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ITALIAN REPUBLIC

THE ADMINISTRATIVE COUNCIL OF JUSTICE FOR THE REGION SICILIAN

Jurisdictional Section

pronounced the present

ORDER

on the appeal number of the general register 1272 of 2021, proposed by

-OMISSIS-, represented and defended by the lawyers Vincenzo Sparti and Roberto De Petro, with digital address as per PEC from the Registers of Justice;

against

University of Palermo, in the person of the *pro tempore legal representative,* represented and defended by the District Attorney of the State of Palermo, domiciliary *under law* in Palermo, via Valerio Villareale, 6;

and with the intervention of

ad adiuvandum:

-OMISSIS-, represented and defended by himself, with digital domicile such as by certified e-mail from the Registers of Justice;

Anief, in the person of the legal representative *pro tempore,* and Mrs. -OMISSIS-, represented and defended by the lawyers Nicola Zampieri and Walter Miceli, with

digital domicile as per PEC from the Registers of Justice;

for reform

of the precautionary order of the Regional Administrative Court for Sicily (Section One) n. 568/2021, made between the parties;

Given the appeal and its annexes;

Given the act of appearance in court of the University of Palermo;

Given the acts of intervention *ad adiuvandum;*

Having seen all the acts of the case;

Speaker in the council chamber on March 16, 2022, Cons. Maria Stella Boscarino and hearing the lawyers for the parties as per the minutes;

1. The appellant, after having stated that he is enrolled in the third year of the course degree in nursing from the University of Palermo and that, al in order to complete his studies, he should have participated in the training internship inside the health facilities, he exposes that he has been prevented from doing so from the University (as not vaccinated against the Sars-CoV-2 virus), with the deeds challenged at first instance, with specific reference to the note, dated April 27, 2021, signed by the Rector and the Director General, with which it was decided that the internships in the medical / health area "will be able to continue in presence within health facilities, following administration anti Covid vaccination - 19 ".

With the appeal in the epigraph he challenged the ordinance before this CGARS of the Sicily Regional Administrative Court which rejected the precautionary request in the proposed appeal against the provision dated 27 April 2021, and the prerequisite acts e consequential.

The appellant argued that he could not be injected with the vaccine both for the experimental nature of the same, and because in the past it had

contracted the Sars-CoV-2 virus, for which he believes he has antibody memory and of perennial natural immunity, and on the other hand, where it is subjected inoculation, would risk dying from ADE (acronym for *Antibody Dependent Enhancement),* phenomenon (described in detail in the consultation part technique produced by the plaintiff) of severe system reaction immune system, which led to a death in the Municipality of Augusta, according to the results of criminal investigations.

The court seised rejected the precautionary request having held "(...) *that, with a view to balancing the opposing interests and the state of affairs, it appears prevailing public interest in avoiding having people attend health facilities not vaccinated, exposing health workers and patients present there to the risk of contagion ".*

2. With the appeal, the erroneousness of the order was complained with regard to the defects found in the application:

- absolute lack of power on the part of the Rector, which he could not introduce limitations on the right to study and processing of vaccination data not provided for by any rule of law;

- violation of recital no. 36 of EU regulation 953-2021 and art. 1, paragraph 6, of Legislative Decree 111 of 6.8.2021 (the so-called green certification is obtained not only after vaccination, but also by virtue of certification medical, where Covid has already been contracted, as in the case of the applicant, or of swab); -

violation of art. 4 dln 44/2021 (converted into ln 76/2021), from which there would be no vaccination obligation for university students;

- erroneousness of the ordinance in the part in which it is alleged that a subject does not vaccinated would expose healthcare workers and patients to the risk of contagion;

- ongoing experimental gene therapy is based on S-protein of the "spikes" of the viral strain originally from Wuhan, which no longer exists

would be more in circulation, having the coronavirus suffered tens of thousands of mutations;

- there could be no vaccination obligation regarding drugs experimental, these being the sera in question, subjected to pharmacovigilance (passive and inactive), for which it is delegated to the owner of the Marketing Authorization to provide the final report on clinical studies;

- it would not be possible in our legal system to impose a vaccination obligation based on experimental drugs, precluding this from the 2014 EU regulation, art. 28 et seq., and art. 32 last paragraph of the Constitution, which prohibits treatments contrary to the human dignity;

- in the VIII AIFA report, more serious adverse events were reported 13% of cases; in addition, the European database “Eudravigilance”, based exclusively on passive surveillance, it counts as many as 23,000 deaths and over 2 millions of adverse events;

- in fact, in the session of the European Parliament no. B9-0475 / 2021 of the day 23.9.2021 the establishment of a «European Compensation Fund for victims of "COVID-19 vaccines" ';

- the figures relating to death and adverse events caused by vaccines would be largely underestimated due to the fact that passive pharmacovigilance does based on spontaneous reports;

- the large number of deceased and seriously disabled persons following the administration of the investigational drugs in question (e.g. in the Kingdom United, the mortality of young people in 2021 would have increased by 47% compared to that at the same period last year, especially for myocarditis) would exclude the configurability of a "vaccination obligation" pursuant to art. 32 of the Constitution;

- where the vaccination obligation is therefore considered applicable to students,

the constitutional illegitimacy of art. 4 dln 44/2021 both for
the violation of art. 117 of the Constitution, and that is for the failure to comply with the Treaty of
Nuremberg on the free consent to the trials, both for the violation
of the art. 3 of the Constitution;

- contrary to what is stated in the defense of the University, it would exist
the irreparable prejudice to the right to study because the appellant has
passed all the other exams and exhausted the lessons to follow;
- the appellant re-proposes the grounds of appeal not examined at first instance
(invalidity derived from illegitimacy of the declaration of the state of
emergency; illegality of the extension of the contained state of emergency
in art. 1 of Legislative Decree 23.7.2021 n. 105; overestimation of deaths due to Covid-19,
as can also be seen from the ISS report updated to 19.10.2021, in
how much is attributed to Covid for every death that occurred in *"the absence of a clear one
cause of death other than Covid-19 "and" for the purposes of evaluating this criterion, no
pre-existing pathologies including cancer are to be considered causes of death other than Covid,
cardiovascular pathologies, diabetes ");*
- invokes the principle of primacy of EU law with reference to, between
the other, to informed consent and to the processing of personal data.

3. With a first brief, the appellant reiterated the uncollectability in his own
regarding the obligation of vaccination, given the natural immunity obtained for
effect of healing.

He then highlighted the continuous increase in deaths and affected by events
adverse, as recorded in the “Eudravigilance” database, also evident in
Italy, despite the limitations of passive surveillance.

He insisted on the objection of the constitutional illegitimacy of the rules for how
raised in the precautionary appeal and in the light of further considerations made in
memory.

4. This Administrative Justice Council for the Sicilian Region, with collegial inquiry ordinance no. 38 of 2022 of 17 January 2022, deemed the existence of the vaccination obligation for the appellant (having to ascribe the university students and trainees within the category of subjects subject to this requirement pursuant to art. 4 of Legislative Decree 44/2021), given some hints on the jurisprudential framework on the subject of vaccination obligation, has arranged investigations instructors, entrusted to a college composed of Secretary General of the Ministry of Health, by the Prime Minister Superior of Health operating at the Ministry of Health and by the Director of the Directorate General for Health Prevention, with the power to delegate.

5. On 11 February 2022 the lawyer -OMISSIS-filed a deed of intervention in court *ad adiuvandum.*

6. On 25 February 2022 the Body in charge of the investigation filed a report, accompanied by illustrative documentation, making i clarifications requested with the preliminary order no. 38/2022.

7. On 11 March 2022 they filed an *ad adiuvandum* intervention deed the Professional and Trade Union Association (in acronym ANIEF) and Ms -OMISSIS-.

The University of Palermo appeared on the same date intimated.

8. All the parties in court, following the preliminary filing, produced memories and documentation in support of the theses discussed therein.

The appellant has also produced two partisan technical consultations, times, between the other, to contest the data and prospects contained in the report investigation.

The University of Palermo pleaded the inadmissibility of the action proposed, both for violation of art. 41 paragraph 2 cpa - not having been the

original appeal notified to *"at least one of the counter-interested parties"* - that due to deficiency of the interest to appeal, since the judicial annulment of the act is not challenged (prot. n. 44582 of 04.27.2021) capable of causing any advantage to the substantial interest of the applicant, declared unsuitable for the carrying out his duties by the Competent Doctor pursuant to art.

41 of Legislative Decree no. 81/2008, with deed (allegedly) not challenged.

On the merits, he highlighted the groundlessness of the arguments made by the appellant as *"focused on personalistic and substantially axioms*

unproven, especially in light of the objective data that emerged during the investigation ".

The contested provision, in any case, would be merely enforceable of the emergency legal provisions, with respect to which they would not remain spaces of discretion of the Administration in its declination "Peripheral".

9. At the chamber hearing of March 16, 2022, subject to prior notice to the parties pursuant to art. 73 paragraph 3 cpa about the existence of profiles of inadmissibility of the deeds of intervention, some clarifications were requested from the Body in charge of the investigation (intervened by delegation to Dr. Giovanni Leonardi and al prof. Franco Locatelli), rendered orally; then, the parties discussed the lawsuit which was withheld in decision.

10. *On the already declared inadmissibility of the interventions ad adiuvandum* With a separate precautionary order (n.117 / 2022) the Board declared the inadmissibility of the acts of intervention *ad adiuvandum* (for the reasons ibid exposed) and all decisions on the suspension request are reserved of the incident of constitutionality that is raised with the present measure.

11. *Matters of ritual.*

11.1. The objections of inadmissibility raised by the Revenue Defense are, ad

notice of the College, unfounded.

11.2. As for the first profile, in consideration of the fact that, alike of pacific indices in jurisprudence (among the most recent Council of justice amm. Sicily section jurisdiction, 21 October 2021, n. 891), in the administrative judgment for counter-interested party means the subject, contemplated or identifiable in the deed contested, which has a substantive interest antithetical to that of the appellant.

In the case in question, from the reading of the contested note of April 27, 2021 there is no indication of a specific hospital health company where the appellant (who is not known to have ever started the internship) had been initiated, nor is it apparent, from the acts of the case, in the context of which hospital facilities the students were left.

11.3. As for the second profile, contrary to what is assumed aside of the University of Palermo, the appellant has certified (see attachment 015 to the appeal) to have challenged the judgment of unsuitability, pursuant to art. 41 paragraph 9 of Legislative Decree no. 81/2008, obtaining the reform, just provision n. 1230 of June 24, 2021 of the Prevention Department at the Health Authority Provincial of Palermo.

12. *The regulatory framework.*

12.1. On the date (27.4.2021) of adoption of the provision challenged with the introductory appeal of the first instance judgment, the original wording of art. 4 of Legislative Decree 44/2021, which, in the previous text, changes made by the conversion law May 28, 2021, n. 76, stated as follows:

<1. In view of the SARS-CoV-2 epidemiological emergency situation, until the complete implementation of the plan referred to in article 1, paragraph 457, of law 30 December 2020, n. 178, and in any case no later than 31 December 2021, in order to protect the public health and maintain adequate safety conditions in the provision of care and assistance services, healthcare professionals and operators of

health interest who carry out their activities in health, social and health and social structures welfare, public and private, in pharmacies, parapharmacies and professional offices are obliged to undergo free vaccination for the prevention of infection with SARS-CoV-2. Vaccination is an essential requirement for the exercise of profession and for carrying out the work performed by the obliged subjects. There vaccination is administered in compliance with the indications provided by the regions, by autonomous provinces and other competent health authorities, in accordance with the provisions contained in the plan.

2. Only in case of ascertained danger to health, in relation to specific clinical conditions documented, certified by the general practitioner, the vaccination referred to in paragraph 1 it is not mandatory and can be omitted or deferred. (omitted)>.

12.2. The conversion law of the legislative decree 44/2021 (l. May 28, 2021, n. 76) amended paragraph 1 of art. 4 identifying which operators of interest health care those referred to in art. 1, paragraph 2, of the law of 1 February 2006, n. 43, a mind of which <*are health professions, nursing, midwifery, rehabilitation, technical-sanitary and prevention, those provided for under the law 10 August 2000, n. 251, and the decree of the Minister of Health of 29 March 2001, published in the Gazzetta Journal No. 118 of 23 May 2001, whose operators perform, under a title qualifying issued by the state, prevention, assistance, treatment or rehabilitation activities>.*

12.3. The art. 1, paragraph 1, lett. b) 4 of the legislative decree 26 November 2021 n. 172, then, replaced art. 4 of the legislative decree 44/2021.

In paragraph 1 it was specified that compulsory free vaccination should to be understood as inclusive, with effect from 15 December 2021, of the administration of the booster dose following the primary vaccination course, in compliance with the indications and deadlines provided by the Ministry circular of health

Paragraph 2 of art. 4 was reformulated as follows:

<2. Only in case of ascertained danger to health, in relation to specific conditions documented clinics, certified by the general practitioner, in compliance with the circulars of Ministry of Health on SARS-CoV-2 vaccination exemption, no the obligation referred to in paragraph 1 exists and vaccination can be omitted or deferred>.

12.4. During the conversion of the legislative decree 172/2021 (with the law of 21 January 2022 n.3), finally, an amendment was approved which added to art. 4 paragraph 1 of Legislative Decree 44/2021, paragraph 1-bis which establishes: <*the obligation referred to in paragraph 1 is extended, starting from February 15, 2022, also to students of degree courses engaged in carrying out practical-evaluative internships aimed at achieving the qualification to exercise the health professions. The violation of the obligation referred to in the first period determines the impossibility of accessing the structures where the internships take place practical-evaluative. The managers of the structures referred to in the second period are required to verify compliance with the provisions referred to in this paragraph according to sample procedures identified by the institutions to which they belong>.*

12.5. As for the cd. informed consent, the general discipline is contained in the l. 22 December 2017, n. 219, which, in article 1 establishes that <*in compliance with principles referred to in articles 2, 13 and 32 of the Constitution and articles 1, 2 and 3 of the Charter of the fundamental rights of the European Union, protects the right to life, health, dignity and self-determination of the person*> <*no health treatment can be started or continued if without the free and informed consent of the person concerned, except in cases expressly provided for by law>.*

The content of the fifth paragraph is correlated to the affirmation of these principles of article 1, according to which every person capable of acting has the right to refuse, in whole or in part, any diagnostic assessment or treatment sanitary.

As for vaccination for the prevention of SARS-CoV-2 infection, the provision for signing the consent form has been updated with

note prot. n. 12238-25 / 03/2021-DGPRE and subsequent 0012469-28 / 03 / 2021-DGPRE-DGPRE-P of the Directorate General for Health Prevention.

The art. 5 of Legislative Decree 44/2021, then, regulated the manifestation of consent to health treatment of the Covid-19 vaccine for incapacitated individuals.

13. *Notes on the main jurisprudential orientations.*

With regard to the problems raised by the vaccination obligation in question, yes numerous judicial rulings have been recorded, in precautionary or in phases merit, among which we can mention:

- the decisions of the Council of State, section III, 20 October 2021, n. 7045 as well as February 28, 2022 n. 1381 (in addition to numerous rulings in the seat precautionary), which have extensively reconstructed the main issues that come into relief in the matter in question (on which see below, in continuation of the exhibition);
- the decision of the Lombardy TAR, first section, which with precautionary order no. 192/2022 of 14.2.2022 announced the constitutionality incident of art. 4, paragraph 4, of the legislative decree 44/2021, in the text currently in force, in the part in which it provides, due to the non-fulfillment of the vaccination obligation, the suspension from exercising the health professions;
- the order of the Labor Court of Padua of 7 December 2021, for reference preliminary ruling to the Court of Justice of the European Union, with reference to the compatibility with regulation number 953/2021 and the principles of proportionality and non-discrimination of the anti-Covid vaccination obligation a burden of health personnel, having regard, among other things, to the doubt about the continuing validity of conditional authorizations relating to vaccines, pursuant to of the art. 4 of regulation no. 507 of 2006, once treatments were approved alternatives for SAR-Cov-2 virus infection, as well as about legitimacy of the vaccination obligation for health workers already infected, who therefore have

achieved a natural immunization, or who oppose the obligation
vaccination in relation to contraindications.

14. *About the relevance of the question.*

14.1. The Board believes that the appeal profiles aimed at supporting, for various reasons,
the inapplicability to student trainees of the vaccination obligation introduced
from art. 4 of Legislative Decree 44/2021 are unfounded, having regard to both the extent
of the forecast (referring to the category of recipient healthcare professionals
of the vaccination obligation) of the legislation (referred to above) applicable *ratione*
temporis, on the date of adoption of the contested act, both at the *ratio* of the same, and
is evidently that of protecting the health of those who frequent health centers,
in particular of patients, who often find themselves in a condition of fragility e
they are exposed to serious dangers of contagion.

The Board reaches this conclusion:

- in compliance with the principles expressed by the decision of the Council of State, section
III, sentence of 20 October 2021, n. 7045, according to which the compulsory selective vaccination
introduced by art. 4 of Legislative Decree 44/2021 for personnel
medical and, more generally, of health interest responds to a clear purpose
protection not only - and above all - of this personnel in the workplace and,
therefore, for the benefit of the person, but for the protection of the patients themselves and of the
public and private healthcare users, according to the principle of solidarity (art.2
Constitution), and more particularly of the most fragile categories and of the most subjects
vulnerable, who are in need of care and assistance, often urgent, and their own
for this reason I am in frequent or continuous contact with the staff
health or social health in the places of care and assistance; -
consistently with the provisions of art. 2 of Legislative Decree no. 81/2008 (supplemented and
amended by Legislative Decree no. 106/2009), on occupational hygiene and safety,
which qualifies the person as a "worker" who, regardless of the type

contractual, carries out a work activity within the organization of a public or private employer, with or without pay, even alone purpose of learning a trade, an art or a profession, including subjects beneficiaries of the initiatives of training and orientation internships, the students of the educational and university institutions and the participants in the courses professional training in which use is made of laboratories, equipment of work in general, chemical, physical and biological agents.

Therefore, in the opinion of the Board, art. 4 of Legislative Decree 44/2021, where it provides the vaccination obligation for *"health professionals and operators of interest health care ",* must be interpreted in the sense of including trainees who, in the of the training course, come into contact with users in the health sector, using the same reasons for the protection of patients.

14.2. The provision of the Cabinet Office of the Rector of the University of the studies of Palermo prot. n. 44582 of 27 April 2021 challenged was adopted in the force of the original formulation of art. 4 of the legislative decree 44/2021, so that, like the proposed interpretation, the provision contested was legitimate, without hindering that conclusion regulatory contingencies (mentioned above) which have, from time to time, reformulated the provision, up to the current text, from whose reading it would seem that the legislator intended to introduce the obligation vaccination for trainee students only when converting the dln 172/2021.

This interpretation, in reality, was not enucleable from the original text of the norm.

The act, therefore, originally corresponded to the regulatory formation of the case in point; nor the legislation that occurred when the provision was issued it can be considered to have affected its validity, in accordance with the general principle

according to which the legitimacy of a measure must be appreciated with reference to the state of fact and law existing at the time of its

emanation, according to the *tempus regit actum principle,* with consequent irrelevance of regulatory contingencies, except for the exercise of the power of self-protection in order to remove the effects of the compliant provision to the legislation dictated *illo tempore* but differs from the supervening legislation; self-protection, in this case, not exercised.

So that the provision challenged at first instance, legitimate to moment of the emanation, it would have become, in theory, affected by “illegitimacy occurred ”within a time span, however, now consumatosi, given that, in any case, from February 15th it is explicitly stated introduced the vaccination obligation for trainees.

But this "supervening illegitimacy", which has now disappeared, does not could certainly determine the cancellation of the provision, with all related consequences, including in terms of compensation.

In the opinion of the College, the correct exegesis of the rule in force at the time did not could only lead to the application of the vaccination obligation also to the trainees.

Undoubtedly we are aware of the delicacy of an interpretation *secundum ratio* on compulsory medical treatment.

But, should it be held otherwise, the unmanifest should be appreciated groundlessness of the doubt of constitutional legitimacy (in relation to articles 3 and 32 of the Charter) of the regulatory complex, where otherwise interpreted, in how much, in the face of the protection ratio of fragile subjects in the area hospital, would have irrationally exempted from mandatory vaccination, until February 15, 2022, one category of subjects (student trainees) intended to operate in close contact with users, in a situation of the whole

similar to doctors and other health professionals, risking to compromise, without any appreciable reason, the protection needs they have determined the introduction of the vaccination obligation.

14.3. Once the trainees were subject to the obligation in question, it comes denied the alleged incompetence of the Administration, as the deed challenged did not introduce a *new* vaccination obligation but gave one correct interpretation of the relevant legislation.

14.4. As already noted with the ordinance of this Council no. 38/2022, al current regulatory status, the vaccination obligation does not exist in the event of an ascertained one health hazard, in relation to specific and documented conditions clinics, certified in compliance with the provisions of the Ministry's circulars of health regarding the exemption from vaccination against SARS-CoV-2 (su which v. *below).* However, this is not evident from the documentation in the file condition of the appellant; as for immunization following natural disease, proven by notification by the attending physician, the itself determines the postponement of vaccination to the first useful date provided for by the circulars of the Ministry of Health, and by the documentation in deeds it appears that this period has been exceeded, so the appellant should undergo to vaccination.

Reason for which the subordinate questions of constitutionality come to the fore of the legislation on the obligation to vaccinate Sars-Cov-2 raised by the appellant.

15. *The grievances of the appellant.*

15.1. During the trial, and also following the preliminary findings, the arguments of the appellant focused on the alleged illegitimacy of the regulatory complex that introduced the vaccination obligation, with reference, on the one hand, to the specific situation of the subjects who have

previously contracted the virus, and in any case in relation to the complained one danger of vaccines currently used in Italy.

15.2. The preliminary findings (which will be discussed below) part applicant has put forward a series of exceptions, summarized in the consultancy techniques filed in view of the chamber hearing.

In a nutshell, the scholars appointed by the appellant, after having recalled that the vaccines available to deal with the SARS-Cov-2 virus belong to three types (traditional type, inactivated virus; protein vaccines; based vaccines on the use of DNA or RNA), they focused on the third type of drugs, for the first time administered on a large scale, the mechanism of which, different from conventional vaccines (and which should determine, to them notice, the inclusion in the category of gene therapies, as defined in point 2.1 All.I, p.IV, of Directive 2001/83 / EC), provides for the release into the tissues and in the organs of active principles that induce the relative cells to produce the viral protein which will then be recognized by the immune system, triggering i antibody production processes.

The scholars appointed by the appellant allege that:

- the average development time of these vaccines ranges from seven to nine years; the pandemic emergency has made it necessary to accelerate the timing of development, enlarging the sample of treated subjects and partially overlapping them various stages of study, but, undeniably, it is impossible to know the effects a medium-long term;

- while admitting that “vaccines protect the immunized subject from more serious consequences of the infection ", the Consultants object that they do not stop the spread of the virus;

- although the vaccinated “showed a lower propensity to get infected ”, the propensity to infect others would be similar among vaccinated

and not;

- “numerous international studies report an increase in mortality general in the post-vaccination period ", unexplained in the presence of the measures protective measures introduced in 2021 and considered the so-called "Harvest effect" charged of the most elderly and frail over the year 2020, and relatively anomalous data mortality in countries with high vaccination rates;

- the European Eudravigilance database shows a number as of February 2022 notable of serious and fatal events, "never seen before with other vaccines", however probably underestimated, both due to the poor efficacy of pharmacovigilance spontaneous, and because the correlation is systematically excluded in presence of other pathologies; aggravated phenomenon, as regards the reports from Italy, also in relation to the recommendation of referred to in the AIFA note of 9 February 2021;

- below, the Consultants of the appealing party offer their interpretation about the reasons why the reported adverse effects of local systemic inflammation, platelet aggregation, thrombosis, hyper-inflammatory response, cardiovascular complications, all phenomena that would be strictly dependent on the operating mechanisms of the mRNA vaccines; highlight the risk of genotoxic and pathogenic effects of the Spike protein, not investigated, as would also be evident from the examination of the Pfizer vaccine card, where it is specified that they have not been genotoxicity and carcinogenicity studies carried out, because they are not required by the WHO guidelines, noting that, however, the exemption was foreseen for i classic formulation vaccines, for which at most a couple of administrations over a lifetime, while in the case in question they are repeated administrations are foreseen, in short times and for periods al undefined moments, amplifying the risk by virtue of the accumulation effect;

- the lack of screening on vaccinators is contested, in relation to potential sources of risk, including a concomitant one Covid-19 infection, despite the case of a deceased soldier, a few hours after vaccination, for ADE (acronym for *antibody dependent enhancement),* as demonstrated during the autopsy;

- the reliability of the pharmacovigilance system is challenged, in the current ones circumstances, considering that, in the case of new technologies, it is essential identify pathophysiological phenomena activated by the drug; the reports are performed only in the presence of a reasonable suspicion of correlation with the administration of the vaccine, while they should be done in each case, referring to a commission of multidisciplinary experts ascertaining the causal link;

- the third AIFA report shows that, within the current vaccinovigilance, a built and validated algorithm is used by the World Health Organization, which takes into account the report time between vaccination and event; reading the report shows that yes comes to the exclusion of responsibility for vaccines in the event of deaths of subjects with previous pathologies such as cardiovascular, oncological diseases, respiratory systems, which, however, the Consultants observe, make up the majority of human diseases in Western countries; moreover, it would appear, in their opinion, the exclusion criterion from the calculation of the deaths occurred is arbitrary after 14 days from the vaccination.

For this and other reasons which, for reasons of synthesis, do not come here reported, the party concludes in the sense of illegality, in relation to the constitutional parameter, the imposition of the vaccination obligation, especially for i subjects who, like the appellant, have already contracted the virus.

16. *The parameter of constitutional legitimacy.*

16.1. The jurisprudence of the Constitutional Court on vaccinations
mandatory is firm in affirming that art. 32 of the Constitution postulates what is necessary
reconciliation of the right to health of the individual person (also in his
content of freedom of care) with the coexisting and reciprocal right of the others
people and with the interest of the community.

In particular, the Court specified that - without prejudice to the necessity that the obligation
vaccination is enforced by law - the tax law of a treatment
health is not incompatible with art. 32 of the Constitution under the following conditions:

- if the treatment is aimed not only at improving or preserving the state of
health of those subjected to it, but also to preserve the state of health of
other;

- if it is expected that it will not adversely affect the health of the person
which is obligatory, except for those consequences “which appear normal
and, therefore, tolerable ";

- and if, in the event of further damage, payment is in any case envisaged
of a fair indemnity in favor of the injured party, regardless of the
parallel compensation protection (Constitutional Court, sentences no. 258 of 1994 and no. 307 of
1990).

In particular, as stated by the judgment of 22 June 1990, n. 307, the
constitutionality of regulatory interventions that have the mandatory nature of
certain health treatments (in the present case it was the vaccine
polio) is subject to compliance with the following requirements:

<the treatment is aimed not only at improving or preserving the state of health of those who are there
subject, but also to preserve the state of health of others, since it is just that
further purpose, relating to health as an interest of the community, to justify the
compression of that self-determination of man which is inherent in everyone's right to
health as a fundamental right.

……. a health treatment can be imposed only in the provision that it does not affect negatively on the state of health of the person subjected to it, except for those alone consequences, which, due to their temporariness and scarce entity, appear normal for each health intervention, and therefore tolerable.

With reference, however, to the hypothesis of further damage to the health of the subject subjected to the compulsory treatment - (...) - the constitutional significance of health as an interest of collectivity alone is not sufficient to justify the health measure. This observation requires that in name of it, and therefore of solidarity towards others, each can be obliged,

thus remaining legitimately limited to its self-determination, to a given treatment health, even if this implies a specific risk, but does not postulate the sacrifice of health of each to protect the health of others>.

And if the risk occurs, in favor of the taxable person of the treatment it must be *insured, at the expense of the community, and for it of the State that disposes the compulsory treatment, the remedy of a fair compensation for the damage suffered>.*

Furthermore, the concrete forms of implementation of the tax law of a medical treatment or material execution of the said treatment must be *<accompanied by cautions or conducted in the manner that the state of the scientific knowledge and art prescribe in relation to its nature. And among these it goes including the communication to the person subjected to it, or to the persons who are required to make decisions for him and / or to assist him, of adequate information about the risks of injury (.), as well as the particular precautions, which, always according to the state of scientific knowledge, are verifiable and adoptable respectively>.*

As stated with the decision no. 5, the reconciliation of these multiple principles leaves room for the discretion of the legislator in the choice of ways to ensure prevention effective from infectious diseases, being able to sometimes select the technique of recommendation, sometimes that of obligation, as well as, in the second case,

variously calibrate the measures, including sanctions, aimed at guaranteeing the effectiveness of the obligation. This discretion must be exercised in the light of the various sanitary and epidemiological conditions, ascertained by the authorities responsible (sentence no. 268 of 2017) *<and of the acquisitions, always in evolution, of the medical research, which must guide the legislator in the exercise of his choices on the subject (thus, the constant jurisprudence of the Court since the fundamental sentence no 2002)>.*

In this regard, it is again specified in decision no. 5/2018, vaccines, like any other drug, are subject to the current pharmacovigilance system which reports mainly to the Italian Medicines Authority (AIFA) and since, although in rare cases, also due to the conditions of each individual, the administration can lead to negative consequences, sorting considers it essential to ensure compensation for such individual cases, without mentioning a what title - obligation or recommendation - the vaccination was administered (as stated again recently in sentence no. 268 del 2017, in relation to the anti-flu one); therefore *<on the level of law for compensation, recommended and compulsory vaccinations do not differ: yes see, lastly, sentence no. 268 of 2017>.*

In this regard, see the sentences of February 26, 1998 no. 27 and 23 June 2020 n. 118, again on the subject of the right to compensation.

16.2. For the purposes of assessing the non-manifest groundlessness of the issues of constitutional legitimacy raised by the appellant party it is therefore necessary to examine in detail the various profiles involved in regulation of the vaccination obligation (in the specific case, in relation to the health personnel), also in light of the findings of the investigation, of the clarifications made by the body in charge during the chamber hearing, of the documentation attached to the preliminary report and of that not attached but

to which the report referred.

17. *The judgment of no manifest groundlessness.*

17.1. Sars-Cov-2 virus is currently estimated to have produced, only in Italy, over 157,000 dead.

In this regard, the appellant complains of the asymmetry between the methodology of count of deaths, which are attributed to Covid-19 even when the patient suffered from other pathologies, and that related to the counting of events fatal as a result of mandatory vaccination, which can be traced back to the latter is excluded in the presence of other pathologies.

Leaving aside, for a moment, the question of adverse events from vaccination, in the opinion of the College the criterion of imputation is not irrational to the virus also of the deaths of "fragile" subjects, suffering, for example, from pathologies cardiovascular, obesity, oncological and respiratory diseases, all conditions rather widespread clinics in the so-called welfare society, which (completely online general) are kept under control by appropriate therapies pharmacological, not significantly precluding an adequate expectation of life, so that the virus actually appears to intervene as a triggering event an impairment of vital functions that otherwise would have remained in equilibrium.

The official figure relating to mortality cannot therefore, in the opinion of the College, be seriously challenged, and must be kept in mind when yes at its root, it disputes the very introduction of compulsory vaccination.

The need to face a pandemic phenomenon of proportions dramatic, such as to overwhelm the health and social systems of the countries involved in the various "waves", it has pushed the scientific community to titanic efforts in the Research.

Many tens of thousands of people have made themselves available to participate in the

trials of the COVID-19 vaccine as early as 2020 and have been completed
unprecedented financial efforts.

Vaccines have not omitted any of the traditional experimental stages;
but, given the urgency of the pandemic situation, these phases have been
conducted in parallel, in partial overlap, which made it possible to
accelerate the marketing of drugs, which, however, have
got a provisional authorization just in relation to the inevitable
lack of data on medium and long-term effects.

In this regard, the general discipline of the authorization procedure to
drug trade in Europe and the authorizations, which are issued
after the normal experimentation period, it is found in the regulation
number 726 of 2004 of the European Parliament and of the Council of 31 March
2004 (which established community procedures for the authorization and the
surveillance of medicines for human and veterinary use, as well as the agency
European Union for Medicines).

Commission Regulation (EC) number 507 of 29 March 2006 has
instead regulated the conditional marketing authorization
of medicines for human use, which allows, in fact, to be carried out in
parallel, rather than sequential, of the clinical trial phases,
accelerating, therefore, the normal timing of carrying out the
experiments.

Medicines marketed under this second type of authorization
they are not "experimental" preparations: although they are vaccines placed on the
market much faster (compared, for example, to 28 years for the
marketing of the chickenpox vaccine and 15 related to that on
papillomavirus), the innovative mRna technique is not absolutely one
novelty, because it has been tested for some time after the start of research in the context of

an effective approach to cancer treatment; also the other two vaccines (Vaxzevria of AstraZeneca and Johnson & Johnson) exploit a technology of more recent introduction, tested in relation to the severe Ebola virus. In both cases are technologies destined to have more and more use, in relation to the particular effectiveness.

Inevitably, the medium and long-term risk profile is unknown, which, moreover, is inherent in an infinity of preparations, given that the scientific research allows constant updating of available drugs, i whose effects are verified over a period of time in any case "finite".

As underlined in the report sent following the preliminary order n. 38/2022, the conditional marketing authorization is tool that allows regulatory authorities to approve a drug quickly and pragmatically when there is an urgent need, ensuring, however, that the approved vaccine meets rigorous standards EU in terms of safety, efficacy and quality, but without considering the concluded evaluation process at the time of placing on the market, as developers are allowed to submit additional data on the vaccine as well subsequently.

From another point of view, the seriousness and gravity of the Covid-19 pathology: if it is true that in mild forms the immune system of the patient manages to control the disease, in severe forms it is found an excessive immune response that can lead to patient death or irreversible damage to organs; many survivors face problems even severe long-term health, with impaired expectations e quality of life, creating an additional burden on health systems.

The validity of the vaccination approach, although introduced in a phase emergency, it seems to maintain its legitimacy (or rather, necessity) too

in the current phase, despite the approval of some drugs that they allow the therapy of infected subjects; the problem is that the effectiveness of almost all the therapies in question depend on the timeliness in the administration, which is rather difficult, considering the onset of the SARS-COV-2 pathology (which mostly presents a symptomatology flu-like) and the duration of the so-called window period (when the test has a false-negative result). So it is difficult to intercept a sick person within the strict deadline recommended by the manufacturers.

17.2. In relation to the arguments developed by the appellant (the vaccination would be useless, not preventing the vaccinated from becoming infected e contagiare), the aforementioned decision of the Council of State no. 7045/2021, which considered legitimate the obligation to vaccinate against the Sars virus CoV-2 for healthcare personnel, excluding (resulting in a large and complex argumentative path), among other things, that vaccines are not effective; there the aforementioned decision recalled that *"the position of the scientific community international, in the light of the most recent research, is in the sense that the phase of elimination viral nasopharyngeal, in the vaccinated group, is so short as to appear almost imperceptible, with the substantial exclusion of any pathogenicity in the vaccinated "... ..*

This Council, in the previous ordinance no. 38/2022, recalled how, in application of the constitutional principle of solidarity, the Council of State stated that, in an emergency phase, faced with the pressing need, dramatic, it cannot be postponed to protect public health against the spread of contagion, the precautionary principle, which is also applied in the field health, operates in an inverse way to the ordinary and, so to speak, counterintuitive, because it requires the public decision maker to allow or, even, to impose the use of therapies which, albeit on the basis of incomplete data (as in the conditional authorization procedure, which however followed the

four phases of the trial required by the authorization procedure), ensure more benefits than risks, as the potential risk of an event adverse for a single individual, with the use of that drug, is by far long less than the real harm to an entire society, without using that drug (in terms, decision no. 7045/2021 cit.).

17.3. More recently, with decision no. 1381 of 28 February 2022, the Section he underlined how the AIFA and ISS monitoring have shown the high vaccination efficacy in preventing hospitalization, hospitalization in intensive care and death; so, the argument of the low incidence of the vaccination to counteract the transmissibility of the virus - taken from finding that vaccinated subjects are able to become infected and infect- is unsuitable to undermine the overall rationality of the campaign by vaccination, conceived, of course, with the aim of achieving a rarefaction of infections and the circulation of the virus, but also for the purpose of avoiding the progression of the pathology towards severe forms that require hospitalization in hospital, an objective still achieved by the preventive system in place, which benefits, thanks to the greater extension of the audience of vaccinated, less pressure on hospitalization and therapy facilities intensive.

17.4. This reasoning is shared by the College: albeit empirically it must be recognized that, in the presence of new variants, vaccination does not appears to guarantee immunity from contagion, so that the vaccinated themselves can to become infected and, in turn, to infect, the same is still effective in the contain deaths and hospitalizations, protecting people from serious consequences of the disease, with a consequent double benefit: for the single vaccinated, which avoids the development of serious pathologies; for the system sanitary, against which the pressure is relieved.

It is worth reporting the data that emerge from the report sent by the body in charge of the investigation, in response to a specific question about this Advise:

<As shown in the "ISS Extended Report" on Covid-19 of 09/02/2021 ..... the rate of population-related age-standardized hospitalization aged ÿ 12 years in period 24/12 / 2021-23 / 01/2022 for the unvaccinated …… .. is about six times more high compared to vaccinated with a full course of ÿ 120 days ..... and about ten times more high compared to vaccinated with additional dose / booster ....., with a prevalence in the same period of the Omicron variant estimated at 99.1%.

The age-standardized ICU admissions rate, relative to the population of age ÿ 12 years, in the period 24/12 / 2021-23 / 01/2022 for the unvaccinated …… results about twelve times higher than vaccinated with a full course of ÿ 120 days ……. and about twenty-five times higher than vaccinated with additional dose / booster ... ...

The age-standardized mortality rate, relative to the population aged ÿ 12 years, in the period 17/12 / 2021-16 / 01/2022, for the unvaccinated ……. turns out about nine times higher than vaccinated with full cycle of ÿ 120 days ..... and about twenty-three times higher than vaccinated with additional dose / booster ... ..>.

With consequent confirmation of the efficacy of the vaccine in reducing the percentage of the risk, at least, for the purpose of preventing cases of severe disease e of the fatal course.

In this perspective, the appellant's reasoning (according to which it would be unfair to subject young people to the risk of side effects from vaccination, in the face of a risk of serious consequences of infection with Covid -19 low or even non-existent) proves to be fallacious in two respects: in the meantime, because the data that emerges from the study of the progress of the pandemic is that, unlike the original version of the virus, the current variants they strike transversally, so much so that cases of

serious illness and deaths in all age groups, including juveniles and infants.

Secondly, because even young people can incur

in accidents, road accidents, various types of pathologies (from cardiovascular to oncology) who need assistance and hospitalization; but the abnormal pressure on healthcare facilities induced by severe Covid-19 patients, such as known, has a dramatic impact on assistance to the population in general.

So that it is clear that vaccination basically protects both

the interest of individuals and the collective interest: as for the second, it is obvious; as for the first, vaccination has the double benefit of prevention

severe forms of infection, which now affect any age group, e

decrease the pressure on health facilities, once again to the benefit of

each citizen, whose health care needs cannot be

adequately satisfied in situations of constant emergency.

Indeed, this concept seems to have been well understood and shared by population, as evidenced by the high *voluntary participation* in the campaign vaccination in the phase prior to the introduction of the various obligations (also, for what it can detect, by the members of this College).

Therefore, in the opinion of the Board, the first of the indices of constitutionality of vaccination obligations (that the treatment is directed to improve or preserve the state of health of both those subjected to it and of other).

18. *The judgment of not manifest groundlessness: criticality profiles of vaccination mandatory for Covid-19 with respect to the other parameters of constitutionality of vaccines mandatory, especially adverse events*

However, critical elements appear to emerge with reference to the others parameters, with specific reference to the problem of adverse events.

18.1. It must be premised that, in relation to this profile, this decision must necessarily depart (for very specific reasons, as will be seen) from recalled precedent constituted by decision no. 1381/2022, which he excluded the recurrence of profiles of doubt regarding the proportionality of the obligation vaccinal, referring (sub 6.7) to the ruling n. 7045/2021, where it was specified how it was not (and had not been proven in court) that the risk of adverse effects was not "within the tolerable *average* of events adverse effects already registered for compulsory vaccinations in use for years ".

Therefore, the aforementioned pronouncements have based their conviction on data which, however, have been recently (and subsequently to the passage in decision of sentence no. 1381/2022, which took place in January 2022) revised, as the annual report was published by AIFA in February 2022 on the safety of Covid-19 vaccines.

The data that emerge from the consultation of the report (also referred to in preliminary report), and from the comparison between it and the 2020 vaccine report (not mentioned in the aforementioned report, but easily viewable by the same AIFA website), show, in fact, a very different situation.

The 2020 Vaccine Report describes the activities of the cd. conducted vaccinovigilance in Italy by the Italian Medicines Agency (AIFA) in collaboration with the Istituto Superiore di Sanità (ISS) and with the Working Group for the vaccinovigilance. These activities consist of monitoring and evaluation of reports of suspected adverse reactions to vaccines.

Well, an examination of this report shows that, with respect to the total of total doses administered in Italy of vaccines (both mandatory and recommended: Hexavalents , Tetravalent, Trivalent, Antipneumococcal, Anti-rotavirus , Antimeningococcus, MPR-MPRV-V and Anti-papillomavirus), in 2020 are been included in the National Pharmacovigilance Network as a whole

5,396 reports of suspected adverse events to vaccines, equal to 17.9 reports every 100,000 doses administered, of which only 1.9 constitute serious reports.

Instead, from the examination of the "Annual report on the safety of anti vaccines COVID-19 "(the essential data of which are reported in the preliminary report, pp. 13 et seq.) It emerges that <*overall, during the first year of the current vaccination campaign, have been included, in the National Pharmacovigilance Network, 117,920 reports of suspected adverse events following vaccination, out of a total of 108,530,987 vaccine doses, with a reporting rate of 109 reports each 100,000 doses administered, …… .., (e) with a rate of 17.6 serious events per 100,000 doses administered*>.

As is evident, not only the number of adverse events from anti vaccines SARS-COV-2 is above the <*average ..... adverse events already recorded for compulsory vaccinations in use for years*>, but it is by several orders of magnitude (109 reports, compared to 17.9, and with a rate of 17.6 serious events each 100,000 doses administered, compared with a rate of 1.9 serious reports).

The preliminary investigations therefore suggest a review of the jurisprudential guidelines expressed up to now on the basis of outdated data.

18.2. The Court has, as mentioned above, held that the tax law of a health treatment is not incompatible with art. 32 of the Constitution on condition, between the other, that it is expected that it will not adversely affect the state of health of he who is obliged, except for those consequences only *"that appear normal and, therefore, tolerable ".*

Therefore, we must first ask ourselves:

- if the status of the collection of information (inherent, as explained above, the characteristics of the procedure for placing on the market through conditional authorization) on adverse events from anti vaccination

Covid-19 shows whether or not phenomena transshipment tolerability;

- if so, if and what relevance it may have, for the purposes of the scrutiny of constitutionality, the percentage of serious / fatal adverse events;

- in the event of both an affirmative and a negative answer to the first question, reliability of the data collection system with regard to side effects.

This last question is of crucial importance, especially for the drugs submitted with conditional authorization, for which, after the marketing, the evaluation process continues (referring to al regarding, for more details, the clarifications acquired during the investigation), likely to be affected so much by an erroneous attribution to the vaccination of events and diseases not causally related to it, how much from an underestimation of side events, especially serious and fatal.

This eventuality would compromise the investigation aimed at comparing the drug la whose administration is legally imposed with the aforementioned parameter constitutional, under a double profile: both because it would make it uncertain the assessment of normal tolerability; both because, as mentioned above, the constitutional jurisprudence has long since clarified how, in the hypothesis in which damage results from vaccination, payment must be provided of a fair indemnity in favor of the injured party, indemnity which, as regards the compulsory vaccination against Covid-19, was already included in the perimeter of the ln 210/1992, and has recently been extended by art. 20 of Legislative Decree 4/2022, to voluntary vaccination, but the achievement of which, in practice, could be thwarted (or otherwise hindered) by the lack of recognition by the party of the Authorities appointed to do so, at the end of the observation period, of an effect collateral.

18.3. It must be premised that, as reported by the body in charge of the preliminary investigation in response to a specific question of this Board, the activity

of pharmacovigilance aims to collect safety information on the field, in order to be able to carry out a constant and continuous updating of benefit-risk profile of individual vaccines, through the detection and communication of suspected adverse events observed after vaccination (AEFI, *Adverse Events Following Immunization)* and any other inherent problem vaccinations (passive pharmacovigilance) and information gathering through appropriate independent studies (active pharmacovigilance).

The report highlights how <*spontaneous reports come from both figures professionals in the health sector that by individual citizens and are included in the Network National Pharmacovigilance (RNF) by the Local Pharmacovigilance Managers (RLFV), which contribute, together with the Regional Centers (CRFV) and AIFA, to proper functioning of the national pharmacovigilance system. … .. A report does not necessarily imply, nor does it establish in itself, a causal link between vaccine and event, but it represents a suspicion that requires further investigation, through a trial precisely defined "signal analysis". Starting from a certain number of reports, relating to a single event and / or from the finding of a statistical disproportion (i.e. the vaccine / reaction pair that is observed more frequently for that vaccine than for all the others vaccines), the local managers of VF (RLFV) and the Regional Centers of VF (CRFV) check, on a daily basis, the completeness of all information (such as the vaccination dates and time of onset of core symptoms).*

With reference to cases defined as serious, the CRFV identifies the causal link through the WHO algorithm, which allows to evaluate the probability of the event / vaccine association. It should be noted that the higher the number of reports of suspected AEFI, the greater the likelihood of being able to observe an adverse event actually caused by a vaccine, especially if it is a rare event. If from this set of activities gives rise to the hypothesis of a potential causal association between a new event and a vaccine, or additional information emerges on a known adverse event, yes

generates a safety signal that requires further careful verification action on the base of available information (signal management).

……. at the outcome of the initial identification, each signal is evaluated and discussed at the level European by the Pharmacovigilance Risk Assessment Committee (PRAC), consisting of representatives of all EU / EEA member states, as well as six experts in several fields, nominated by the European Commission and by representatives of the health professions and patient associations.

With specific regard, however, to active pharmacovigilance studies, …… the latter are based on pacing or systematic collection of adverse event reports in observational studies, often conducted in specific settings (eg hospitals) or limited to specific security problems or on the analysis of specific databases (administrative archives, drug or patient records). The events collected prospectively as part of these studies they are, however, included in the RNF and contribute to evaluation of signals. The objective of active pharmacovigilance is, therefore, that of increase the reports and, through ad hoc studies, quantify any risks that have emerged from passive pharmacovigilance.

…… .. The reports collected in the National Pharmacovigilance Network ..... are transferred to EudraVigilance (the pharmacovigilance database of the EMA), through which, subsequently, they also transit in VigiBase (database of pharmacovigilance of the Uppsala International Medicines Monitoring Center WHO).

Through the aforementioned European and global sharing system, reports of reactions adverse Italians are therefore evaluated in a broader international context. Indeed, it seems easy to observe how the shared discussion that arises and the availability of data from all over Europe, on a global level, make it possible to verify the risk potential on a much higher number of cases than those available in individual national databases.

The purpose of vaccinovigilance, at national, European and global level, is therefore that of monitor the safety of the vaccine in its real context of use, in order to collect any new information and implement measures to minimize the individual and collective risk. Such activities, which are routinely conducted for all medicinal products, have been intensified in the pandemic context in reference to anti-COVID-19 vaccines, as well as drugs needed to contain the disease>.

18.4. Given the above, the collection of the data that emerge from the consultation of the European database (EudraVigilance, easily accessible through the AIFA website) makes it possible to note that at the end of January 2022 they were administered in the EU / EEA 570 million doses (full cycle and *booster)* of the Cominarty vaccine (BioNTech and Pfizer), in relation to which 582,074 reports of adverse events have been acquired, of which 7,023 with fatal outcome; as for the Vaxzevria vaccine (AstraZeneca), compared to 69 million of doses there were 244,603 reports of adverse events, of which 1447 with a fatal outcome; as for the Spikevax vaccine (Moderna), compared to 139 million of doses, 150,807 adverse events were reported, of which 834 with outcome fatal; as for Covid-19 Vaccine Janssen, compared to 19 million doses there were 40,766 reports, of which 279 with fatal outcome.

Undoubtedly, most of the side effects, listed in *the database,* show modest and transient symptoms; the most serious adverse events include disorders and diseases affecting the circulatory systems (including thrombosis, ischemia, immune thrombocytopenia), lymphatic, cardiovascular (including myocarditis), endocrine, immune system, connective tissue and musculoskeletal, nervous, renal, respiratory systems; neoplasms.

Obviously, pathologies also fall within the category of this list serious, such as to compromise, in some cases irreversibly, the state of health of the vaccinated subject, causing the invalidity or, in the most unfortunate cases, the

death.

It is, therefore, doubtful which drugs against which they are being collected reports on such side effects meet the constitutional benchmark referred to above.

It is true that severe reactions make up a small part of the events overall adverse events reported; but the criterion set by the Court constitutional on the subject of compulsory health treatment does not seem to leave space for a quantitative evaluation, excluding legitimacy the imposition of vaccination obligations using preparations whose effects on the state health of the vaccinated exceed the threshold of normal tolerability, which is not seems to leave room for the admission of serious and fatal adverse events, provided they are few in relation to the vaccinated population, a criterion that, moreover, would imply delicate ethical profiles (for example, who is responsible for identifying the percentage of "expendable" citizens).

It seems, therefore, that, in general, it is never possible to exclude the possibility of adverse reactions to any type of drug, the *discrimen,* like the criteria that can be found in the aforementioned constitutional jurisprudence, should be recognized in the hypothesis of *chance* and *unpredictability of the individual reaction.*

But in the present case, the examination of the data published on the EudraVigilance website disaggregated by reporting State shows a certain homogeneity in the type of adverse events reported by the various countries (on the sidelines the major or lower flow of data, highlighted by the consultants of the appellant party), which leaves little room for the chance chance / unpredictable reaction option.

In this condition, the consistency of the current vaccination plan is questionable obligatory with the principles affirmed by the Court, in reference, it goes underlined, to situations that are so to speak ordinary, not recognizing them as precedents referring to emergency situations generated by a serious pandemic.

18.5. Both the appellant and the same body in charge of the verification they dwelt extensively on the limitations of the monitoring system, reaching opposite conclusions, since the first argues about the underestimation of adverse events, the second specifies that events temporally associated with vaccination are not necessarily causally associated with vaccination connected, which is why they need to be further investigated in the context of periodic safety assessments.

An objectively important theme is introduced, that of adequacy of anti-Covid-19 vaccine monitoring systems in order to identify the connection between vaccination and adverse events affecting the population vaccinated as part of a *"mass" vaccination plan.*

Now, within a given time interval, a percentage of the population is destined to incur serious / fatal events (heart attack, stroke, cancer and so on).

If a vaccination occurs in this period of time, the same percentage of subjects will incur the same events, independently from the administration of the drug.

Reason why the passive pharmacovigilance system (which, as noted in the preliminary report, it allows both professionals in the sector health that to individual citizens to transmit spontaneous reports) exposes the risk of data pollution from any reports of effects collateral incorrectly attributed to the vaccine.

For this reason, the amount of data forwarded must be the subject of further studies.

Conversely, there is no doubt that this system presents the risk of a deficit of reliability also in the opposite sense.

Limiting himself to the information that can be deduced from the preliminary report and from the reading the recently published vaccination reports, it is clear that the flow of

transmitted data is intercepted by local managers and regional centers of pharmacovigilance, which carry out various skimmings, both in order to completeness of the information entered in the reporting form, both in about the search for causation through the WHO algorithm, set in order to evaluate the probability of the event / vaccine association.

For what emerges from reading the preliminary report and the reports vaccine, a criticality profile derives from the requested temporal connection between vaccination and the manifestation of the adverse event, jointly the circumstance that health workers are required, based on art. 22 of decree of the Ministry of Health of 30 April 2015, to report promptly "suspected adverse reactions" from the medicines they come to knowledge in the context of their business.

But in the hypothesis of conditionally licensed drugs, the profile of medium and long-term risk must emerge precisely from the study of adverse phenomena that can also occur after some time from the administration of the drug (thus placing himself outside the window reference time between administration of the vaccine and suspected reaction on which the algorithm is set) and be unexpected or unusual with respect to known and expected adverse events, and therefore likely to be ruled out by health workers because they were not mistakenly considered "suspicious".

Not to mention that, as confirmed by reading the preliminary report, under this vaccination plan, there being no obligation to submit a report by the family doctor at the vaccination center, i citizens can independently decide to undergo vaccination (in vaccination *hubs* , pharmacies, etc.), without any prior consultation with the doctor base, which may not even be aware of the fact that its own patient has been vaccinated (it is true that the vaccination carried out is recorded

at the vaccination registry, but it is unlikely that medical doctors general check the database for daily and on their own initiative check if and which of the thousands of them assisted they have undergone vaccination).

Nor can excessive expectations be placed on spontaneous reports of citizens, either because of the heterogeneity of the population (not all, for various ages and socio-economic conditions, are familiar with the tools IT and the bureaucratic procedures necessary to fill in and submit an adverse event reporting form complete with all required data), want because the citizen struck by a serious pathology (not to mention the deceased one) is likely to have other concerns than to forward reporting.

Under such conditions, crucial information for the detection of adverse events and, consequently, for a correct ed exhaustive profiling of the benefit-risk ratio of the individual vaccines.

This limit, of course, is inherent in this detection methodology which is adopted in the majority of countries, but that due to the type of drugs in issue presents obvious criticalities.

On the other hand, it is the same recently published Covid-19 vaccine report by the AIFA, to report (with regard to passive pharmacovigilance) that <*the under-reporting ..... it is in fact an intrinsic limit to the very nature of the report, well known and extensively studied also in the international scientific literature, which has some of its specific determinants in the low sensitivity to reporting suspects adverse reactions by healthcare professionals and non-healthcare professionals and in the accessibility of systems reporting*>.

The same use of the algorithm, which expands the reporting of events distant, in time, from the date of vaccination, does not seem consistent with

the need to study the medium-long term risk profiles of drugs subject to conditional approval.

The active pharmacovigilance monitoring methodology, which integrates passive pharmacovigilance, on the other hand, allows for observation aseptic so to speak a sample of the population, of which they come collected, over time, all the data relating to the subsequent state of health taking the drug, and allowing you to acquire the data of many people vaccinated and compare them to those that would be expected in that age group only by chance, it allows to highlight unexpected adverse events potentially serious and biologically plausible.

The general collection of information on the state of health of people in the time, not polluted by the prejudice of the expected effect (either for the recurrence statistics of a certain side effect, you want to connect temporal versus vaccination), which may cause doctors to overlook the reporting of pathological states which, by own conviction, at the state of their knowledge, they are considered not connected to taking the drug, and the evaluator to expel events reported but erroneously deemed not to be relevant, allows for that crucial advancement in post-vaccination study an effective assessment of the drug's risk profile, which could also change over time, leading to the abandonment of some vaccines a advantage of others, as indeed happened in Italy when, compared to some cases of suspected fatal events, has been prudently suspended administration of the AstraZeneca vaccine.

Appellant party, through the consultations of the deposited party, it is particularly widespread on the subject of underestimation of reports, also in the same way as the AIFA note of 9 February 2021.

This document, produced in court, was not contested by the Defense

Tax authorities, although it should be noted that AIFA is not a party to the judgment; but, at state, there seems to be no reason to doubt its authenticity.

The appellant believes that this note was intended to discourage the forwarding of reports relating to adverse events, but the Board does not agree with this prospection.

The note, recalling previous communications, is intended to provide details on the management of reports of suspected adverse reactions resulting from the use of vaccines within the national network of pharmacovigilance, and, among other things, bears the following indication:

<as per the previous note ..... it is recommended to trace the operations of the individual ones regional structures for the management of reports of suspected adverse reactions within of the RNF and the adoption of the tools made available by AIFA, following the normal procedure reporting flow and the timescales envisaged by current legislation with an invitation to reduce them as much as possible, so as not to generate unjustified alarms or delays in evaluations conducted at European level>.

In the opinion of the college, the invitation *"to reduce them"* is referred (already from a point of view strictly grammatical) to the timing; this conclusion is supported by the reading of the previous notes, available on the AIFA website, such as n. 0148253-30 / 12/2020, where (more clearly) it is indicated that < *considered the current pandemic situation, it is recommended to reduce the time as much as possible necessary for the registration in the RNF of reports of suspected adverse reactions to COVID-19 vaccines>;* or 0012518-03 / 02/2021, in which, given that some facilities had adopted the practice of using paper forms or other than those approved for adverse event reporting, comes found that these reports could flow into the network nationally late or irregularly, *"resulting in clusters of adverse reactions easily equivocal ".*

The coordinated reading of the previous communications, therefore, leads to interpret the note in question in a different sense from that proposed by the appellant.

The problem, therefore, must be traced back to the fact that, in the presence of drugs subject to additional monitoring in connection with authorization conditioned, active vigilance studies allow you to get a better picture complete with any major side effects and unfortunate events.

It should be noted that, in the context of the preliminary report, it is summarized reference to some active pharmacovigilance studies; more information yes portray from reading the aforementioned annual report on Covd-19 vaccines, where some pharmacoepidemiology studies are given in more detail in course.

It appears, therefore, that such activity is in an implementation phase, albeit there are no precise details about the extent of monitoring e especially about the submission of data to organisms composed of subjects competent and completely independent who meet with the appropriate time periodicity.

Coming to the question, raised by the appellant, relating to some statistics from other countries about a supposed increase in deaths subsequently at the start of the vaccination campaign, the preliminary report offers, to the pages 14-15, a different reading of said data, underlining the anomalous decrease of deaths recorded during 2020 due to the restrictions imposed by the pandemic.

Again, adequate active pharmacovigilance studies would result suitable in order to monitor said phenomena, allowing to observe the trend of mortality, divided by age groups, over a period of time sufficiently large (five or ten years) to sterilize phenomena

contingents such as high mortality, for some age groups, due to Covid-19 infections during the year 2020, and, by contrast, the decrease in deaths among young people, intuitively attributable to the long term period of confinement *(lockdown)* in the same period of time.

Already the data that can be obtained from the mortality tables (the statistical tables elaborated by ISTAT to identify the probability of death and survival of the population, which indicate for each age the number of living, dead, the frequency of death, average life, and are usually used for calculate the demographic component of insurance premiums) would allow to ascertain whether there is, actually, or not, a variation statistically significant, territorial and by age group, in the mortality that may be placed in temporal correlation with the trend of vaccinations.

In this sense, see the provision of the Austrian Constitutional Court issued on January 26, 2022 with which they were submitted to the Ministry federal society, health, care and consumer protection a number of related questions (in addition to the acquisition of data relating to hospitalized persons and died *"due to"* or *"with"* Covid-19; the percentage of incidence of vaccinations on the risk of hospitalization and death as well as the effectiveness of protection of vaccines from contagion, broken down by age groups; also) to verify the existence of the excess mortality reported by the local media and, if not related to the virus, how it can be explained.

In conclusion, there remains the doubt about the adequacy of the system of monitoring carried out up to now, although it must be acknowledged that, as yes emerges from the reading of the annual report, some studies have now begun active pharmacovigilance.

18.6. *Additional critical issues: the inadequacy of the pre-vaccination triage*

Further critical issues emerge from the circumstance that, as emerged from the

findings of the investigation, it is not expected, the purposes of vaccination,
a report from the general practitioner, who usually has an in-depth report
knowledge of their clients. The pre-vaccination triage is therefore delegated
to the healthcare personnel who carry out the vaccination, who in turn must rely on it
to the (inevitably variable) abilities of the subject initiated to vaccinate
represent (in the limited time frame intended for this) facts and circumstances
relevant about their general condition and state of health.
Moreover, as confirmed by the body in charge of the investigation, no
laboratory tests are required, such as diagnostic tests from
perform before vaccination, or tests, including those of a genetic nature,
despite the findings included in the annual vaccine report as well
emerging from the European database have highlighted some side effects
severe such as myocarditis and pericarditis (mainly related to vaccines a
RNA-based) and thromboembolic events (more frequent in vector vaccines
viral), which could be avoided by exempting from vaccination, or
subjecting in advance to suitable drug therapy, subjects who
show specific risk profiles (such as hereditary thrombophilias).
The circumstance that it is not foreseen before the
administration of the vaccine, not even a Covid swab, which could
highlight a condition of infection in progress, which is obviously not recommended
the administration of the vaccine, having regard to the risk of an abnormal reaction
of the immune system, on which scholars have extensively argued
in charge of the consultations of the appellant.
It is true that in a situation of mass vaccination it is extremely difficult,
and hardly sustainable financially, also a mass screening;
but a recovery of the filter function of general practitioners, who can,
according to science and knowledge (also of specific individual situations)

prescribe, or at least suggest or recommend, pre-tests vaccinations, could likely lower the level of risk (albeit statistically contained) that drug treatment inevitably implies and, indirectly, contributes to overcoming the phenomenon of cd. vaccination hesitation.

The problem raised by the appellant, in relationship to your previous (and now dated) Covid-19 infection, object of specific investigation in the preliminary report, where, after extensive examination of the problems raised by the case of the subjects already infected, it is specified that the antibody level is not currently known necessary to protect the individual from SARS infection or reinfection COV-2, so that it does not appear useful to measure the antibody titer, for the purposes of definition of individual risk, considering that, in any case, once a certain period of time, the vaccination of subjects who have undergone a previous infection would not involve additional risks, indeed, the combination of vaccination and infection, regardless of the order in which occur, according to recent studies provides a high degree of protection immune against the virus and its potential variants.

This approach was widely contested by the appellant through the technical advice produced in court.

The College observes that, although the applicant's thesis appears to be supported from some studies, which would have hypothesized that, beyond the mere count of specific antibodies, which tend to shrink over time, T lymphocytes could give long-term protection to those who have contracted Covid-19, as a type of immune cells in the bone marrow of patients recovered from the virus would produce long-lasting antibodies, capable of providing immunity “extraordinarily lasting "(Turner, JS, Kim, W., Kalaidina, E., et al., *SARS-COV-2 infection*

induces long-lived bone marrow plasma cells in human, Nature 595,421-425, 2021, available at https://www.nature.com/articles/s41586-021-03647-4), for conversely we are observing how the cases of reinfection in subjects previously healed are increasingly common and numerous, perhaps because the variants currently in circulation produce a longer antibody response light and short-lived.

For this reason, the specific case of the appellant was not considered by the Board that can be resolved on the basis of the individual condition of the subject previously infected and not even an exempt person, second the provisions of the application documents of the legislation referred to up to now, basically the circular of the Ministry of Health n. 0035309 of 4

August 2021 (which, however, provides for a rather small number - correlated only to some of the side effects of the vaccines retractable from the official databases of specific documented clinical conditions, which may be issued SARS vaccination exemption certificates

COV-2), given that the following ones concern aspects of detail and the more recent Prime Ministerial Decree of 4 February 2022 contains the technical specifications of the certifications.

18.7. *Additional critical issues: informed consent*

Further critical issues emerge from the legislation regarding consent informed, referred to in the introduction, in consideration of the fact that not the collection of consent is expressly excluded even in the hypothesis of administration of mandatory health treatment.

As confirmed in the preliminary investigation, in compliance with the legislation in question, consent is obtained at the time of the pre-vaccination history informed.

The body in charge of the investigation underlines that, in the case of vaccination

mandatory, the consent should be understood as acknowledgment by the citizen of the information provided.

But this interpretation cannot be shared, since, from a point of literal, logical and legal view, consent is expressed downstream of a free volitional self-determination, irreconcilable with the fulfillment of a obligation required by law.

The request for subscription of this is obviously irrational manifestation of will at the time of undergoing a vaccination indispensable for the purposes of the implementation of a constitutionally protected right such as the right to work; and since this determination derives from the circumstance that the law, in having introduced and regulated informed consent, does not have dictated a specific safeguard clause in the hypothesis of treatment mandatory pharmacological, it is clear the intrinsic irrationality of the dictation regulatory.

Nor is it possible to reach the reading proposed by the Administration, as also confirms the comparison with the provisions issued by the Ministry of health with the circular of 16 August 2017, containing the first indications operational for the implementation of Legislative Decree 73 of 7 June 2017, converted with amendments from l. 31 July 2017, n. 119, where, correctly, it was specified: <*Good vaccination practices require parents / guardians / custodians to be informed about benefits and risks of vaccination and that, at the end of this interview, it is delivered a form stating that this step has been performed. This information model, in the presence of a recommended vaccination, it has taken on a consensus value informed, i.e. of conscious choice to a recommended vaccination. In light of the decree law in the epigraph, it is specified that the informed consent form should be limited to recommended vaccinations only; for mandatory vaccinations will come only an information form delivered*>.

19. *The incident of constitutionality*

In light of the factual, regulatory and jurisprudential reconstruction referred to in ai preceding paragraphs,

a) recalled that the conditions dictated by the Court in terms of compression of the freedom of health self-determination of citizens in the vaccination field yes substantiate in the non-harmfulness of the inoculation for the single patient e benefit for public health, and in particular that:

- the treatment <*does not negatively affect the state of health of the person who is there subject*>, without prejudice to the tolerability of modest side effects extent and duration;

- communication is ensured *to the person who is subject to it, or to the persons who they are required to make decisions for it and / or to assist it, of adequate information about the risks of injury (...), as well as the particular precautions, which, always in the state of knowledge scientific, are respectively verifiable and adoptable>;*

- the discretion of the legislator is exercised in the light <*of the acquisitions, always in evolution, of medical research*> and therefore that the vaccine choice can be re-evaluated and reconsidered, with a view to enhancing the dynamics development of the medical-scientific knowledge that must support the regulatory choices in the health field (sentence no. 5/2018);

b) considered that:

b.1) following the constitutional indexes referred to up to now, it must be considered on the one hand, it is essential that the monitoring of adverse events, the collection and the evaluation of the data are as broad and complete as possible, that they occur (or are at least validated) by independent bodies, what constitutes an essential prerequisite for the very verification of the amplitude of the side effects; on the other hand, that the citizen receives complete information and correct that they are easily and freely accessible; and, again, that, in

compulsory medical treatment, the insurmountable limit imposed is respected "Respect for the human person" (Article 32, paragraph 2, of the Constitution);

b.2) for all the reasons described above, (apart from the controversial adequacy of the monitoring system, mainly focused on passive pharmacovigilance) that the constitutional parameters to evaluate the legitimacy of the vaccination obligation, as established by constant jurisprudence of the Constitutional Court, do not seem to be respected, as there is no evidence of certain advantage for the individual and collective health superior to the damage for i individuals, there is no evidence of total absence of risk or risk within a normal margin of tolerance, and there is no evidence that –in lack of efficacy duration of the vaccine - an indeterminate number of doses, however close together over time, it does not amplify the side effects of the drugs, damaging the health; no "mitigation measures" and "measures of precaution "accompanying the vaccination obligation, as appropriate assessments in the pre-vaccination triage phase, and adequate post pharmacovigilance vaccination, with the risk that in the name of mass vaccination it will result the consideration of the single human person, which would go instead, faded supported and reassured, all the more so as reluctant to vaccinate, with in-depth medical history and information, with costs borne by the Service national health;

b.3) it does not seem possible to arrive at an alternative reading, constitutionally oriented, of the legislation referred to *below;*

b.4) the current provision of the anti-SARS-COV-2 vaccination obligation presents criticality profiles, with reference to the percentage of adverse and fatal events (well above the average of the other vaccines, compulsory or not), which moreover at present they do not seem to be the object of prevention (through a systematic involvement of general practitioners and the performance of pre-diagnostic tests

vaccinations);

b.5) the informed consent collection system is irrational where
requires an expression of will for which there is no room for
who suffers the compression of the right to health self-determination, a
faced with an inescapable legal duty;

b.6) the regulatory complex described above is under tension, for all
motivations articulated above, with the following articles of the Constitution: 3 (below
the parameters of rationality and proportionality); 32 (having regard to
compression of the freedom of health self-determination in relation to
pharmacological treatments likely to generate adverse effects that are neither mild nor
transient); 97 (good performance, also in relation to the criticalities of the
monitoring); 4 (right to work), as well as art. 33 and 34 (right to education),
subject to compression as they are subject to submission to the
compulsory vaccination; 21 (right to free expression of thought,
which includes the right to express one's dissent), in relation
the obligation to sign informed consent in order to access a
imposed health treatment; as well as with the principle of proportionality e
with the precautionary principle inferable from art. 32 of the Constitution (having regard to the
criticalities of the monitoring system have been identified several times, as well as the absence of
adequate risk mitigation measures such as pre-vaccination analyzes and tests e
post vaccination checks);

b.7) an adequate balance between all relevant values appears to be lacking
constitutional, and in particular between health protection on the one hand, and protection of the
study and work on the other, which equally satisfy the primary needs of
citizen;

b.8) deemed conclusively the relevant issues and not manifestly
unfounded, in relation to the conditions dictated by the Court in relation to

compression of citizens' freedom of health self-determination in
vaccination area indicated above, i.e. non-harmfulness of the inoculation for the
individual patient and public health benefit,
the CGARS, pursuant to art. 23 paragraph 2 l. 11 March 1953 n. 87, considering them
relevant and not manifestly unfounded, raises the question of legitimacy
constitutional:

a) of art. 4, paragraphs 1 and 2, of Legislative Decree 44/2021 (converted into Law 76/2021),
in the part in which it provides, on the one hand, the obligation to vaccinate staff
health care and, on the other hand, due to the non-fulfillment of the vaccination obligation,
suspension from the exercise of the health professions, by contrast with the
articles 3, 4, 32, 33, 34, 97 of the Constitution, from the point of view that the number of
adverse events, the inadequacy of passive and active pharmacovigilance, the
lack of involvement of family doctors in pre-vaccination triage e
however, the lack in the triage phase of in-depth investigations and even of positive / negative
tests for Covid do not allow us to believe
satisfied, at the current stage of development of anti-Covid vaccines and
scientific evidence, the condition, set by the Constitutional Court, of
legitimacy of a mandatory vaccine only if, among other things, it is expected
does not negatively affect the state of health of the one who is obliged, except
that only for those consequences "which appear normal and, therefore,
tolerable ";

b) of article 1 of l. 217/2019, in the part in which it does not provide for the express
exclusion from the signing of the informed consent of the hypotheses of mandatory health
treatments, and of the art. 4, of the legislative decree 44/2021, in the part in
which does not exclude the burden of signing informed consent in the case of
compulsory vaccination, in contrast to the articles 3 and 21 of the Constitution.

The process must, therefore, be suspended pursuant to and for the purposes of

articles 79 and 80 cpa and 295 cpc, with immediate transmission of the documents to the Court constitutional.

Any further ruling in the rite, regarding and in relation to expenses, in relation the pending precautionary incident is reserved for the final decision.

PQM

The Administrative Council of Justice for the Sicilian Region, in its headquarters jurisdictional,

- having regard to art. 23 l. 11 March 1953 n. 87, declares relevant and not manifestly the question of constitutional legitimacy is unfounded:

a) of art. 4, paragraphs 1 and 2, of Legislative Decree 44/2021 (converted into Law 76/2021), in the part in which it provides, on the one hand, the obligation to vaccinate staff health care and, on the other hand, due to the non-fulfillment of the vaccination obligation, suspension from the exercise of the health professions, by contrast with the articles 3, 4, 32, 33, 34, 97 of the Constitution, from the point of view that the number of adverse events, the inadequacy of passive and active pharmacovigilance, the lack of involvement of family doctors in pre-vaccination triage e however, the lack in the triage phase of in-depth investigations and even of positive / negative tests for Covid do not allow us to believe satisfied, at the current stage of development of anti-Covid vaccines and scientific evidence, the condition, set by the Constitutional Court, of legitimacy of a mandatory vaccine only if, among other things, it is expected does not negatively affect the state of health of the one who is obliged, except that only for those consequences "which appear normal and, therefore, tolerable ";

b) of article 1 of l. 217/2019, in the part in which it does not provide for the express exclusion from the signing of the informed consent of the hypotheses of mandatory health treatments, and of the art. 4, of the legislative decree 44/2021, in the part in

which does not exclude the burden of signing informed consent in the case of compulsory vaccination, in contrast to the articles 3 and 21 of the Constitution;

- suspends this judgment pursuant to art. 79 paragraph 1 cpa;

- arranges, by the Secretariat of the CGARS, the immediate transmission of the acts to the Constitutional Court;

- postpones any further rulings on the rite, on the merits and on the costs of the litigation to the outcome of the incidental proceedings promoted with this ordinance.

Order that this ordinance be notified, by the Secretariat of CGARS, to all the parties involved, and that it is communicated to the President of Council of Ministers, the President of the Senate of the Republic and al President of the Chamber of Deputies.

Considering that the conditions referred to in art. 52, paragraphs 1 and 2, of legislative decree 30 June 2003, n. 196, and art. 9, paragraphs 1 and 4, of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 and art. 2-septies of the legislative decree 30 June 2003, n. 196, as amended by Legislative Decree 10 August 2018, n. 101, sends to the Secretariat of proceed, in any hypothesis of dissemination of this provision, to obscure the GENERAL INFORMATION of the appellant and interveners (with the exception of ANIEF).

So decided in Palermo in the council chamber on March 16, 2022

with the intervention of the magistrates:

Rosanna De Nictolis, President

Marco Buricelli, Director

Maria Stella Boscarino, Director, Writer

Giovanni Ardizzone, Director

Antonino Caleca, Director

THE EXTENDER
Maria Stella Boscarino

PRESIDENT
Rosanna De Nictolis

THE SECRETARY

In case of disclosure, omit the personal details and other identification data of the interested parties in the terms indicated.