary status”. During a subsequent phase, by Resolution No. 1327 of 4 September 2003, the Regional Executive had decided to provide local healthcare facilities with “operating directions” to be implemented on an ongoing basis in relation to the vaccination of adolescents against the hepatitis A virus.

This was therefore the context, as summarised by the referring court, within which the private party in the main proceedings, who was born in 1990 and vaccinated by two shots administered in 2003 and 2004, was asked to come forward to receive the vaccine.

3.2.– In view of the conditions laid down in the case law of this Court (Judgments Nos. 268 of 2017, 107 of 2012, 423 of 2000 and 27 of 1998), this case too effectively involved a broad and insistent campaign of awareness-raising and information by the public health authorities, in this case the regional authorities, as to why it was highly appropriate for certain classes of individuals to be vaccinated against hepatitis A.

The vaccination campaign under examination was based on rigorous scientific and epidemiological foundations, which revealed the risk of the widespread dissemination of the hepatitis A virus, including by person-to-person infection. Thus, as has moreover been the case for the campaigns conducted at a later stage, it pursued the objective of achieving suitable immunisation cover throughout the population in order to ensure the health of each individual, of persons at risk, of the most fragile and ultimately of society as a whole.

3.3.– As noted above, the vaccination strategy drawn up by Puglia Region was based on recommendations and not on mandatory requirements (leaving aside what specifically occurred in this case, in which the interested party was in fact summoned by the health authorities to receive the vaccine). However, according to the literal provision of the contested Article 1(1) of Law No. 210 of 1992, the fact that the vaccination was recommended precludes any right to compensation for individuals who complain that they have suffered irreversible injury or illness as a consequence of it.

However, as has also been stressed within the case law of this Court (Judgment No. 268 of 2017), 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.

Notwithstanding the different focus of the two techniques, the key issue is the essential objective pursued by both of preventing infectious diseases: 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 close link between mandatory and recommended vaccination has been reiterated by this Court also in more recent judgments within constitutional review proceedings launched by direct applications against regional or state laws, and thus concerning aspects that in part differ from those concerning the right to compensation, which is at issue in this case. Nevertheless, it has been observed in these judgments that “in the epistemic area of medical and health practice, the gap between recommendation and duty is much narrower than the one that separates the two concepts as applied to legal relationships. In the medical field, to recommend and to prescribe are actions perceived as implying an equal level of obligation in light of a set objective” (Judgment No. 5 of 2018; see also Judgment No. 137 of 2019), i.e. the protection of (also) collective health.

3.4.– Where a campaign is conducted in favour of a particular vaccine, it is natural for individuals to rely on the advice provided by the health authorities: this in itself means that the individual choice to follow the recommendation is objectively

aimed at safeguarding also the collective interest, leaving aside any specific motivation for a given individual's actions.

This Court has consequently acknowledged that, according to Articles 2, 3 and 32 of the Constitution, it is necessary to shift to the collectivity, which benefits from individual choices, any harmful effects that may result from those choices.

The basis for the right to compensation of the individual is thus not the fact that he or she has undergone mandatory treatment: it rather flows from the need for society as a whole to comply with a duty of solidarity, where the adverse consequences for psychological and physical integrity result from a healthcare treatment (whether mandatory or recommended) provided in the interest of society as a whole, as well as in the interest of the specific individual.

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 solidarity laid down in the Constitution and the need to protect the right to health require that it must be society at large that takes on the burden of harm suffered by individuals, whilst it would be unfair to require that an individual who has been injured should have to bear the cost of the benefit, which is also collective (Judgments Nos. 268 of 2017 and 107 of 2012).

It must also be reiterated, as previously done on other occasions (Judgments Nos. 5 of 2018 and 268 of 2017), that the availability of a right to compensation – in relation to diseases that are causally related to a mandatory vaccine or, subject to the clarifications made above, a recommended vaccine – is not dependent at all on any assessments as to the medical and scientific unreliability of the vaccine administered. On the contrary, the provision for compensation completes the “solidarity pact” between the individual and the collectivity as regards the protection of health and affords greater weight and reliability to any healthcare programme involving mass vaccination, in order to obtain broad coverage throughout the population.

3.5.– Finally, it must be stressed that any arguments concerning the merely regional (and not national) scale of the vaccination campaign under examination, or the fact that it was directed predominantly at a particular class of “at-risk” individuals (selected, as far as is relevant in this case, with reference to age) would be immaterial, either in terms of finding the questions of constitutionality raised well founded or with a view to any limitation of the class of potential recipients of compensation (through a “targeted” ruling of unconstitutionality). Moreover, the fact – also noted within proceedings before the lower court – that the recommended vaccine concerned is provided free of charge by the National Health Service for classes of individuals deemed to be “at risk” on the grounds that it falls within the essential level of assistance cannot have any relevance for the purpose of any hypothetical restriction of the individuals to whom compensation is payable.

First of all, whilst the vaccination campaign was essentially regional in nature, it was also confirmed and mirrored in various respects within national plans (including in particular the recent National Vaccine Prevention Plan for 2017-2019), as well as within a specific recommendation of the Ministry of Health of 26 July 2017 (containing an “Update to the recommendations on prevention and immunoprophylaxis in relation to the Hepatitis A epidemic”); these are acts that were not and are not rooted in any specific territory.

Secondly, the fact that an awareness-raising campaign recommending a particular vaccine was aimed directly at persons considered to be “at risk” (by virtue of age, lifestyle or geographical location) is irrelevant for our present purposes.

The important point is in any case the reliance on the health authorities’ recommendation by the individual, of whatever type (whether an at-risk person or not), and it is also from this starting point that the basis for compensatory relief must be established.

Secondly, this Court has already observed (Judgment no. 268 of 2017) that, in as much as they may be aimed directly at particular categories of individual, 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 lifestyle: thus, even though the treatment was originally conceived of for particular classes of person, its application enables both individual and collective health to be protected, preventing the potential contagion of persons who are not at risk and thereby contributing also to the protection of all persons, including those who cannot be vaccinated on account of a specific health condition, notwithstanding that they are specifically at risk. Ultimately, the circumstances of at-risk persons do not by any means negate the collective significance that the protection of health – which is also implemented through the mere recommendation of particular vaccines – takes on also for the population in general.

Thirdly and finally, not even the fact that the recommended vaccine is administered free of charge (as occurred in this case for the vaccine against hepatitis A) could justify any subjective limitation on the class of recipients of compensation.

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 (as is the case for the vaccine against hepatitis A), these constraints certainly cannot justify any release from the duty to pay an indemnity where the statutory prerequisites are met.

Ultimately, a logic of “targeted” cover (according to category of individuals or territorial location) would not only run contrary to the scientific basis to vaccination (which considers widespread immunity coverage as an instrument for protecting health) but would also be at odds with the very rationale for compensatory relief, under which “everybody” bears the cost of harm suffered in the interest of “everybody”. This is because it would thwart the very basis for the recommendation, so much so as to downgrade the choice by a member of an at-risk category or a resident of a particular area to receive the vaccine to a voluntary one (notwithstanding that it is presumably indispensable for the individual’s health), devoid of any direct social ramifications, which would not then be granted any mandatory constitutional relief but rather, at most, attract only discretionary payments (Judgments Nos. 55 of 2019, 293 of 2011, 342 of 1996 and 226 of 2000).

4.– In the light of all of the considerations set out above, Article 1(1) of Law No. 210 of 1992 must be declared unconstitutional 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 vaccine against hepatitis A.

ON THESE GROUNDS
THE CONSTITUTIONAL COURT

declares that Article 1(1) of Law No. 210 of 25 February 1992 (Compensation for individuals harmed by irreversible complications resulting from compulsory vaccinations, transfusions and the administration of blood derivatives) is unconstitutional insofar as it does not make provision for the right to compensation, under the conditions and according to the procedures laid down by the said Law, for those who have suffered injury or illness resulting in a permanent impairment of physical and psychological integrity as a result of vaccination against infection by the hepatitis A virus.

Decided in Rome, at the seat of the Constitutional Court, *Palazzo della Consulta*, on 26 May 2020.

Signed:

Marta CARTABIA, President

Nicolò ZANON, Author of the Judgment