

Mandatory COVID-19 Vaccination and Free Self-Determination in the Health Field in Italy

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Abstract

The COVID-19 pandemic and the issues related to health emergency management have raised concerns about fundamental rights protection. One of the most complex and contentious issues in doctrine and jurisprudence is the introduction of mandatory COVID-19 vaccination for specified categories of subjects, such as healthcare workers and individuals of a specific age range, as occurred in Italy. The debate in Italy over the mandatory COVID-19 vaccination requirement focuses on whether this obligation interferes with the individual's fundamental right to free self-determination as guaranteed by Article 32 of the Italian Constitution. In jurisprudence and doctrine, conflicting opinions are noted concerning this topic. Part of the doctrine argue that mandatory COVID-19 vaccination compromises some fundamental rights guaranteed by the Italian Constitution, such as the right to free self-determination and respect for human dignity. Other opinions find the basis of the vaccination in the community's best interests, citing Article 32 of the Italian Constitution, which allows for the imposition of compulsory health treatment to safeguard citizens' health. In this regard, the issue of mandatory COVID-19 vaccination requires a reflection on the balance of two fundamental rights: the individual right to free self-determination and the community's interest in terms of protecting public health.

Keywords: Mandatory COVID-19 vaccination, free self-determination, fundamental rights, human dignity, Italian Constitution

Introduction

This contribution analyses the much-discussed issue of the mandatory Covid-19 vaccination requirement that the Italian state adopted during the health emergency caused by the COVID-19 pandemic. The Decree-Law of April 1, 2021, No. 44, converted into Law No. 76 of May 28, 2021, concerning the "*Urgent measures for the containment of the COVID-19 epidemic, in the matter of anti-SARS-CoV-2 vaccinations,*

justice, and public competitions,"¹ provided for the COVID-19 vaccination as an essential requirement for the exercise of the profession for all health professionals who carry out activities in public and private health, social-assistance establishments, as well as in pharmacies, parapharmacies, and professional offices. Subsequently, the mandatory COVID-19 vaccination has been extended to workers in residential and social facilities by Decree-Law No. 122/2021² and all Italian and non-Italian citizens residing in Italy of at least 50 years of age by Decree-Law No. 1/2022³.

This obligation has been the subject of several rulings by some regional courts, which have raised the question of constitutional legitimacy because it interferes with the enjoyment of some fundamental rights guaranteed by the Italian Constitution.

A second relevant profile relating to mandatory COVID-19 vaccination is the provision of informed consent before the vaccination. In this regard, a brief reflection on the nature of informed consent is necessary, considering that the latter assumes relevance only for voluntary medical treatment.

Methodology

This paper carries out a legal and philosophical analysis of the mandatory COVID-19 vaccination requirement introduced by the Italian legislator. For this purpose, the study is composed of three parts: The first section addresses the concept of free self-determination in the health field, its relevance in health protection, and the restrictions placed on this principle by the Italian Constitution. The second section explores the diverse doctrinal and legal perspectives on obligatory COVID-19 vaccination. The last part of the study focuses on discussions regarding the principal concerns and issues raised by various Italian courts about mandatory COVID-19 vaccination.

To better comprehend the topic of compulsory COVID-19 vaccination, the study employs qualitative research methods, taking into account the various perspectives offered by doctrine and jurisprudence.

¹ Decree-law 1 April 2021, No. 44, converted into law 28 May 2021, No. 76, "*Urgent measures for the containment of the COVID-19 epidemic, in the matter of anti-SARS-CoV-2 vaccinations, justice, and public competitions*", in GU General Series No. 128 of 31-05-2021.

² Article 2, Decree-Law No. 122/2021, "*Urgent measures to deal with the COVID-19 emergency in schools, higher education, and social and healthcare facilities*", in GU No. 217 of 10-09-2021.

³ Decree-Law 7 January 2022, No. 1, "*Urgent measures to deal with the COVID-19 emergency, in particular in the workplace, schools, and higher education institutes*", converted with amendments by Law 4 March 2022, No. 18, in GU No. 56 of 03/08/2022.

Free self-determination as a fundamental right

Informed consent is an essential prerequisite for any medical treatment. In line with Article 32 of the Constitution, no medical treatment can be carried out without the person's prior and explicit consent. The necessity of informed consent to medical treatment is foreseen by a variety of sources, including international law sources such as the Convention on Human Rights and Biomedicine, adopted in Oviedo on April 4, 1997, ratified by law No. 145 on March 28, 2001, in Article 5 and Article 3 of the Charter of Fundamental Rights of the European Union, proclaimed in Nice on December 7, 2000.

The patient's free self-determination in the constitutional design includes not only the right to express free consent after being informed but also the right to express dissent and refuse (See Montange, 1973-1974, p. 1664; Furramani & Bushati, 2021, pp. 268 et seq.) or suspend a medical treatment already in progress when possible. The purpose of informed consent is to make the patient aware of his state of health (Bilancetti, 1997, pp. 354 et seq.) while also allowing him to participate in the selection of medical treatment by adequately informing him (See Cass. Pen., Sez. Un., 21 January 2009, No. 2437; Pulitanò, 2007, p. 1209; Rodriguez, 2014, p. 572) on health conditions, diagnosis, prognosis, potential risks of treatment, alternative medical treatments, and the consequences of refusing the medical treatment¹ (See Furramani & Bushati, 2021, p. 266 et seq.; Furramani, 2017, pp. 364-365; Fresa, 2008, p. 67; Ruggiero, 1996, p. 192; Norelli & Mazzeo, 2001, pp. 63 et seq.). It is crucial to recognize that free self-determination is a fundamental right that safeguards a person's health², and for this reason, a considerable part of the doctrine considers it an essential instrument for fully implementing the right to health (Casonato, 1995, p. 195; Gennari, 2006, p. 1413; Guerra, 2008, p. 438; Gorgoni, 1999, pp. 488 et seq.; Santossuoso, 1996, p. 16; Furramani, 2017, p. 364).

Limits to the patient's free self-determination: Compulsory health treatment

The implementation of compulsory health treatment is an exception to the general rule that medical treatment must be voluntary. In the constitutional provision, obligatory medical treatment is covered by the absolute legal reserve (Veronesi, 2011, p. 63; Mazzacuva, 1984, pp. 424 et seq.; Gribaudo, 2012, p. 6; Casciaro & Santese, 2012, p. 234; Della Rocca, 2014, p. 394; Vallini, 2008, p. 71; Eusebi, 1995, p. 734; Negroni, 2021, p. 110) to protect public health (Veronesi, 2011, p. 64)³, while respecting the human person.

¹ Article 1, Law 22 No. 219, December 2017, "Rules on informed consent and advance directives on treatment", in GU No. 12 of 16. 01. 2018.

² Article 2 of the Italian Constitution: "The Republic recognizes and guarantees the inviolable rights of man, both as an individual and in the social formations where his personality takes place, and requires the fulfillment of the mandatory duties of political, economic, and social solidarity."

³ See Cass., Sez. III, 30 January 2009, No. 2468, in *Giust. civ.*, 2009, 4-5, I, p. 885.; Even when public interest is in danger, Law No. 180/1987, in Article 1, Paragraph 5, provides that: "The compulsory medical

On closer inspection, compulsory health treatment must necessarily involve a benefit for the community's health since it compromises the fundamental rights of the individual, such as his free self-determination and his right to health (Casciaro & Santese, 2012, pp. 112–113), and from here we can notice the collective dimension of the right to health as an interest of the community. According to Italian legislation, to impose compulsory health treatment, it is necessary to present a current, concrete, and direct danger to the community (Veronesi, 2011, p. 69). In addition to protecting collective health, medical treatment must also protect the health of the individual who undergoes it¹ (Veronesi, 2011, p. 69; Mantovani, 1992, p. 61). Only in this way is it permissible to limit a person's free self-determination and ensure a fair balance in the protection of fundamental rights.

In the opinion of Carlassare, "*any limitation to freedom (...) must find an adequate justification in the collective interests, taking into account that in principle, the Constitution makes affirmations of freedom and the limitations are not the rule but the exception*" (Carlassare, 1967, pp. 110–111). According to this opinion, the Constitution guarantees individual freedom, and the latter can be limited only in exceptional cases in the presence of a relevant interest of the community (See Negroni, 2021, p. 41).

This orientation finds its basis in the jurisprudence of the Italian Constitutional Court in Decision No. 307 of 1990, in which the Court examines the admissibility requirements of compulsory health treatment. In this case, the Court found that "*compulsory health treatment is applied only when it does not negatively affect the state of health of the person who is obliged, except for those consequences which, due to their temporariness and insignificance, appear normal for any health intervention and therefore tolerable.*"² The Court also recognized the right of the individual to compensation for damage, even minimal damage, suffered as a consequence of compulsory health treatment (See C. Cost., June 22, 1990, No. 307; Flick, 2013, p. 19; Fineschi, 1990, pp. 924 et seq.).

According to a part of the doctrine that carries out a combined reading of Article 32 of the Constitution, compulsory health treatment necessarily requires the coexistence of individual and collective interests. In this context, it must not have a detrimental impact on personal health and must avoid causing harm or endangering community health³ (Carlassare, 1967, pp. 109 et seq.; Vincenzi Amato, 1976, p. 172 et seq.;

examinations and treatments (...) must be accompanied by initiatives aimed at ensuring the consent and participation of those who are obliged."

¹ ECHR, *Vavříčka and others v. The Czech Republic*, applications nos. 47621/13 and 5 others.

² In this sense, Italian Constitutional Court Decisions Nos. 5/2018; 307, 22 June 1990, in *Riv. it. med. leg.*, 1990, p. 914; 218/1994, 258/1994, and 118/1996.

³ Italian Constitutional Court, Decisions Nos. 307/1990; 218/1994; 258/1994; 118/1996; 27/1998; 226/2000; 107/2012; 368/2017; 5/2018.

Sandulli, 1978, p. 517; Luciani, 1980, p. 782; Modugno, 1982, pp. 311 et seq.; Veronesi, 2011, pp. 154-155; Negroni, 2021, pp. 39-40).

In this sense, also based on the jurisprudence of the Constitutional Court, compulsory health treatment does not represent any incompatibility profile with Article 32 of the Constitution if the latter is aimed at safeguarding both individual and community health¹. On the other hand, it should be noted that in Decision No. 307 of 1990, the Constitutional Court also stated that: "*The constitutional importance of health as an interest of the community is not alone sufficient to justify the health measure. This observation (...) does not imply that each person's health should be sacrificed for the protection and health of others*"².

The mandatory COVID-19 vaccination requirement in the Italian legislation

The imposition of the mandatory COVID-19 vaccination requirement by the Italian legislator, in Article 4 of the law decree of 1 April 2021, No. 44, converted into Law No. 76/2021, has involved great debates in doctrine and jurisprudence, and it must be noted that today there is still no univocal interpretation on the topic. The basic question is whether this vaccination violates some fundamental rights that are constitutionally guaranteed, such as the right to free self-determination in the medical field and human dignity, along with a series of other constitutionally guaranteed rights, such as the right to work and to receive a salary. The issue has been the subject of legal debates and several decisions by regional administrative courts.

Part of the doctrine, contrary to the mandatory COVID-19 vaccination requirement, has advanced the theory that COVID-19 vaccines, such as those from Pfizer BioNTech, AstraZeneca, and Moderna, approved by the European Union's competent authorities, represent a type of experimental medical treatment (Negroni, 2021, p. 128). In support of this thesis, the doctrine underlines that those vaccinations have been authorized by the EMA through conditional marketing authorization, taking into account that it is impossible to report comprehensive and complete data on the drug's effectiveness and long-term side effects. Conditional marketing authorization is usually issued when the pharmaceutical product presents insufficient data and evidence compared to the regular approval, and the producer must submit comprehensive risk and benefit data after the authorization (Cenci, 2021, p. 5). In this respect, part of the doctrine (Negroni, 2021; Cenci, 2021) considers that mandatory vaccination against COVID-19 exposes the person to unknown health risks, given that long-term damage is impossible to predict and the safety and efficacy of vaccines are not certified by complete clinical evidence.

In this regard, the doctrine highlights that the notion of free self-determination in the medical field, as enshrined in Article 32 of the Italian Constitution, contains another

¹ Italian Constitutional Court, Decision No. 307/1990.; In the same direction ECHR, *Vavříčka, and others v. The Czech Republic*, applications nos. 47621/13 and 5 others.

² In the same direction, the Italian Constitutional Court, Decision No. 118/1996.

fundamental principle according to which no one can be subjected to medical experimentation. This concept emphasizes respect for human dignity and human beings. Consequently, experimental medical treatment, including mandatory vaccination, cannot be imposed even by law as it contrasts with the letter and spirit of Article 32 of the Italian Constitution (Negroni, 2021, pp. 120–122).

Another concern about obligatory vaccination is the harm caused by COVID-19 vaccines. Doctrine and jurisprudence perceive these damages as superior to normal tolerance, resulting in a conflict between the individual and collective dimensions (Baccarra & Rinaldi, 2022, p. 64). A part of the doctrine, based on the Constitutional Court's ruling No. 307 of 1990, considers that mandatory vaccination generally affects individuals' health, causing damages in the pursuit of collective interest, but these damages are permissible if they are bearable or of normal tolerance. Accordingly, the doctrine based on statistics, argues that adverse events, including fatal ones caused by COVID-19 vaccines, are significantly superior to those of vaccines practiced for years and cannot fall into the category of events of normal tolerability (Cenci, 2021, p. 19).

The court of Padua intervened on the topic of mandatory vaccination and evaluated the vaccination obligation based on the proportionality of the measure taken in relation to the objective it seeks to achieve. In this sense, the Court of Padua ruled that compulsory vaccination against COVID-19 is "*unsuitable – and thus unreasonable (...) – to achieve the intended purpose*¹," declaring it in violation of the principles of proportionality, adequacy, and reasonableness guaranteed by Article 3 of the Italian Constitution and Articles 15 and 52, first paragraph, of the European Union Charter of Fundamental Rights (Tundo, 2022).

Contrary to the above, another part of the doctrine believes that vaccines against COVID-19 are not experimental and that even if approved by the competent authorities with conditional authorization, they have exhausted the experimentation phase (Barracca & Rinaldi, 2022, p. 54). In the same direction, we find the decision of the Italian Council of State No. 7045 of 20.20.2021, which highlights that COVID-19 vaccines are effective and not experimental (Baccarra & Rinaldi, 2022, p. 68). With this decision, the Council of State emphasized the significance of two fundamental rights: on the one hand, the right of the individual to free self-determination and, on the other hand, the right to health as a community interest, both guaranteed by Article 32 of the Constitution, accentuating the need for a fair balance between these two fundamental rights². In this regard, the Council of State refers to Decision No. 5 of 2018 of the Italian Constitutional Court concerning the mandatory vaccination requirement for minors introduced in 2017, where the latter declares that the imposition of compulsory health treatment is not incompatible with Article 32 of the

¹ Court of Padua, Judgment of 28 April 2022. In this direction also T.A.R. Lombardia, Sez. 1, 16 giugno 2022, No. 1397.

² Council of State, Third Section, 20 October 2021, No. 7045, para. 35.

Italian Constitution if the medical treatment is directed to recover or preserve the health of the person who is obliged and to protect the community's health¹ (See Pisani, 2022, p. 911); the compulsory health treatment must not adversely affect the state of health of those subjected to it, except for tolerable consequences; and in the case of damage to the subject's health, the law must provide fair compensation in favor of the latter. However, in all cases, this treatment must respect the human person² (Negroni, 2021, p. 38). Therefore, the Council declared that the doubts about the constitutional legitimacy of the mandatory COVID-19 vaccination requirement, introduced by Decree-Law No. 44/2021, were manifestly unfounded.

This decision has been the subject of criticism from a part of the doctrine (Conti, 2022), specifically when it considers manifestly unfounded the question of constitutional legitimacy proposed by the applicants. On this occasion, Article 4 of Decree-Law No. 44 of April 1, 2021, converted with amendments into Law No. 76 of May 28, 2021, was alleged to be in contrast with Article 32 (free self-determination) and Article 3 of the Italian Constitution in terms of reasonableness, proportionality, and equality, together with a series of other articles, including Articles 2, 9, 33, 1, 2, 4, 35, and 36 of the Italian Constitution. As a result, Conti observes that the rejection of the constitutional legitimacy check of the mandatory COVID-19 vaccination requirement reveals the system's poor health in terms of constitutional guarantees (Conti, 2022).

Despite the rejection of the question of constitutional legitimacy by the Council of State, several regional courts have found this question not unfounded³, leaving the final verdict to the Constitutional Court, which has scheduled a hearing for the following November 29th. The Administrative Justice Council for the Region of Sicily, with Ordinance No. 351 of March 22, 2022, was one of the courts that considered the issue of constitutional legitimacy to be not unfounded. In this ordinance, the Council analyzes the requirements for the legitimacy of obligatory health treatment. Based on Constitutional Court Decision No. 307/1990, the Council reaffirms that compulsory medical treatment must preserve and benefit the health of the obliged subject, as well as protect public health and if adverse events occur, they must enter the limit of normal tolerability.

The Council ordinance raises critical issues concerning mandatory vaccination, including the adverse effects of COVID-19 vaccines. In this regard, the Court refers to the Supervisory Institute's statistics on the side effects of the COVID-19 vaccine, where it is noted that the percentage of adverse events occurring is well above the average of adverse effects occurring with vaccines used for years⁴. The Court's

¹ Italian Constitutional Court, Decision No. 5/2018.

² Italian Constitutional Court, Decision No. 307/1990.

³ See T.A.R. Lombardia, Sez. 1, 16 giugno 2022, No. 1397; Administrative Justice Council for the Region of Sicily, Ordinance No. 351 of March 22, 2022.

⁴ Administrative Justice Council for the Region of Sicily, Ordinance No. 351 of 22.03.2022, para. 18.1.

concern is whether adverse effects fall within the normal tolerance, considering the relatively low number of cases with fatal outcomes. In light of the findings of pharmacovigilance controls based on spontaneous reporting of adverse events, the Council concludes that the tolerance limit for adverse events has been surpassed (Gambardella, 2022). Another critical profile that the Council highlights concerns the collection of informed consent, even in the case of mandatory vaccination. The Council observes that informed consent is relevant in the context of free willful self-determination but not in the context of a legal obligation¹. In case of compulsory vaccination should be provided an information document². In the opinion of the Council, Article 4, paragraphs 1 and 2 of the Decree-Law No. 44/2021 (converted into Law No. 76/2021) conflicts with some Articles of the Italian Constitution, such as: "*Article 3 (under the parameters of rationality and proportionality); Article 32 (in terms of the impact on free self-determination regarding health treatments that have effects that are neither mild nor transitory); Article 97 (good performance, also about the criticalities of the monitoring system); Article 4 (right to work); Articles 33 and 34 (right to education); Article 21 (right to free expression, which includes the right to dissent)*"³.

However, the question of the legitimacy of the mandatory COVID-19 vaccine requirement has not yet found a definitive answer. Consider the orientation of the European Court of Human Rights, which has deemed inadmissible the request to suspend the mandatory vaccination requirement under Article 39 of the ECHR, presented by firefighters and first aid workers in France due to the provision of the mandatory COVID-19 vaccination requirement⁴. The Court ruled that the applicant's request was inadmissible because there was no risk of infringement of the rights guaranteed by Articles 2 and 8 of the European Convention on Human Rights⁵.

¹ According to Giovanni Maria Flick, informed consent has no relevance in front of a legal obligation (Milella, 2022).

² Administrative Justice Council for the Region of Sicily, Ordinance No. 351 of 22.03.2022, para. 18.7.

³ *Ibid.*

⁴ French Law No. 1040/2021, 5 August 2021.

⁵ ECtHR, *Abgrall and other 671 v. France*, dec., No. 41950/21, 24 August 2021.

Discussions

To adequately address the topic of compulsory vaccination against COVID-19, we have to consider several issues. In the first place, we have to assess whether this obligation violates human dignity, as noticed by Negroni (See Negroni, 2021). Accordingly, it is necessary to analyze whether vaccination against COVID-19 represents an experimental treatment. In this respect, we have to consider that the vaccines against COVID-19 have obtained conditional marketing authorization from the EMA for the immediate use of drugs due to the grave health situation caused by COVID-19 after having exhausted the experimental phase (Barracca & Rinaldi, 2022, p. 54). Based on these statements, part of the doctrine and jurisprudence exclude that they constitute an experimental treatment (Barracca & Rinaldi, 2022; Council of State, No. 7045/2021). On the other hand, we have to take into account the fact that these vaccines produce adverse effects, and this has been reported by the evidence of the institute of pharmacovigilance based on spontaneous reporting of adverse events¹ and long-term effects are impossible to know, considering the lack of complete and exhaustive evidence.

The second concern is the infringement of the principle of free self-determination in the health field. In this sense, Article 32 of the Italian Constitution guarantees the right to free self-determination in all decisions concerning health and psycho-physical integrity; on the other hand, this article provides a limitation of free self-determination to protect public health in the cases explicitly provided for by law. For this purpose, we should consider the decision of the Italian Constitutional Court No. 5/2018, which recently declared that the vaccinal obligation imposed on minors is not incompatible with Article 32 of the Italian Constitution.

When interpreting this statement, we must consider the requirements that need to be met by mandatory medical treatment. According to the Italian Constitutional Court decision No. 307/1990, compulsory medical treatment must preserve and benefit the health of the obliged subject, as well as protect public health, and if adverse events occur, they must enter the limit of normal tolerability. So the question that doctrine and jurisprudence see as crucial is whether adverse events caused by COVID-19 vaccines, including the rare fatal ones, fall into the category of tolerable events. In this context, the principal question is what should be considered "tolerable" in light of the Italian Constitutional Court's view. On the other hand, this assessment may require complete and exhaustive evidence regarding the long-term adverse effects of these vaccinations, which is currently lacking.

The last concern is whether the legislator's obligation complies with the principles of proportionality, equality, and rationality of the measure adopted concerning the goal

¹ *Rapporto sulla sorveglianza dei vaccini anti COVID-19*, 12, 27.12.2020 – 26.6.2022, retrieved from: https://www.aifa.gov.it/documents/20142/1315190/Rapporto_sorveglianza_vaccini_COVID-19_12.pdf.

to be achieved, as outlined in Article 3 of the Italian Constitution¹. In this sense, we have to assess whether this is the only measure to protect public health or whether other more appropriate measures with the same purpose are possible. It is crucial to recognize that the issue of mandatory Covid-19 vaccination is a complex and delicate ethical, political, and legal issue with two significant interests at stake that are diametrically opposed: on the one hand, the individual's interest in protecting his health and not being forced to undergo unwanted medical treatment; on the other hand, public health protection.

Conclusions

The aim of the present research was to examine the different concerns that the mandatory Covid-19 vaccination requirement has raised in Italy. The findings of this study indicate that we have to consider the issue of mandatory COVID-19 vaccination in light of two fundamental principles: free self-determination in health choices on one side and public health on the other. In this context, the Italian Constitutional Court has the difficult task of analyzing whether the mandatory COVID-19 vaccination interferes with the delicate balance between individual and public health, considering the adverse events caused by COVID-19 vaccines.

The most acceptable thesis seems to be the less intrusive policy, which respects individual autonomy in decisions involving health and psycho-physical integrity (Negroni, 2021, pp. 86–87). In this respect, the lawmaker is recommended to consider appropriate measures that respect individual autonomy while also preserving public health.

The issue of the mandatory COVID-19 vaccination requirement in Italy is still controversial, considering that several regional courts have raised doubts about its constitutional legitimacy. Subsequently, the Italian Constitutional Court has set the first hearing for November 29, 2022, in such a way as to express the compliance of this obligation with the fundamental rights guaranteed in the Italian Constitution.

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¹ See T.A.R. Lombardia, Sez. 1, 16 giugno 2022, No. 1397; Court of Padua, Judgment of 28 April 2022.

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