JUDGMENT NO. 5 YEAR 2018

In this case, the Court considered two applications from the Veneto Region contesting a Decree-Law laying down urgent provisions concerning vaccinations. The provisions listed ten vaccines mandatory for all minor children under the age of sixteen residing in Italy (including unaccompanied minor aliens), four of which were already mandatory, and six of which were elevated from recommended to mandatory status. Under the decree-law, the mandatory vaccines are a requirement for access to early childhood educational services, making enrollment contingent upon the presentation of a certificate of vaccination, and non-compliance can also result in administrative fines. The Applicant claimed that these requirements unduly compressed both constitutionally guaranteed freedoms of individuals and regional autonomy. The Court disagreed, and held these allegations to be unfounded. After ruling that interventions by third parties were inadmissible, the Court first described the history of vaccine legislation in Italy, which was marked by a mixture of compulsory and recommended vaccines, all provided free of charge, and varying degrees of regional autonomy in the area of vaccine regulation, particularly when vaccine coverage peaked in the nineteen nineties. Then it noted the current epidemiological context in Italy, marked by a troubling decline in vaccine coverage to levels considered alarming by national and international health organizations and a measles outbreak that had caused four deaths. It also pointed out that there was no scientific basis for a trending popular opinion that considered vaccines to be futile or even dangerous. Then, recalling the Legislator's discretion in carrying out a reasonable balancing of these factors with regional and individual autonomy, the Court drew several conclusions: first, that urgent provisions were appropriate given the preventive nature of vaccination and the critical level of coverage in Italy, and that the Applicant inappropriately conflated epidemic emergencies with the kind of urgent need that could justify legislative intervention. Second, it noted that in medical practice, recommendation and obligation are conjoined concepts, and, therefore, shifting six vaccinations from the recommended to the compulsory category did not represent a significant change in their status. Third, it stated that requiring a certificate to enroll in school and imposing fines were reasonable, not least of all because the Legislator had provided for initial steps that included one-on-one meetings with parents and guardians to inform them about vaccine efficacy. Finally, it noted that, under certain conditions, Regions may experiment with downgrading certain vaccines from mandatory to suggested status, and that the Legislator could, in the future, extend this flexibility to other vaccines as well, under changed epidemiological conditions.

[omitted]

THE CONSTITUTIONAL COURT

[omitted]

gives the following

JUDGMENT

in proceedings concerning the constitutionality of Articles 1(1), (2), (3), (4), (5), and (7) of Decree-Law no. 73 of 7 June 2017 (Urgent provisions concerning vaccination) and Articles 1(1), (1-*bis*), (1-*ter*), (2), (3), (4), and (6-*ter*); 3; 3-*bis*; 5; 5-*quater*; and 7 of the same Decree-Law, converted, with modifications, by Law no. 119 of 31 July 2017, initiated by the Veneto Region with applications served on 24-28 July and 14-15

September 2017, filed with the Registry on 25 July and 21 September 2017, and registered as no. 51 and 75 of the 2017 Register of Applications.

Considering the entries of appearance of the President of the Council of Ministers, as well as the acts of intervention by the association "*Aggregazione Veneta – Aggregazione delle associazioni maggiormente rappresentative degli enti ed associazioni di tutela della identità, cultura e lingua venete*" [An aggregation of the associations that best represent the entities and associations that work to protect the identity, culture, and language of the Veneto Region], as well as L.P.; by the "*Associazione per Malati Emotrasfusi e Vaccinati*" [Association of persons injured by blood transfusions and vaccines] (AMEV), jointly with (regarding the proceedings registered as R.R. no. 75 of 2017) L.B. and C.C., as parents acting on behalf of the minor L.C.; of the CODACONS associations and "*Articolo 32 – Associazione italiana per i diritti del malato*" [Italian association for the rights of the sick] (AIDMA) (concerning the proceedings registered as R.R. no. 51 of 2017); by the "*Coordinamento nazionale danneggiati da vaccino*" [National collaboration of those injured by vaccines] (CONDAV) (concerning the proceedings registered as R.R. no. 75 of 2017);

having heard from Judge Rapporteur Marta Cartabia during the public hearing of 21 November 2017;

having heard from counsel Marco Della Luna on behalf of the *Aggregazione Veneta* and L.P., Marcello Stanca on behalf of AMEV, L.B., and C.C., Tiziana Sorriento on behalf of CODACONS and AIDMA, Vanni Domenico Oddino on behalf of CONDAV, Luca Antonini and Andrea Manzi on behalf of the Veneto Region and State Counsel Enrico De Giovanni and Leonello Mariana on behalf of the President of the Council of Ministers.

[omitted]

Conclusions on points of law

1.– The Veneto Region has raised questions concerning the constitutionality of Decree-Law no. 73 of 7 June 2017 (Urgent provisions concerning vaccination), as a whole and with regard to Article 1(1)-(5), and Articles 3, 4, 5, and 7 (Application registered as R.R. no. 51 of 2017); as well as the same Decree-Law as converted, with modifications, by Law no. 119 of 31 July 2017 (which also modified its title, which became "Urgent provisions concerning vaccination, infectious diseases, and disputes relating to the administration of medicinal drugs"), as a whole and with regard to Article 1(1), (1-*bis*), (2), (3), (4), and (6-*ter*) and to Articles 3, 3-*bis*, 4, 5, 5-*quater*, and 7 (proceedings registered as R.R. no. 75 of 2017).

The two applications raise largely overlapping questions, the object of which is, in brief, the provision of ten (initially twelve) vaccines that are compulsory for all minors up to sixteen years of age, including unaccompanied minor aliens, and the imposition, in cases of noncompliance, of administrative fines and exclusion from early childhood educational services.

[omitted]

3.– Before examining the constitutional questions, and within the limits of what is necessary for purposes of constitutional scrutiny, it is necessary to establish two sets of premises with regard to particular aspects of the vaccine regulations that were in place prior to the contested provisions, the context in which these provisions took shape, and their contents.

3.1.– On the eve of the adoption of D.L. no. 73 of 2017, the general vaccine obligations for the pediatric segment of the population were provided by Law no. 891 of 6 June 1939 (Compulsory diphtheria vaccine), Law no. 292 of 5 March 1963 (Compulsory tetanus vaccine), Law no. 51 of 4 February 1966 (Compulsory poliomyelitis vaccine), and Law no. 165 of 27 May 1991 (Compulsory vaccine against hepatitis B virus).
These laws required students enrolling in primary schools and other childhood group settings to present certification of vaccination at the time of enrollment. [omitted] In cases of noncompliance, they provided for [omitted] administrative sanctions in the form of fines.
[omitted]
3.2.– In the meantime, particularly starting with the National health plan for the three-year period 1996-1998 (approved with the decree of the President of the Republic 23 July 1998), vaccine policy goals were established (including some concerning coverage for particular segments of the population) regarding additional vaccines that were not included among the compulsory ones, but were nevertheless considered worthy of recommendation and, for this reason, actively offered free of charge to all relevant parties through the engagement and upon the direct initiative of the public healthcare services.
[omitted]
In the context of this gradual evolution, and in order to further its objectives, a series of vaccine schedules were also adopted, which included both the compulsory and the recommended vaccines. This was accomplished first with the ministerial decree of 7 April 1999 (New schedule of the compulsory and recommended vaccinations for the developing years), and later with the schedules included in the 2005-2007 *Piano nazionale di prevenzione vaccinale* [National Plan for Prevention through Vaccination] (PNPV), the 2012-2014 PNPV, and the 2017-2019 PNPV.
3.3.– At the same time, doubts were raised concerning the ability of the aforementioned fines to effectively contribute to achieving vaccine policy objectives. For this reason, although the laws on compulsory vaccines already mentioned remained in force, starting with the 2005-2007 PNPV, Regions in which vaccination services met certain criteria for effectiveness and efficiency (i.e. an effective system for spreading information, with a well-organized registrar of vaccinations; adequate coverage; a surveillance system that is sensitive, specific, and integrated into the regional and local public health service's information flow; and active monitoring of adverse events).
The Veneto Region, among others, took steps in this direction by adopting aforementioned Regional Law no. 7 of 2007, followed by a series of administrative measures, which, taken together, gave shape to the system that is referred to time and again by the Applicant in the present case.
[omitted]
3.4.– In brief, leaving aside the legal obligation to undergo the "historical" vaccines against diphtheria, tetanus, poliomyelitis, and hepatitis B, the national legislator, in recent years, has gradually expanded the category of vaccines that are offered to the population actively and free of charge, partly by adding all those provided for in D.L. no. 73 of 2017, as converted by Law no. 119 of 2017. Moreover, over the last decade, the Regions have been permitted, under certain conditions, to experiment with a temporary suspension of the legislative obligations, in order to obtain vaccine coverage exclusively through recommendations and persuasion aimed at the relevant population.

However, for some years since, there has been a decline in vaccine coverage. For present purposes, suffice it to recall that, according to the 2017-2019 PNPV, to be very brief, vaccine coverage grew until the mid-2010s, when the growth trend stabilized, reaching a maximum of ninety-five percent, except for measles, mumps, and rubella. In contrast, the most recent data (from 2015, concerning the 2013 cohort) confirm a downward trend, already underway in the three preceding years.
[omitted]
3.7.– The 2017-2019 PNPV, which came out a few months before the adoption of the contested decree-law, also provides context. It took a neutral position on compulsory vaccines and the possibility of moving beyond this requirement, in the part in which it pointed out that the downward trend, which was also evident on the basis of region-level data, had to be more thoroughly investigated and understood, leaving open the possibility of creating "updated standards, which guarantee the protection of individuals and the community, with measures suited to the purpose, for example by requiring certification that the vaccinations provided by the schedule have been administered in order to enroll in schools."
3.8.– Then, in 2017, after the publication of the 2017-2019 PNPV, a measles outbreak raised new concerns. The outbreak peaked in spring of that year and was marked by some unusual characteristics, including the number of cases (4,885, including four deaths, according to the weekly newsletter of the *Istituto Superiore di Sanità*, or ISS [Higher Institute of Health], as of 12 December 2017), the median age of the patients (27 years), and the level of complications and hospitalizations.
4.– It was in this context that D.L. no. 73 of 2017 was adopted, and it is relevant now to turn to an examination of its contents, both before and after the conversion effected by Law no. 119 of 2017.
4.1.– Initially, Article 1(1) provided twelve compulsory and free vaccinations: in addition to the four that were historically compulsory (against diphtheria, tetanus, poliomyelitis, and hepatitis B), it included pertussis, Hib, meningitis B and C, measles, rubella, mumps, and varicella. The obligation falls on minors from zero to sixteen years of age, "on the basis of the specific indications of the Vaccine Schedule concerning each birth-year cohort."
Since all the vaccines in question were already provided for in the vaccine schedules, with the timeframes established therein, and in precisely the same timeframes were rendered compulsory by the contested decree-law, none of them may be said to be new. What are new, on the contrary, are the compulsory requirements and the measures intended to make them effective, including sanctions. Therefore, the decree-law did not introduce new vaccines, but reinstated, or rather, extended the obligation to subject minors to the vaccines already envisaged by the health plan.
Sections (2) and (3) of Article 1 identify two exceptions to compulsory vaccinations: cases of pre-existent immunity stemming from having naturally contracted a disease, in relation to which proof must be provided, and cases in which they pose a danger to one's health due to specific, documented medical circumstances. In these cases, vaccines may be omitted or deferred.
When it was converted, a clause stating that these compulsory requirements also apply to unaccompanied minor aliens was added to Article 1.
Moreover, leaving in place the reference to the specifications provided by the national vaccine schedule for each birth-year cohort, the compulsory and free vaccines were reduced from twelve to ten. Those that remain compulsory are poliomyelitis, diphtheria,

tetanus, hepatitis B, pertussis, and Hib (section 1), as well as measles, rubella, mumps, and varicella (section 1-*bis*).
The vaccines for meningitis B and C, as well as those for pneumococcal disease and rotavirus are not compulsory, but are offered actively and free of charge (section 1-*quater*).
The conversion law also introduced section 1-*ter*, which provides that for vaccines described in section 1-*bis*, after the passage of three years after the adoption of the conversion law, and every three years thereafter, the Minister of Health may, by decree, suspend the compulsory requirement, in light of new data resulting from epidemiological studies, adverse reactions, or coverage goals met, following a procedure that involves technical-scientific bodies, the State-Region Conference, and the competent parliamentary committees.
4.2.– As for the sanctions that apply in cases of noncompliance, the conversion law introduced significant modifications.
[omitted]
After the conversion, [omitted], non-complying persons are, first of all, "summoned by the competent local health service for the area [ASL] for an interview intended to provide further information on vaccines and urge the administration thereof" (sentence one). The provision confirms that any potential objection brought by the ASL will not be followed by sanctions if, within the timeframe established by that ASL, the vaccination, or the administration of the first dose thereof (provided that the cycle is then duly completed), does, indeed, take place.
In case of noncompliance, a fine is imposed that is significantly lower than the one provided by the original decree-law: from a minimum of 100 to a maximum of 500 euros (instead of minimum 500 and maximum 7,500 euros).
The conversion law abolished Article 1(5), which called for notifying the public prosecutor's office at the juvenile court of the violation.
[omitted]
4.3.– Articles 3 through 5 regulate the verification of vaccination compliance at the time of enrollment and other aspects that fall under the competence of the schools administration.
Under Article 3 (which the conversion law modified in ways that are not relevant here), at the time of the minor's enrollment, and within the enrollment deadline, the administrators of the educational institution are required to ask parents and guardians to present one of the following records (section 1): a certificate of vaccination, deferment, or exemption; a substitutive declaration, with the successive presentation of certificates; or a request, made to the ASL, for the vaccinations. The school administration must notify the ASL within ten days of any failure to present at least one of these records (section 2).
With regard to admission to educational institutions, Article 3(3) of the decree distinguishes between, on one hand, educational services and schools for early childhood, access to which is contingent upon compulsory presentation of the necessary records, and, on the other, all other schools, in which students may attend and take exams despite the failure to present the necessary records.
Article 3-*bis*, which was introduced by the conversion law, simplifies the duties of families in question, beginning from the 2019/2020 school year.
Article 4, converted with modifications to the original text that are irrelevant for present purposes, involves the placement of minors who have not undergone the compulsory

vaccinations in the education system: as a rule, they should be placed in classes made up exclusively of vaccinated or otherwise immune minors, without prejudice to the number of classes determined by the applicable regulations and the limits of the human resources derived from the rules mentioned in the same Article 4. Moreover, administrators must notify ASL on an annual basis of any classes containing more than two unvaccinated minors.

Article 5 (which was modified by the conversion law) lays down transitional rules for the 2017-2018 school year.

4.4.– Law no. 119 of 2017 inserted Articles 5-*bis*, 5-*ter*, and 5-*quater* into D.L. no. 73 of 2017. These articles deal with the compensation described in Law no. 210 of 25 February 1992 (Compensation for persons damaged by irreversible complications caused by compulsory vaccinations, transfusions, and the administration of blood products). In particular, Article 5-*quater* provides that "[t]he provisions of Law no. 210 of 25 February 1992 apply to all persons who have suffered injury or illness caused by the vaccinations indicated in Article 1, and from which the permanent impairment of his or her physical or psychological integrity has resulted."

[omitted]

6.– The questions raised in reference to Article 77(2) of the Constitution are unfounded.

6.1.– From Judgment no. 29 of 1995 until the present, constitutional case law has consistently held that the prerequisites of necessity and urgency found in Article 77 of the Constitution are necessary conditions for decree-laws to be valid and that, therefore, it falls within the powers of this Court to verify their existence.

This Court has also held, with equal constancy, that it must limit its review to the clear absence of these prerequisites, distinguishing the purview of its judgment from that of the purely political evaluation, which is the purview of Parliament in issuing conversions approving decree-laws: indeed, Article 77 of the Constitution is characterized by "a broad degree of flexibility" (Judgment no. 171 of 2007; see also Judgment no. 93 of 2011), so that only the clear absence of a situation that actually involves the necessity and urgency to take action determines both a defect in the decree-law as well as a procedural defect in the conversion law (see, most recently, Judgment no. 170 del 2017).

For the purpose of scrutinizing the fulfillment of the requirements found in Article 77(2) of the Constitution, this Court has highlighted a number of intrinsic and extrinsic indicators: the title, preamble, contents and reasoning behind the decree-law, the explanatory memorandum of the draft conversion law, and the parliamentary working sessions.

6.2.– Applying the principles here described to the present case, it is relevant, first of all, to observe that the preamble to D.L. no. 73 of 2017 refers to the need to "guarantee, in a homogeneous way throughout the national territory, activities the purpose of which is to prevent, contain, and reduce threats to the public health and to ensure that adequate conditions for epidemiological safety are consistently maintained in terms of prophylaxis and vaccine coverage;" as well as ensuring "respect for the obligations undertaken and strategies agreed upon at the European and international level and the common objectives established in the European geographic area." Similar expressions can be found in the text of Article 1(1) of the decree-law, to which the conversion law added a reference for the purpose of meeting the overriding objectives of the 2017-2019 PNPV.

The explanatory memorandum on the draft conversion law, in the part relevant for present purposes, retraces the legislative history of vaccines, highlighting the decline in vaccine coverage in recent years, the instances within Italy of preventable illnesses (including measles, which breaks out periodically in epidemic form), which have led Regions and local institutions to launch initiatives intended to control access to public services for early childhood. The report expands upon the reasons that justify the imposition of a duty to undergo each of the vaccines, corroborating these claims with data about the level of coverage reached in each case and the occurrences of the individual diseases. It then draws attention to the fact that even diseases no longer occurring in Italy have not been entirely eradicated and could come back, potentially also in consequence of migratory flows (for example, it refers to the outbreak of polio in Syria). Referring to statistics from the WHO (*World Health Statistics*, published in May 2017), the report lists ninety-three per cent vaccine coverage for Italy, a lower number than that reported in many European States.

A review of the most important indicators for purposes of evaluating the decree-law's prerequisites must also account for the fact that in the course of the legislative investigation carried out for the draft conversion law by the 12th Permanent Commission of the Senate (Health and Hygiene), the WHO Regional Office for Europe expressed concern about the current situation involving diseases preventable by vaccine in Italy, particularly measles, as well as the tendency of vaccine coverage to stagnate or regress. The letter from the WHO also highlights the importance of compulsory vaccines, as well as the benefits of checking children's vaccine histories at the time of their enrollment in schools.

6.3.– In light of the factors just described, and in consideration of the context surrounding D.L. no. 73 of 2017 (characterized, among other things, by a downward trend in vaccine coverage, see point 3.4 of the *Conclusions on points of law* above) the Government, first, and then the Parliament, cannot be held to have overstepped the limits of the wide margin of discretion to which they are entitled under Article 77(2) of the Constitution, in evaluating the prerequisites of extraordinary necessity and urgency that justify the adoption of a decree-law in this area.

6.4.– None of the arguments put forward to the contrary by the Veneto Region is convincing. First of all, the finding that the ninety-five percent threshold should be considered optimal and not critical is questionable. It seems that none of the competent national and international institutions draw such a distinction in their official guidelines; on the contrary, in at least one instance, and in reference to "vaccine coverage for measles-mumps-rubella," the 2017-2019 PNPV defines ninety-five percent as the "critical threshold necessary to prevent the circulation of the virus and, therefore, to achieve the elimination objective envisaged for 2015 in the WHO European region." In any case, the central point is that the unmet objectives were a part of various vaccine plans adopted in Italy over the course of many years, most recently by the 2017-2019 PNPV just mentioned. In the face of vaccine coverage that is unsatisfactory in the present and trending toward critical levels in the future, this Court holds that it falls within the discretion (and the political responsibility) of government bodies to appreciate the overriding urgency to intervene, in light of the new data and new epidemiological phenomena that have emerged in the meantime, including in the name of the principle of precaution, which must preside in an area as crucial for the health of every citizen as that of prevention.

Concerning the 2017 measles epidemic, the fact that it has particularly impacted a certain segment of the population (adults) does not undercut the opportunity to increase the prophylaxis among the population in early stages of development, both for their protection, and in order to reverse the decline in coverage.
Nor should one deny, as the applicant appears to do, that the adopted measures, in and of themselves, have immediate effect: one need only consider that the regulations in question impose a non-deferrable obligation, albeit by laying down specific terms for each of the vaccines and articulating the necessary procedural steps, according to a reasonable regulatory technique, considering the ubiquity of the impact. In any case, this Court has already recently stated that, "extraordinary necessity and urgency do not necessarily posit immediate application of the regulatory provisions contained in the Decree-Law, but may well be based upon the need to act with urgency, even when the result may, in certain respects, be necessarily deferred" (Judgment no. 16 of 2017).
Again: in one of its memoranda, the Veneto Region writes that, if sporadic cases of diseases currently inexistent in Italy were to reappear, "one may rest assured that the vaccine coverage would leap to 100 percent in a matter of days!" A consideration such as this one reveals an improper conceptual melding of the concept of urgency to act with that of a public health crisis: vaccine coverage is a preventative tool to be used independently of any ongoing epidemic. It is, therefore, necessary to conclude that it falls within the discretion of the Government and the Parliament to intervene prior to the emergence of crisis scenarios and to decide – in the face of a long-term situation of unsatisfactory vaccine coverage – not to delay further before addressing it through extraordinary measures, including in light of the deadlines connected with the start of the school year.
[omitted]
8.2.– The questions raised in reference to Articles 2, 3, and 32 of the Constitution are unfounded.
In reference to these parameters, the Applicant states that it has no intention of contesting, as a matter of principle, the usefulness of vaccines for the preservation of health, nor to underestimate the need for a public commitment in order to spread them ubiquitously throughout the population. What the Applicant does contest, however, is the challenged regulation's sudden introduction of a significant list of compulsory vaccines. To make this point, the Application contrasts the choice made by the State legislator with the effectiveness of the different strategy adopted by the Veneto Region with the regional law mentioned above, no. 7 of 2007, based on efforts to convince and persuade the public. It claims that this method better respects the free self-determination of the individual and effects a more even balancing between needs related to individual and collective health protection and those related to freedom from imposed medical treatments, parameters enshrined in Article 32 of the Constitution, as well as by many international and supranational legal instruments, to which the Application refers, without, however, developing any independent constitutional questions or specific arguments in relation to them.
8.2.1.– It bears noting, first and foremost, that the case law of this Court in the area of vaccinations has been unwavering in holding that Article 32 of the Constitution posits the necessary balance between the individual right to health (including in reference to freedom concerning treatment) and the coexistent and reciprocal right of others and the interests of the collectivity (see, most recently, Judgment no. 268 of 2017), as well as, in the case of compulsory vaccinations, the interests of children, who require protection

even vis-à-vis parents who do not fulfill their duties of care (see, among many, Judgment no. 258 of 1994).
Specifically, this Court has stated that the law imposing a health-related treatment is not incompatible with Article 32 of the Constitution if: the treatment is intended not only to improve or maintain the health of the individual in receipt of treatment, but also to preserve the health of others; it is provided that the treatment may not have a negative impact on the health of the recipient, with the exclusive exception of those consequences that normally result and, as such, are tolerable; and, in the case of further injury, the payment of equitable compensation to the injured party is provided for, separate and apart from any damages to which they may be entitled (Judgments no. 258 of 1994 and 307 of 1990).
Thus, the vaccination issue involves many constitutional values, which implicate, in addition to the individual freedom of self-determination in choices inherent in healthcare treatments and the protection of individual and collective health (enshrined in Article 32 of the Constitution) also the interests of the minor child, which should be pursued, first of all, through the parents' exercise of their right-duty to take action that is well-suited to protecting the health of their children (Articles 30 and 31 of the Constitution), guaranteeing, however, that this freedom is not employed to make choices that are potentially detrimental to the health of the minor child (on this point see, for example, Order no. 262 of 2004).
The coexistence of these multiple principles leaves room for legislative discretion in choosing the ways in which to ensure effective prevention of infectious diseases, since the legislator may, at a given time, select the technique of recommendation and, at others, that of obligation, and in the latter case may calibrate the measures (including those imposing sanctions) that are intended to guarantee the effectiveness of the requirement. This discretion must be exercised in light of the various health and epidemiological conditions, as ascertained by the responsible authorities (Judgment no. 268 of 2017) and of the constantly evolving discoveries of medical research, to which the legislator must turn for guidance in the exercise of its choices in this area (as confirmed by the well-established case law of this Court since its landmark Judgment no. 282 of 2002).
8.2.2.– A look at comparative law also reveals a variety of approaches. Given a general legal preference for policies that spread vaccine use – based on statistics and experimental evidence drawn from the competent authorities, and particularly the WHO, which consider vaccination to be an indispensible measure for guaranteeing public and individual health – different legal systems select different tools for meeting these common objectives.
At one extreme are measures which, even recently, attach criminal sanctions to compulsory vaccine laws (France); at the opposite end of the spectrum are vaccine promotion programs that leave maximum room for individual autonomy (like in the United Kingdom). Falling between the two are a variety of choices calibrated in different ways, which include examples in which vaccination mandatory in order to enter the school system (like in the United States, certain autonomous communities of Spain, and France to this day) and others that require parents (or guardians exercising parental responsibility) to consult a doctor prior to making a choice themselves, or else face fines (Germany).
The varying intensity of these obligations corresponds to an equally variegated landscape when it comes to the number of vaccines suggested or required.

In many countries, moreover, debate concerning vaccination policies is ongoing, aimed at finding more effective legal tools for achieving the shared objective of protecting public health against infectious diseases and diseases that may lead to serious complications, which are containable through preventive vaccination.

8.2.3.– The evolution of Italian legislation in this area also manifests as a succession of vaccine policies of varying kinds, in which the emphasis has alternated between the side of obligation and that of recommendation (as described above at point 3.4. of the *Conclusions on points of law*).

In the late 1990s, in keeping with the greater emphasis being placed on sensitivity toward the rights of individual self-determination, including in the area of healthcare, vaccine policies based on awareness, information, and persuasion were favored over those based on obligation. These nevertheless ensured that all vaccinations were actively offered, were included in the category of essential services, and were administered free of charge to all citizens at the intervals established by the vaccine schedules. In this context, certain regions experimented with a policy that suspended mandatory vaccination, just as the Veneto region did with Regional Law no. 7 of 2007.

However, over the past few years, a troubling downturn in coverage has occurred, encouraged in part by the spread of the conviction that vaccines serve no purpose, or are even harmful. It is worth noting that this conviction has never been substantiated by scientific evidence, which, on the contrary, supports the opposite conclusion. On this topic it is useful to stress that vaccines, like every other medicinal drug, are subject to the existing pharmacovigilance system, which is chiefly headed by the *Autorità italiana per il farmaco* [Italian Drug Authority] (AIFA). For vaccines, as for other medications, advances in scientific research have permitted the achievement of high levels of safety, except in those individual cases, moreover exceedingly rare according to current scientific findings, in which, for reasons that include the physical makeup of the individual in question, administering vaccines can have negative effects. For this reason, the Italian system considers it crucial to guarantee compensation for these individual instances, whether or not the vaccine was administered per obligation or recommendation (as Judgment no. 268 of 2017 confirmed again recently, in relation to the influenza vaccine). Paradoxically, the very success of vaccines is what leads many people to erroneously consider them superfluous, if not injurious: indeed, with declining perceptions of the risk of contagion and the damaging effects of disease, fears about the adverse effects of vaccines may increase in some segments of the population.

In the face of this phenomenon, the debate over whether to reinstate compulsory vaccination has remained ongoing in various fora. The CNB addressed the topic in 2015, as mentioned above, as did the 2017-2019 PNPV. The *Accademia nazionale dei Lincei* (in its 12 May 2017 report "I Vaccini, issued prior to the adoption of the decree-law), and the ISS, during the parliamentary investigation related to the drafting of the conversion law, expressed reasoning and positions in line with the assumptions underlying D.L. no. 73 of 2017. Moreover, after the decree-law's adoption was communicated to the public, four scientific and professional associations expressed their approval of its position (and actually requested stronger measures to guarantee its effectiveness). These associations (the *Società italiana di igiene, medicina preventiva e sanità pubblica*; the *Società italiana di pediatria*; the *Federazione italiana dei medici pediatri*, and the *Federazione italiana dei medici di medicina generale*) have long been active in the field of vaccine policy, with publications and proposals in the field. During the parliamentary investigation, as mentioned above, the WHO also expressed approval

of the Italian institutions' initiatives, citing some of its own programs in the area of vaccines (*Global Vaccine Action Plan 2011-2010*; *Measles and Rubella Global Strategic Plan 2012-2020*; *European Vaccine Action Plan 2015-2020*). It is also significant that, during the parliamentary working sessions, the *Conferenza unificata* expressed its approval of the provisions of the regulatory scheme in question, albeit with some requested changes, some of which were made in the conversion law ("Opinion, under Article 9(3) of Legislative Decree 197, no. 281, on the draft law for the conversion of Decree-Law no. 73 of 7 June 2017, laying down urgent provisions in the area of vaccination," *Repertorio Atti* no. 71/CU of 6 July 2017), speaking almost unanimously (with the exceptions of the Autonomous Region of Valle d'Aosta/Vallée d'Aoste and the Veneto Region). Some regional legislative initiatives, as mentioned above, had already taken steps along similar lines.

8.2.4.– Thus, today a trend reversal is underway (from recommending vaccines to making them mandatory), and the regulatory scheme under review in the present case is a part of this sea change. Examined in light of the context described in its essential elements, the choice made by the State legislator cannot be condemned on reasonableness grounds for having unduly and disproportionately sacrificed free individual self-determination in view of the protection of the other constitutional goods involved, frustrating, at the same time, the different vaccine policies implemented by the Applicant. Indeed, the legislator, stepping into a scenario in which the tool of persuasion seemed lacking in effectiveness, made ten vaccines mandatory, or, more precisely, it reaffirmed and reinforced the duty, which was never formally abolished, to undergo the four vaccinations already compulsory under State law, and it introduced the duty for the other six vaccines, which were all already offered to the population as "recommended." It is, therefore, incorrect to state – as the Applicant does – that the law abruptly began to impose a large number of vaccines out of thin air; rather, it merely updated the legal title under which some vaccines are administered, having made a certain number of vaccines compulsory that were, in any case, already recommended.

The legal obligation has certainly become more stringent: what was previously recommended has now become mandatory. But in assessing the intensity of this change – for purposes of judging the reasonableness of the balancing operation carried out by the legislator with Decree-Law no. 73 of 2017 and the resulting compression of regional autonomy – it is necessary to consider two sets of factors.

First, 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 (so much so that, when it comes to the right to compensation, no differentiation is made between recommended and mandatory vaccines: see, most recently, Judgment no. 268 of 2017). From this perspective, then, it is important to consider that, even under the preexisting regime, the vaccines that were not legally compulsory were, in any case, suggested with the authoritativeness proper to medical advice.

Second, under the new regulatory framework, based, as already mentioned, on (legal) duty, the legislator, through its conversion law, determined it necessary to preserve adequate space for a relationship with the citizenry based on information, dialogue, and persuasion. In cases of noncompliance with compulsory vaccinations, Article 1(4) of Decree-Law no. 73 of 2017, as converted, provides a procedure that aims, in the first

place, to provide parents (or guardians exercising parental authority) further information about vaccines and to encourage them to see to their administration. To this end, the legislator has called for a designated interview between health authorities and parents, establishing a moment for personal encounter, a tool that is particularly conducive to mutual understanding, persuasion, and informed compliance. Only when this procedure has been completed, and an adequate time frame has been allowed, may administrative fines provided be imposed. The fines have, moreover, been significantly mitigated by amendments introduced by the conversion law.

8.2.5.– In the present context, therefore, the legislator determined that it had to reinforce the binding nature of the tools of vaccine prophylaxis, and crafted a not unreasonable way of intervening given the current state of epidemiological conditions and scientific knowledge. Nothing prevents this choice from being reevaluated and reconsidered should conditions change. From this perspective, which appreciates the evolving dynamic of the medical and scientific knowledge that must shore up regulatory choices in the healthcare field, the legislator, under Article 1(1-*ter*) of Decree-Law no. 73 of 2017, as converted, has properly introduced, through the conversion law, a periodic monitoring system that may lead to lifting the compulsoriness of certain vaccines (specifically those listed in Article 1(1-*bis*): measles, rubella, mumps, and varicella). This element, which provides flexibility within the regulatory scheme, and is triggered by new data findings by the appropriate scientific sources, indicates that the legislator's option to create a duty is solidly anchored to its context and is susceptible to a different evaluation if that context changes.

Moreover, it bears noting that this flexibility applies to only four of the ten vaccines that are compulsory under the law. Changes in the epidemiological conditions, revealed by the data on adverse reactions and vaccine coverage, could suggest to the legislator to provide an analogous mechanism that can also relax the rule in application to the six vaccines indicated in Article 1(1) (poliomyelitis, diphtheria, tetanus, hepatitis B, pertussis, and Hib B).

[omitted]

ON THESE GROUNDS

THE CONSTITUTIONAL COURT

having joined the proceedings,

1) *declares* that the interventions of "*Aggregazione Veneta* - a collective of the associations that best represent the entities and associations that work to protect the identity, culture, and language of the Veneto Region" and L.P., of "*Associazione per Malati Emotrasfusi e Vaccinati*" (AMEV), and of CODACONS and "*Articolo 32 – Associazione italiana per I diritti del malato*" (AIDMA) in the proceedings initiated by the Veneto Region with Application no. 51 of 2017 indicated in the Headnote, are inadmissible;

2) *declares* that the interventions of "*Aggregazione Veneta*" and L.P., of "*Coordinamento nazionale danneggiati da vaccino*" (CONDAV), of AMEV, L.B., and C.C., acting as parents on behalf of the minor L.C., in proceedings initiated by the Veneto Region with Application no. 75 of 2017 indicated in the Headnote, are inadmissible;

3) *declares* that the questions concerning the constitutionality of Article 1(6-*ter*) of Decree-Law no. 73 of 2017 (Urgent provisions concerning vaccination, infectious diseases, and disputes relating to the administration of medicinal drugs), converted by Law no. 119 of 31 July 2017, raised by the Veneto Region in reference to Articles 2, 3,

5, 31, 32, 34, 77(2), 81(3), 97, 117(3) and (4), 118, and 119(1) and (4) of the Constitution, with Application no. 75 of 2017 indicated in the Headnote, are inadmissible;

4) *declares* that the contested action raising the questions concerning the constitutionality of Article 1(1)(*g*) and (*h*), 4, and 5 of Decree-Law no. 73 of 2017 (Urgent provisions concerning vaccination), raised by the Veneto Region in reference to Articles 2, 3, 31, 32, 34, 77(2), 81(3), 97, 117(3) and (4), 118, and 119 (1) and (4) of the Constitution, with Application no. 51 of 2017 indicated in the Headnote, has become devoid of purpose;

5) *declares* that the questions concerning the constitutionality of the entire text of D.L. no. 73 of 2017, and of Articles 1(1), (1-*ter*), (2), (3), (4), and (6-*ter*); 3; 3-*bis*; 4; 5; 5-*quater*; and 7 thereof, as converted by Law no. 119 of 2017, raised by the Veneto Region in reference to Article 77(2) of the Constitution, with the Applications indicated in the Headnote are unfounded;

6) *declares* that the questions concerning the constitutionality of Articles 1(1), (1-*bis*), (2), (3), (4), and (6-*ter*); 3; 3-*bis*; 4; 5; 5-*quater*; and 7 of D.L. no. 73 of 2017, as converted by Law no. 119 of 2017, brought by the Veneto Region in reference to Article 118 of the Constitution, with the Applications indicated in the Headnote are inadmissible;

7) *declares* that the questions concerning the constitutionality of Articles 1(1), (1-*bis*), (2), (3), (4), and (6-*ter*); 3; 3-*bis*; 4; 5; 5-*quater*; and 7 of D.L. no 73 of 2017, as converted by Law no. 119 of 2017, brought by the Veneto Region in reference to Article 5 of the Constitution, with Application no. 75 of 2017 indicated in the Headnote are inadmissible;

8) *declares* that the questions concerning the constitutionality of Articles 1(1), (1-*bis*), (2), (3), (4), and (6-*ter*); 3; 3-*bis*; 4; 5; 5-*quater*; and 7 of D.L. no. 73 of 2017, as converted by Law no. 119 of 2017, raised by the Veneto Region in reference to Article 117(3) and (4) of the Constitution, with the Applications indicated in the Headnote, are unfounded;

9) *declares* that the questions concerning the constitutionality of Articles 1(1), (1-*bis*), (2), (3), (4), and (6-*ter*); 3; 3-*bis*; 4; 5; 5-*quater*; and 7 of D.L. no. 73 of 2017, as converted by Law no. 119 of 2017, raised by the Veneto Region in reference to Articles 31, 32, 34, and 97 of the Constitution, with the Applications indicated in the Headnote, are inadmissible;

10) *declares* that the questions concerning the unconstitutionality of Articles 1(1), (1-*bis*), (2), (3), (4), and (6-*ter*); 3; 3-*bis*; 4; 5; 5-*quater*; and 7 of D.L. no. 73 of 2017, as converted by Law no. 119 of 2017, raised by the Veneto Region in reference to Articles 2, 3, and 32 of the Constitution, with the Applications indicated in the Headnote, are unfounded;

11) *declares* that the questions concerning the unconstitutionality of Articles 1(1), (1-*bis*), (2), (3), (4), and (6-*ter*); 3; 3-*bis*; 4; 5; 5-*quater*; and 7 of D.L. no. 73 of 2017, as converted by Law no. 119 of 2017, raised by the Veneto Region in reference to Article 119(1) and (4) of the Constitution, with the Applications indicated in the Headnote, are inadmissible;

12) *declares* that the questions concerning the constitutionality of Articles 1(1), (1-*bis*), (2), (3), (4), and (6-*ter*); 3; 3-*bis*; 4; 5; 5-*quater*; and 7 of D.L. no. 73 of 2017, as converted by Law no. 119 of 2017, raised by the Veneto Region in reference to Article

81(3) of the Constitution, with the Applications indicated in the Headnote, are unfounded.
Decided in Rome, at the seat of the Constitutional Court, *Palazzo della Consulta*, on 22 November 2017.