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EDITORIALE SCIENTIFICE

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MANDATORY COVID-19 VACCINATIONS AND HUMAN RIGHTS IN EUROPE: HOW TO FIND A DELICATE BALANCE?

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1. Introduction

Vaccinations are considered amongst the greatest medical achievements of modern medicine. The discovery of the COVID-19 vaccines and the roll out of mass vaccination campaigns (including booster doses and vaccines for minors), have allowed developed countries to slowly come back to normal life, immunizing most of their populations and entering a 'post-pandemic scenario'.¹

The development of a vaccine is a lengthy process, usually taking several years and different stages (preclinical, studies on animals, clinics and then large-scale vaccine production and licensing).

The speed with which COVID-19 vaccines have been devised was notably faster if compared to other vaccines. Their discovery first raised the challenge of how to make these vaccines rapidly, fairly and equitably accessible to the whole world populations. Against this backdrop, there is the wider issue correlated with vaccine nationalism,² that raised a distributive dilemma and the problem of timely access to affordable medicines, since the COVID-19 pandemic has generated a global demand for such vaccines that by far exceeds supply, and as a consequence a world's vaccination imbalance.³

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¹ The first safe and effective vaccine against COVID-19 was authorized in the European Union by the European Commission through a conditional marketing authorization in December 2021 (https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2466).

² D. P. FIDLER, Vaccine nationalism's politics, in Science, 2021, p. 749 ss.

³ A. SYKES, Short Supply Conditions and the Law of International Trade: Economic Lessons from the Pandemic, in AJIL, 2020, p. 647 ss.

The COVID-19 vaccines race has highlighted a fracture between the call to a universal and equitable access to COVID-19 vaccination by the UN and its Specialized Agencies, and multilateral initiatives towards this goal, such as COVAX on one side, and national isolationism on the other side.

At the same time, another major critical challenge related to COVID-19 vaccines – referred to as 'vaccine hesitancy – has emerged.⁴ Vaccine hesitancy is the delay in acceptance or refusal of vaccines despite availability of vaccination services.⁵ In 2019, it was classified by the WHO as one of the ten threats to global health.⁶

In general terms, the increase of social resistances towards vaccinations – especially in industrialized countries – has forced some States to adopt restrictive policies that imply a vaccination duty especially with reference to minors. Nowadays a wide literature – that analyzes the c.d. 'determinants' (psychological, social, cultural, demographical and economic factors) of vaccine hesitancy – has been developed. Amongst these – as is well known – a key role is played by misinformation ('fake news') conveyed by the groups against vaccinations through the use of social networks.

In general terms, a few individuals are hesitant towards vaccines on scientific grounds (they are reluctant about the safety and efficacy of the vaccines), others for religious reasons. With reference to the COVID-19 vaccines, extremist religious groups have contested the fact that some of them (in particular Johnson & Johnson and Astra Zeneca) have been presumably developed using embryonic or fetal cells. In the United States, historical fetal cell lines have been stored in the 1960's and 1970's and have been already used to fabricate vaccines for several diseases (in particular, hepatitis A, rubella, and rabies). The fetal cell lines which have allegedly been used to produce COVID-19 vaccines – that relied on adenovirus approaches – have however never required or solicited new abortions.⁹

Vaccine hesitancy raises the issue of which strategies can be adopted in order to have the widest coverage of population immunized (mandatory vaccination policies, mechanisms based on incentives, indirect vaccination obligation through a wide use of vaccine passports).

⁴ As previously stated, the attainment of herd immunity against the COVID-19 pandemic would require the vaccination of at least 70 % of the world population, and is hence a major challenge. OECD (2021), "Access to COVID-19 vaccines: Global approaches in a global crisis", OECD Policy Responses to Coronavirus (COVID-19), OECD Publishing, Paris, https://doi.org/10.1787/c6a18370-en.

⁵ According to the European Centre for Disease Prevention and Control "vaccine hesitancy refers to delay in acceptance or refusal of vaccines despite availability of vaccination services. Vaccine hesitancy is complex and context specific varying across time, place and vaccines. It includes factors such as complacency, convenience and confidence"; https://www.ecdc.europa.eu/en/immunisation-vaccines/vaccine-hesitancy.

⁶ https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019.

⁷ See amongst other, A. GRIGNOLIO, Vaccines: Are They Worth a Shot?, Springer, 2018.

⁸ It is worth recalling that the key scientific publication arguing a causal link between autism and vaccinations Measles, Mumps and Rubella vaccines (A.J. WAKEFIELD, S.H. MURCH, A. ANTHONY "Lleal-lymphoid-nodular hyperplasia, nonspecific colitis, and pervasive developmental disorder in children", in *The Lancet*, 1998, p. 637) has been then retracted. According to the retraction, "no causal link was established between MMR vaccine and autism as the data were insufficient". This is the most famous case of scientific fraud. Dr Wakefield's claims caused a serious drop in vaccination's rates in the United Kingdom since they had a deep impact on the public opinion and Wakefield's findings are still used by the no vax as evidence that vaccines are a public health risk. This link has been then refuted by several scientific studies. See, for instance, A. JAIN, J. MARSHALL, A. BUIKEMA, Occurrence by MMR Vaccine Status Among US Children With Older Siblings With and Without Autism, in *JAMA (The Journal of American Medical Association*), 2015, p. 1534 ss.

⁹https://www.health.nd.gov/sites/www/files/documents/COVID%20Vaccine%20Page/COVID19_Vaccine_Fetal_Cell_Handout.pdf.

In particular, it refers to the relationship between a compulsory and mandatory vaccination for the prevention of the SARS-CoV-2 infection based on public health reasons and individual human rights (such as the right to private life and right to conscious objection of both the patient and the physician). Vaccine hesitancy is a serious threat in the fight against the COVID-19 pandemic and has forced several countries to adopt direct or indirect compulsory mechanisms on vaccinations for the prevention of the SARS-CoV-2 infection. ¹⁰ In this respect, this paper highlights the importance of science in assessing to what extent pandemic-related measures are proportional to the risks and in choosing the least restrictive and the most individualized options when restricting civil and political rights due to public health reason.

This paper revolves around three key assumptions. First, the collective dimension of the right to health prevails over its individual feature. Therefore, the collective interest to the protection of public health takes precedence over the interest of individual to (allegedly) protect his/her own health against side effects of vaccines, to provide his/her informed consent to a medical treatment and to preserve his/her privacy not to disclose any information about the health status.

Coercion in liberal societies can only be justified in order to prevent harm to other member of a given community. Vaccination generally protects those vaccinated against a given infectious disease but it also has an effect on others. During a pandemic, such as the case of COVID-19, it is essential to immunize most of the population for two simple reasons: first, people that are infected, even if asymptomatic, can be a deadly threat to others; second, if a large part of the population is affected by the virus, it might overburden the health care system and impede others from having access to essential health assistance.

Against this backdrop, under the lens of European interstate relations, the paper is divided in three parts. First, it makes a brief reconstruction of the current legal frameworks for administering vaccines against the most common infectious diseases adopted by domestic authorities to reach the goal of 'herd immunity', with particular reference to Council of Europe's Member States, such as Italy, Germany, France, United Kingdom. Second, it will have a focus on the policies of some European countries to tackle the COVID-19 pandemic in the 'hot period' of diffusion of the virus between the end of 2021 and early 2022. Third, the paper will have a specific focus on the jurisprudence of the European Court of Human Rights on compulsory childhood vaccination and its implication on State policies on COVID-19 vaccinations.

A particular focus will be devoted to the 'key case' Vavřička and Others v. the Czech Republic (2022) which highlighted the Court's approach to the issue of mandatory vaccination, since the Court's decision was adopted at the height of the COVID-19 pandemic.

On this basis, the paper argues that COVID-19 compulsory vaccination – a path slowly followed by some European countries like Austria – is perfectly consistent with the ECHR and does not violate fundamental rights. Third, it claims that a vaccine obligation is in line with the evolutionary interpretation of the Strasbourg's Court.

¹⁰ C.S. WIYSONGE, D. NDWANDWE, J. RYAN, A. JACA, O. BATOURÉ, B.P. MELANGA ANYA, S. COOPER, Vaccine hesitancy in the era of COVID-19: could lessons from the past help in divining the future?, in Human Vaccines and Immunotherapeutics, 2021, p. 1 ss.

¹¹ With reference to the Council of Europe, it is worth recalling that following the expulsion of the Russian Federation from the Council of Europe on 16 March 2022, as consequence of the invasion of Ukraine, this country ceased to be a party to the European Convention on Human Rights on 16 September 2022, https://www.coe.int/en/web/portal/-/the-russian-federation-is-excluded-from-the-council-of-europe.

2. A brief history of vaccinations

An individual's decision to receive or to refuse a vaccine has significant implications for the whole community. Indeed, a vaccine provides a direct benefit to the individual and an indirect asset to the community by reducing the risk of spread of a specific outbreak through 'herd immunity'. The security threshold represented by the community immunity is a mechanism according to which, once reached the coverage of immunized population below 95%, a given infectious disease would not spread neither amongst the subjects that voluntarily or due to health reasons (such as immunosuppressed children) are not vaccinated. It is worth recalling that a few individuals cannot be vaccinated for health reasons, and must hence rely on the indirect benefits of the vaccination.

The maintenance of a high vaccination coverage, is, therefore, critically important. Domestic authorities have adopted several strategies to promote and maintain a higher immunisation rate coverage among their populations, including but not limited to mandatory vaccination. ¹³ The first compulsory vaccination program was related to smallpox in the XIX Century. Compulsory vaccination is connected to a school of thought developed in Germany according to which the State would have had a specific duty of taking care of the health of its own citizens, since they were tax payers and potential soldiers. In 1874, vaccination obligation was introduced in the *Reich*. ¹⁴ United Kingdom had instead strong resistances due to its liberal tradition of non-interference by the State in private life. States policies on compulsory or voluntary vaccination must find a delicate balance between different rights and values (individual dimension of health and self-determination *versus* the collective dimension of health). ¹⁵

Vaccination against a given infectious disease can be voluntary or mandatory. Within this spectrum, three different legislative approaches can be highlighted.¹⁶ The first is represented by legal frameworks based on promotional logics through incentives (Australia, Germany, Spain, United Kingdom); it means that immunisation is not a basic requirement to attend school, but it is highly recommended. The second relates to a legal order with a 'tendency' towards obligatoriness (Canada and United States).¹⁷ The third is a legal regime with a paternalistic footprint (France, Italy).

In a continuum that goes from the maximum protection of the self-determination of the individual to on one side, to the maximum attention to the requirements of public health

¹² https://www.nhs.uk/conditions/vaccinations/why-vaccination-is-safe-and-important/.

¹³ K. Gravagna, A. Becker, R. Valeris-Chacin, I. Mohammed, S. Tambe, F.A. Awan, T.L. Toomey, N.E. Basta, *Global assessment of national mandatory vaccination policies and consequences of non-compliance*, in *Vaccine*, 2020, p. 7865 ss.

¹⁴ G. KRAUSE, The historical development of immunization in Germany: From compulsory smallpox vaccination to a National Action Plan on Immunization, in Bundesgesundheitsblatt - Gesundheitsforschung – Gesundheitsschutz, 2012, p. 1512 ss.

¹⁵ Vaccination Act 1840, 1841, 1853: universal and complimentary vaccination. Obligation abolished in 1898.

¹⁶ For more details, M. TOMASI, Vaccini e salute pubblica: percorsi di comparazione in equilibrio fra diritti individuali e doveri di solidarietà, in Diritto pubblico comparato ed europeo, 2017, p. 455 ss.

¹⁷ Y. PENG, Politics of COVID-19 vaccine mandates: Left/right-wing authoritarianism, social dominance orientation, and libertarianism, in Pers. Individ. Dif. (2022), p. 1 ss.

protection on the other side, Germany and United Kingdom give more weight to the individual dimension of the right to health.

In United Kingdom the parents – as the trustees of their children's best interests – are entitled to decide whether to vaccinate or not their offspring. The intervention of the public authority can only be registered in case, for instance, of disagreement of views amongst the parents; in this case, the *favor* towards vaccination emerges in light of the jurisprudence of the domestic courts.

The idea according to which the choice whether to vaccinate or not a child is mainly a matter of the parents is strongly rooted also in Germany, whereas there is a strong emphasis on the necessity of a real conscious choice: Germany has not introduced, indeed, a duty of vaccination, but rather of advice and consult with the medical staff in order to have a clear framework of the risks and benefits related to the vaccination. Such an obligation is reinforced by the provision of a financial fine and it is a pre-condition for the enrollment of the minor at school. However, measles vaccination became mandatory in 2020 for children, teachers and health professionals.¹⁹

A compulsory model can be defined as legal framework which envisages negative consequences as a result of the refusal of an individual to vaccinate himself/herself or his/her offspring. This duty is not, therefore, directly imposed through coercion upon an individual, but the legislation is levying penalties against those who decide not to fulfill their obligations. This scheme contemplates various degrees of severity spanning from financial penalties, to the exclusion from school services, to the limitation of social and health services, up to the loss of parental rights.²⁰

These ranges of penalties have been classified in four categories: the less intrusive are financial sanctions (those that have an impact on the finances of an individual through the imposition of a fine) or educational sanctions (those that have a direct impact on the education of a child through the missed enrollment to school). ²¹ More severe implications imply parental rights' sanctions (such as the loss of parental rights) and liberty penalties (that do have a direct implication on the personal freedom of an individual, such as imprisonment).

3. The European model on vaccinations

European countries rely on financial penalties more frequently than any other region of the world (56% of European countries with evidence of a national mandate).²²

¹⁸ E. CAVE, Voluntary vaccination: the pandemic effect, in Legal Studies, 2017, p. 279 ss.

¹⁹ I. TORJESEN, German parliament votes to make measles vaccination mandatory, in British Medical Journal, 2019, p. 367

Legislative Approaches to Immunization Across the European Region. Sabin Vaccine Institute; 2018.
Available

https://www.sabin.org/sites/sabin.org/files/legislative_approaches_to_immunization_europe_sabin_0.pdf. ²¹ K. Gravagna, A. Becker, R. Valeris-Chacin, I. Mohammed, S. Tambe, F.A. Awan, T.L. Toomey, N.

E. BASTA, Global assessment of national mandatory vaccination policies and consequences of non-compliance, in Vaccine, 2020,p. 7865 ss.

²² O.M. VAZ, M. K. ELLINGSON, P. WEISS, S. M. JENNESS, A. BARDAJÍ, R.A. BEDNARCZYK, S. B. OMER, *Mandatory V accination in Europe*, in *Pediatrics*, 2020, p.1 ss.

Additionally, Italy is the only country to list temporary loss of child custody as a penalty for non-compliance.²³

Amongst Council of Europe's Member States, vaccine is mandatory for a cluster of infectious diseases, such as Polio, Tetanus, Hepatitis B (France, Greece, Italy, Portugal and countries of Eastern Europe, such as Bulgaria, Czeck Republic, Latvia, Poland, Slovakia).

In Italy, the National Bioethics Committee registered in 2015 in statistical and epidemiological terms a significant drop of the percentage of people vaccinated in relation to infectious diseases considered at high risk of diffusion and contagion. ²⁴ In response to this negative trend, the Italian public authorities have introduced measures oriented towards a reinforcement of vaccination duties. The political and normative intervention was structured on two levels. One was of a programmatic nature and was concretized in the updating of the domestic vaccine prevention plan 2017-2019, ²⁵ the other was a legal intervention represented by the adoption of Legislative Decree n. 73/2017²⁶ and in the following conversion Law n. 73/2017 that improved the range of compulsory vaccines and reinforced coercive measures. Now, the National Immunisation Plan (NIP) makes compulsory for children aged under 6 vaccinations against pertussis, measles-mumps-rubella (MMR), varicella and Haemophilus influenzae type b (Hib), in addition to diphtheria, tetanus, hepatitis B and polio. It comported a significant rise in vaccine coverage over 90% for measles, mumps and rubella. ²⁷

Also the French legal framework on compulsory vaccinations can be considered as basically prescriptive, since vaccination of infants up to two years against 11 diseases (amongst which diphtheria, tetanus, poliomyelitis) is the *conditio sine qua non* for school enrollment, without the possibility of legal loopholes, with the exception of strictly medical conditions, related to the existence of counter indications.²⁸ To reinforce the compliance mechanism, the French legal framework envisages criminal sanctions addressed to the parents that have not provided

²³ F. D'ANCONA, C. D'AMARIO, F. MARAGLINO, G. REZZA, S. IANNAZZO, The law on compulsory vaccination in Italy: an update 2 years after the introduction, in Eurosurveillance, 2019, p. ss.

²⁴ Comitato Nazionale per la Bioetica, Mozione: l'importanza delle vaccinazioni, 24 April 2015, https://bioetica.governo.it/media/1409/m14_2015_vaccinazioni_it.pdf.

²⁵https://www.salute.gov.it/portale/vaccinazioni/dettaglioContenutiVaccinazioni.jsp?lingua=italiano&id=48 28&area=vaccinazioni&menu=vuoto.

²⁶ Decreto Legislativo n. 73/2017, Ministero della Salute, 19 gennaio 2017, Disposizioni urgenti in materia di prevenzione vaccinale, di malattie infettive e di controversie relative alla somministrazione di farmaci, G.U. Serie generale - n. 130 del 7 giugno 2017, https://www.gazzettaufficiale.it/eli/id/2017/08/05/17A05515/sg.

²⁷ F. D'ANCONA, C. D'AMARIO, F. MARAGLINO, G. REZZA, S. IANNAZZO, *The law on compulsory vaccination in Italy: an update 2 years after the introduction*, in *Eurosurveillance*, 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6607737/.

²⁸ Code de la santé publique, Article L3111-2: "I. – Les vaccinations suivantes sont obligatoires, sauf contreindication médicale reconnue, dans des conditions d'âge déterminées par décret en Conseil d'Etat, pris après avis de la Haute Autorité de santé : Antidiphtérique ; Antitétanique ; Antipoliomyélitique ; Contre la coqueluche ; Contre les infections invasives à Haemophilus influenzae de type b ; Contre le virus de l'hépatite B ;Contre les infections invasives à pneumocoque; Contre le méningocoque de sérogroupe C ; Contre la rougeole ; Contre les oreillons; Contre la rubéole. "II – Les personnes titulaires de l'autorité parentale ou qui assurent la tutelle des mineurs sont tenues personnellement responsables de l'exécution de l'obligation prévue au I. La preuve que cette obligation a été exécutée doit être fournie, selon des modalités définies par décret, pour l'admission ou le maintien dans toute école, garderie, colonie de vacances ou autre collectivité d'enfants." For details, X. BIOY, *Vaccination obligatoire et droits fondamentaux*, in *Droit, Santé et Société*, 2022, p. 7 ss.

for the given vaccinations. This extremely rigid system has been endorsed by the *Conseil* constitutionnel.²⁹

The case of Australia is emblematic of the efficacy of financial sanctions even in absence of a specific duty.³⁰ The programme "No Jab No Pay" ('no vaccination, no family tax benefits') in the Australian economic-social context where several families cannot afford assistance to their children without such financial exemptions, was a remarkable success. ³¹ Six months after the implementation of the program at the beginning of 2016, a total coverage of immunized children aged between 1-5 was reached.³²

The liberal model is represented by countries like Austria, Cyprus, Denmark, Estonia, Finland, Ireland, Lithuania, Luxembourg, the Netherlands, Norway, Portugal, Spain, and Sweden and United Kingdom.

In United Kingdom, for instance, according to sect. 45 C of the Public Health (Control of Disease) Act 1984: "the appropriate minister may [...] make provision for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in England and Wales". The sect. 45 E ('Medical treatment'): every health measure under sect. 45 E "may not include provision requiring a person to undergo medical treatment." The term 'Medical treatment' includes "vaccination and other prophylactic treatment".

Canada, Germany and United States are cases of a 'mixed model', which mainly focuses on education and appropriate information. Although vaccines are not mandatory, social goods or services offered by the State can be withdrawn to families that choose not to vaccinate their kids.

In Canada, the States of Ontario³³ and New Brunswick require immunisation for several infectious diseases. Valid exonerations are envisaged for health reasons, religious belief and conscious objection. However, in case of disease outbreak, the kids can be exempted by school admission.

The key question is which model works better? According to a report by the Asset Society³⁴, a mechanism based on compulsory vaccinations does not always corresponds to a major coverage. Latvia – that has foreseen 12 compulsory vaccinations – does not reach higher coverage levels if compared to the other Baltic States which do not have a mandatory system.

Décision n. 2015-458 QPC du 20 mars 2015, https://www.conseil-constitutionnel.fr/en/decision/2015/2015458QPC.htm; J.L. VILDÉ, *L'obligation vaccinale en question*, in *Laennec*, 2015, p. 8 ss.

³⁰ K.WARD, B. P. HULL, J. LEASK, Financial incentives for childhood immunisation – a unique but changing Australian initiative, in Medical Journal of Australia, 2013, p. 590 ss.

https://www.health.gov.au/health-topics/immunisation/when-to-get-vaccinated/national-immunisation-program-schedule. According to the National Immunisation Program Schedule, the increasing of the national immunisation coverage can help to prevent the spread of infectious diseases amongst the population; https://www.servicesaustralia.gov.au/what-are-immunisation-requirements?context=41186.

³² T. J. CORDINGLEY, M.A.G. WILSON, K.M. WESTON, The success of Australia's No Jah, No Pay' policy at a local level; retrospective clinical audit of a single medical practice assessing incidence of catch-up vaccinations, in Health Soc Care Community, 2022, p. 353 ss.

³³ Between 4 and 6 years old, children should receive the following vaccines: tetanus, diphtheria, pertussis, polio, measles, mumps, rubella, chicken pox. In grade 7, children should receive the following vaccines: meningococcal conjugate (Men-C-ACYW), hepatitis b, human papillomavirus (HPV). Between 14 and 16 years old, teens should receive the following vaccine: tetanus, diphtheria, pertussis. See https://www.ontario.ca/page/vaccines-children-school.

³⁴ http://www.asset-scienceinsociety.eu/reports/page1.html.

At the same time, countries with different policies register the same trend (Austrian liberal model *versus* Romanian compulsory model).

There are, therefore, other factors – such as more or less efficient health systems and the level of health literacy in the general population – which influence the attitude towards vaccinations.

After this brief overview of selected legislations, in the next paragraph I will focus my analysis on national COVID-19 vaccination strategies and policies.

4. COVID-19 and Mandatory Vaccinations

The upturn in infections caused by the Delta and Omicron variants in autumn 2021 and early 2022 forced several governments to adopt stringent measures under the form of i) mandatory shots for health workers, high-risk groups, public servants; ii) indirect mechanism represented by mandatory COVID-19 certifications (showing vaccination of at least two doses through the Green Pass, recent negative test, or proof of recovery usually within the past 6 months through a RT-PCR or antigen test); iii) a reinforced indirect mechanism that allows *de facto* only to vaccinated people (and not to person with a negative test) the possibility to obtain the Green Pass, and therefore, to carry on a normal life, such as going to the office or attending sport events or having dinner at the restaurant.

The policy of adopting several restrictions on unvaccinated has been followed in several EU countries.³⁵

Italy imposed compulsory vaccination for health care professionals.³⁶ Italy strengthened its Green Pass through the introduction of the Super Green Pass, requiring a third shot of COVID-19 vaccine in order to have access to the workplace, public transportation, and to a wide range of social, cultural and sporting activities (such as restaurants, swimming pools, tennis clubs and gyms).³⁷ In few words, the strengthened version of the Green Pass is available only after vaccination or recovery; therefore, a negative test result is no longer sufficient.³⁸ The (strengthened) version of the green pass is provided after vaccination or recovery, and no longer in case of a negative test result. It is be needed to attend sports events, concerts, theatres, indoor restaurants, and more.

Ecuador was the first country in the world to make COVID-19 vaccination obligatory with the exception of patient that have a relevant medical condition or an incompatibility.

³⁵ It is worth recalling an upsurge of contagions in China (almost 250 million people infected with SARS-CoV-2 in the first half of December 2022), https://edition.cnn.com/2022/12/23/china/china-covid-infections-250-million-intl-hnk/index.html.

³⁶ Law of 28 May 2021 no. 76 (conversion into law, with amendments, of decree-law no. 44 of 1 April 2021, containing urgent measures for the containment of the COVID-19 epidemic, on the subject of SARS-CoV-2 vaccinations, justice and public competitions); see P.FRATI, R. LA RUSSA, N. DI FAZIO, Z. DEL FANTE, G. DELOGU, V. FINESCHI, Compulsory Vaccination for Healthcare Workers in Italy for the Prevention of SARS-CoV-2 Infection, in Vaccines, 2021, p. 1 ss.

³⁷ "Misure urgenti per il contenimento della diffusione dell'epidemia da COVID-19 e disposizioni in materia di sorveglianza sanitaria (decreto-legge)", Legislative Decree No. 229 of 30 December 2021, https://www.gazzettaufficiale.it/eli/id/2021/12/30/21G00258/sg.

³⁸ S. ZAAMI, COVID-19 vaccine mandates: what are the current European public perspectives, in European Review for Medical and Pharmacological Sciences, 2022, p. 643 ss.

Austria, which faced one of the lowest rates of population vaccinated against COVID-19 (around 68%), was eventually forced in at the end of 2021 to make COVID-19 vaccines compulsory for people aged from 18 amid rise of cases, envisaging fines up to € 3,600 for holdouts. This extraordinary measure was introduced after a targeted lockdown for unvaccinated citizens (the same kind of measure was adopted in Germany). Were exempted by this obligation persons which had particular medical conditions, pregnant women, and patients that have been recently affected by COVID-19. Compulsory vaccination mandate was eventually suspended in March 2022, as the Austrian government considered it disproportionate to the threat posed by the Omicron variant.³⁹

Vaccination continues to be mandatory in Tajikistan, Turkmenistan, Indonesia, Micronesia, New Caledonia.

In Costa Rica vaccination is compulsory for persons aged over 5; against this backdrop, a specific agreement has been signed with Pfizer in order to obtain enough shorts to immunize all the children aged between 5 and 12.⁴⁰

In the United States, the Food and Drug Administration (FDA) has provided an 'emergency authorization' for Children Down to 6 Months of Age. 41

5. The European legal framework

5.1. The European Union

The possibility to issue a vaccination mandate with the goal of immunizing a high percentage of the population against infectious diseases was raised within the WHO in 1960s. ⁴² In order to reach the goal of covering at least 70% of the population against most common infectious diseases, the WHO highlighted two practical solutions: compulsory vaccination and /or persuasion through an expensive campaign of health education.

At regional level, on 1st December 2014, the Council of the European Union adopted specific conclusions on vaccination as an effective tool in public health, noting, *inter alia*, that: "... communicable diseases, including some re-emerging ones, such as Tuberculosis, measles, pertussis and rubella, still present a public health challenge and can cause a high number of infections and deaths, and that the recent emergence and outbreaks of communicable diseases, such as polio, avian influenza H5N1 and H7N9 ... and Ebola virus disease have confirmed that vigilance must remain high also with respect to diseases that are not currently present in the territory of the Union".⁴³

The Council recognized that "many vaccines used in community vaccination programs have been able to prevent disease in individuals and at the same time interrupt the circulation of pathogens through the so-called 'herd immunity' phenomenon, contributing to a healthier

https://www.reuters.com/business/healthcare-pharmaceuticals/austria-scraps-already-suspended-covid-vaccine-mandate-2022-06-23/.

⁴⁰ https://www.reuters.com/article/health-coronavirus-costa-rica-idUSL1N2LD1HL.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children.

⁴² "Compulsory or Voluntary Vaccinations", WHO Secretariat, A/13 Technical Discussion, 25 April 1960, https://apps.who.int/iris/bitstream/handle/10665/134370/WHA13_TD-

 $^{2\}_eng.pdf? sequence = 1 \& is Allowed = y.$

⁴³ Council conclusions on vaccinations as an effective tool in public health. (2014/C 438/04).

global society. Community immunity could thus be considered an objective in national vaccination plans."

On 19 April 2018, the European Parliament enacted a resolution on vaccine hesitancy in response to the drop in vaccination rates in Europe, which calls on Member States to ensure sufficient vaccination of healthcare workers, take effective steps against misinformation, and implement measures for improving access to medicines.⁴⁴ It also calls on the Commission to facilitate a more harmonized schedule for vaccination across the European Union.

The importance of vaccines as a the most powerful and cost-effective device to protect public health has been expressly recognized on 7 December 2018 by the Council of the European Union on a recommendation on strengthened cooperation against vaccine preventable diseases.⁴⁵

Health is, however, a competence of EU Member States *ex* art. 168 TFEU, which have the faculty to decide who to vaccinate and whether to impose specific vaccination duties;⁴⁶ therefore, the EU cannot directly determine whether the vaccination against COVID-19 or a given infectious disease should be compulsory or not.

EU Member States have – according to public health reasons related to the spread of the COVID-19 pandemic – highly limited the right of free movement of EU citizens. As specified in Recommendation (EU) 2020/1475, such restrictions have been based on the principles of proportionality and non-discrimination.

The EU Regulation n. 953/2021⁴⁷ has introduced the EU digital COVID certificate as a necessary tool to freely circulate in the European area.⁴⁸ The objectives of Regulation n. 953/2021 are to facilitate safe cross-border movement, precluding more restrictive national measures, preventing discrimination and coordinating the actions of Member State. According to Para. 36, "it is necessary to prevent direct or indirect discrimination against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the COVID -19 vaccine is currently administered or allowed, such as children, or because they have not yet had the opportunity or chose not to be vaccinated. Therefore, possession of a vaccination certificate indicating a COVID-19 vaccine, should not be a pre-condition for the exercise of the right to free movement or for the use of cross-border passenger transport services such as airlines, trains, coaches or ferries or any other means of transport. In addition, this Regulation cannot be interpreted as establishing a right or obligation to be vaccinated." This last wording means that the EU does not take a clear stance on the issue of mandatory vaccination against COVID-19 that relies within the margin of appreciation of each State.

⁴⁴ European Parliament resolution of 19 April 2018 on vaccine hesitancy and the drop in vaccination rates in Europe (2017/2951(RSP).

⁴⁵ Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases (2018/C 466/01).

⁴⁶ The State's reservation is also confirmed by Art. 35 of the EU Charter on Fundamental Rights (Nizza, 2000), according to which "one has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities".

⁴⁷ Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic.

⁴⁸ I. GOLDNER LANG, EU COVID-19 Certificates: A Critical Analysis, in European Journal of Risk Regulation, 2021, p. 291 ss.

5.2. The Council of Europe

The problem of vaccine hesitancy and the most effective legal options to immunize a wide range of the population has been debated within the Council of Europe (CoE) from the 90s. On 19 March 1997, the Parliamentary Assembly of the Council of Europe adopted Recommendation 1317 (1997) on vaccination in Europe.⁴⁹

Two resolutions of the Council of Europe of 2021 have then addressed in detail the issue of the compatibility between compulsory vaccinations and human rights: Resolution n. 2361/2021⁵⁰ and Resolution n. 2383/2021.⁵¹ Para. 4 of Resolution n. 2361 recognizes that "vaccine hesitancy and vaccine nationalism have the capacity to derail the so-far surprisingly fast and successful Covid-19 vaccine effort, by allowing the SARS-CoV-2 virus to mutate and thus blunt the world's most effective instrument against the pandemic so far". Para. 7.1.5, then encourages Member States to "put in place independent vaccine compensation programmes to ensure compensation for undue damage and harm resulting from vaccination".

With respect to ensuring high vaccine uptake, the CoE takes a clear stance on the fact that citizens must be informed that vaccination is *not mandatory* and that "no one is politically, socially, or otherwise pressured to get themselves vaccinated, if they do not wish to do so themselves" (Para. 7.3.1). Furthermore, States must avoid any form of discrimination if an individual does not want to be vaccinated due to possible health risks (there is no mention to religious beliefs).

In addition, they must adopt effective measures against "misinformation, disinformation and hesitancy regarding Covid-19 vaccines" (Para. 7.3.3). To this aim, transparent information on the safety and possible side effects of vaccines must be distributed (Para. 7.3.4).

Against this backdrop, guidance is also provided by the European Convention on Human Rights and Biomedicine (or Oviedo Convention), namely Article 5, which recognizes informed consent as a fundamental right of each individual.⁵²

⁴⁹ The Assembly considers that efforts to improve the immunisation level should not be concentrated solely on the plight of the countries undergoing transition. The immunisation level of populations in Western Europe has been steadily declining in recent years. The low percentage of fully vaccinated people, coupled with outbreaks of infectious diseases in the same geographic area, raises fears of major epidemics in Western Europe too. The Assembly therefore recommends that the Committee of Ministers invite member states: to devise or reactivate comprehensive public vaccination programmes as the most effective and economical means of preventing infectious diseases, and to arrange for efficient epidemiological surveillance.

⁵⁰ Resolution 2361 (2021), Covid-19 vaccines: ethical, legal and practical considerations.

⁵¹ Resolution 2383 (2021), Covid passes or certificates: protection of fundamental rights and legal implications. ⁵² Article 5 of the Biomedicine Convention states "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time". Article 14 of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS No. 195), adopted on 25/01/2005 and entered into force on 01/09/2007 affirms that "no research on a person may be carried out, subject to the provisions of both Chapter V and Article 19, without the informed, free, express, specific and documented consent of the person. Such consent may be freely withdrawn by the person at any phase of the research." See R. ANDORNO, *Principles of international biolaw seeking common ground at the intersection of bioethics and human: Seeking Common Ground at the Intersection of Bioethics and Human Rights*, bruylant, 2013, p. 21 ss; I.R. PAVONE, *La Convenzione europea sulla biomedicine*, Giuffrè, 2009; S. E. SALAKO, *Informed consent under the European Convention on Biomedicine and the UNESCO Declaration on Bioethics*, in *Medicine and Law*, 2011, p. 101 ss.

The Convention also includes detailed norms devoted to vulnerable persons, such as minors or incapable adults (Article 6, 'Protection of persons not able to consent'; Article 7, 'Protection of persons who have a mental disorder').

Article 26 ('restrictions on the exercise of the rights') affirms that "no restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the of crime, for the protection of public health or for the protection of the rights and freedoms of others". Therefore, compulsory interventions in the field of health are in line with the norms of the Convention if they are "prescribed by law" and are "necessary in a democratic society" in the interest of the protection of public health or the protection of the rights of others, among other reasons (Art. 26).

The problem of the relationship between compulsory vaccinations and the ECHR has been dealt by the ECtHR with reference to both the imposition of compulsory vaccination on minors and the specific case of COVID-19 vaccines.

As previously explained, most of CoE's Member States have in place legislations that envisage compulsory vaccination against specific infectious diseases.

With reference to COVID-19, an individual has not a specific obligation to vaccinate himself/herself, but in case of refusal, the State has envisaged a series of indirect sanctions. Indeed, a compulsory vaccination policy against COVID-19 interferes – under a theoretical point of view – with the civil and political rights contained in the ECHR, namely the right to life (Art. 2), the right to respect of private life (Art. 8, Para. 1) and freedom of thought, conscience and religion (Art. 9, Para. 1), that enshrines the right to conscious objection.

Against this backdrop, the Court faced in 2021 three requests for interim measures under Rule 39 of the Rules of the Court ⁵³ presented by a number of professional categories against France⁵⁴ and Greece.⁵⁵

Having said that, in the following paragraphs I will argue that the decision by a State to impose compulsory vaccination on health grounds – particularly in a pandemic stage of an infectious disease – is not in contrast with the ECHR, and it can be included within the wide margin of appreciation that States enjoy to foresee derogations to their rights.

6. Vaccines and Right to life

Many opponents to compulsory vaccination policies ('no vax') argue that the possible sideeffects related to a vaccine are a threat to their life. The 'no vax' movement is opposed to

Interim measures are urgent measures which, in accordance with the established practice of the Court, apply only where there is an "imminent risk of irreparable damage" (see *Mamatkulov and Askarov v. Turkey*, case No. 46827/99 and 46951/99, Para. 104, 4 February 2005; *Paladi v. Moldova*, case no. 39806/05, Paras. 86-90, 10 March 2009). In the Court's practice, they are generally granted in cases regarding deportation and extradition, serious risk to private or family life, or grave situations of inhumane treatments (such as torture). https://www.echr.coe.int/documents/fs_interim_measures_eng.pdf.

⁵⁴ On 19 August 2021, the ECtHR received a first complaint by 672 French firemen (members of the *Services départementaux d'incendie et de secours de France*) against the obligation of COVID-19 vaccination imposed by the *Loi n. 2021-1040 du 5 août 2021 'relative à la gestion de la crise sanitaire'*;

⁵⁵ On 2 September 2021, a similar application was presented before the ECtHR by 30 Greek healthcare workers who claimed the illegitimacy of the Greek Legislation (Law no. 4820–2021). S.R. VINCETI, COVID-19 Compulsory Vaccination and the European Court of Human Rights, in Acta Biomed, 2021, p. 1 ss.

vaccination in general, not only compulsory vaccination. There are many people who are favorable to vaccination and want to get vaccinated (and who, therefore, are not 'no vax', but are opposed to compulsory vaccination).⁵⁶

Art. 2 of the ECHR affirms that "the right to life is an inalienable attribute of the human beings and forms the supreme value in the hierarchy of human rights". According to the Court's case-law, Article 2 is one of the most fundamental provisions of the Convention.⁵⁷ It safeguards the right to life as a precondition for the enjoyment of any of the other rights and freedoms protected by the Convention.⁵⁸

In addition, the Court has established that Art. 2, Para. 1, obliges States Parties not only to refrain from intentional and unlawful deprivation of life (duty of *non facere*),⁵⁹ but also to take positive steps to safeguard the lives of persons within their jurisdiction.⁶⁰

Under certain circumstances, this duty also entails the undertaking to protect individuals against suicide attempts, especially in the case of detainees.⁶¹

The right to life was raised in proceedings before the Court with reference to both beginning and end of life issues in the field of bioethics. The first time that the Court dealt with abortion and beginning of life problems was in *X v. the United Kingdom*, when the former Commission received a complaint by a potential father, who lamented that his wife had been allowed to undergo an abortion on health reasons. The Commission affirmed that the term "everyone" ("toute personne") in the ECHR could not apply to the unborn (embryo/foetus). As to the term "life" and, in particular, the beginning of life, the Commission noted "a divergence of thinking on the question of where life begins" and added "while some believe that it starts already with conception, others tend to focus on upon the moment of nidation, upon the point that the foetus becomes "viable" or upon live "birth" (*X v. the United Kingdom*, Para. 1).

In further cases, the Court has, however, never recognized that the unborn (embryo/foetus) is entitled to "a right to life", considering that "... the unborn child is not regarded as a person directly protected by Article 2 of the Convention and that, if the unborn does have a "right" to "life", it is implicitly limited by the mother's rights and interests (Vov. France, Para. 80), allowing single States, within their margin of appreciation, to determine in their domestic legislation "when the right to life begins" (Vov. France, Para. 82).

As to end of life, in the landmark case *Pretty v. United Kingdom* (2002),⁶⁵ the Court did not admit a right to die with dignity as a corollary of the right to life: therefore, all the following

⁵⁶ K. SCHMELZA, S. BOWLES, Opposition to voluntary and mandated COVID-19 vaccination as a dynamic process: Evidence and policy implications of changing beliefs, in PNAS, 2022, p.: 1 ss.

⁵⁷ Mc Cann and Others v. the United Kingdom, 27 September 1995, Series A no. 324, Paras. 146 and 147.

⁵⁸ W.A. SCHABAS, The European Convention on Human Rights: A Commentary, Oxford, 2015, p.117 ss.

⁵⁹ L.C.B. v The United Kingdom (1998).

⁶⁰ L.C.B. v. the United Kingdom, Application No. 23413/949 June 1998, Para. 36.

⁶¹ L.C.B. v. the United Kingdom, 9 June 1998, Para. 36, Reports of Judgments and Decisions 1998-III.

⁶² I.R. PAVONE, Case Law of the Strasbourg Court in the Field of Bioethics and the Biomedicine Convention, in M.I. ISABEL TORRES CAZORLA (ed), Bioderecho Internacional y Universalización: el Papel de las Organizaciones y los Tribunales Internacionales, Valencia, 2020, p. 119 ss.

⁶³ X v. United Kingdom, Application No. 8416/78, Decision of 13 May 1980.

⁶⁴ J. PICHON, Does the Unborn Child Have a Right to Life? The Insufficient Answer of the European Court of Human Rights in the Judgment Vo v. France, in German Law Journal, 2019, p. 433.

⁶⁵ Pretty v. The United Kingdom, Application No. 2346/02, decision of 29 April 2022; A. PEDAIN, The Human Rights Dimension of the Diane Pretty Case, in The Cambridge Law Journal, 2003, p. 181 ss.

cases regarding active euthanasia and assisted suicide (such as *Haas v. Switzerland*)⁶⁶ were rejected by the Court on the basis of the general obligation upon States to protect life in an absolute manner, irrespective of the quality of life.

Therefore, the Court stated that "Article 2 cannot, without a distortion of language, be interpreted as conferring the diametrically opposite right, namely a right to die; nor can it create a right to self-determination in the sense of conferring on an individual an entitlement to choose death rather than life" (Para. 39).

Situations that might only endanger health but not life are, however, not covered by Art. 2 ECHR, but rather by the scope of Art. 8 ECHR.⁶⁷

Positive duties to do imply "all that could have been required of it to prevent the applicant's life from being avoidably put at risk". 68

In the domain of public health and of a compulsory vaccination, the interpretation of Art. 2 implies, first, that States should adopt all the necessary precautions to avoid the collateral effects related to the particular health situation of an individual (that might for instance have an allergic reaction to vaccines). Once all the necessary safeguards have been adopted on the possible side effects of a given vaccine – which represents a health hazard, but does not pose a serious risk to health – it is easy to affirm that compulsory vaccination does not correspond to a violation of State duties under Art. 2 ECHR.

In few words, a danger to life falls within the scope of Art. 2 ECHR, while a mere danger to health is included within Art. 8 ECHR. For instance, States must adopt additional measures to ensure physical and mental integrity of patients in hospitals.⁶⁹

The former Commission, in Association of Parents v. the United Kingdom clearly argued that if a State sets up a control and monitoring system with the aim of minimizing vaccine-associated side effects, isolated fatalities that were unforeseeable do not amount to a violation of the right to life.⁷⁰

An effective health policy by a given State implies a particular attention to single cases and the provision of exemptions for given categories, such as patients that might have adverse immune reactions.

Once assumed that a mandatory vaccination policy does not violate Art. 2 ECHR, does the right to life imply, instead, a specific duty upon the States to immunize their population through its positive obligations instead that to refraining from a vaccination campaign?

States do also have specific duties in the health sphere – although a right to health is not envisaged by the ECHR – as affirmed in *Lopes de Sousa Fernandes v Portugal.*⁷¹

The positive obligation arising from Article 2 may lead to the claim that, in the context of an epidemic or a pandemic, a vaccine should be made compulsory not only to protect the

⁶⁶ Case of Haas v. Switzerland, Application no. 31322/07.

⁶⁷ W. SCHABAS, The European Convention on Human Rights: A Commentary, Oxford, 2015, at 124.

⁶⁸ LCB v. the United Kingdom, Appl. No. 23413/94, 9 June 1998, Para. 36.

⁶⁹ Vasileva v Bulgaria App No 23796/10 (EctHr, 17 March 2016), Para. 63.

⁷⁰ Association of Parents v the United Kingdom App no 7154/74 31 (Commission Decision, 12 July 1978), 32 et seq. ⁷¹ Para. 165 of Lopes de Sousa Fernandes v Portugal reads as follows "The Court has stressed many times that, although the right to health – recognized in numerous international instruments – is not as such among the rights guaranteed under the Convention and its Protocols (see Vasileva v. Bulgaria, no. 23796/10, § 63, 17 March 2016), the aforementioned positive obligation must be construed as applying in the context of any activity, whether public or not, in which the right to life may be at stake [...] including in the public-health sphere".

recipients, but also those who rely on herd immunity for protection against a given infectious disease.⁷²

In Calvelli and Ciglio v. Italy (2002), the Court recognized that States do have specific positive obligations falling within Art. 2 ECHR in "the public health sphere", stating that this duty "requires states to make regulations compelling hospitals, whether public or private, to adopt appropriate measures for the protection of their patients' lives".⁷³

7. Vaccines and right to private life

The Strasbourg Court has over time interpreted in an extensive and dynamic way the rights enshrined in the Convention according to the "living instrument doctrine".⁷⁴

The last decades have, in particular, registered several rulings of the ECtHR on matters related to bioethics, ranging from beginning of life (abortion, access to reproductive technologies, the legal status of the human embryo) to end of life issues (right to refuse life sustaining treatments, assisted suicide). These complex problems are increasing being raised before the Strasbourg Court by invoking breaches of Articles 2, 3, 5, 6, and most often, Articles 8, 9 and 14.75

As a matter of principle, compulsory vaccination amounts to an interference with the right to respect for private life. Since 1984, the former Commission had already mentioned that "a requirement to undergo medical treatment or a vaccination, on pain of a penalty, *may* amount to interference with the right to respect for private life". The applicants denied the authorization concerning their children to undergo methods of tuberculosis screening – namely the tuberculin test and chest x-ray. They argued that the Belgian law violated their personal conviction and was an unnecessary interference with private life.

In another case (*Solomakhin v. Ukraine*)⁷⁷ the claimant had been administered a diphtheria vaccine against his will in an epidemic context. The Court has established that physical integrity concerns one of the most intimate aspects of private life and even a non-invasive medical intervention (such as an injection) amounts to an interference with the enjoyment of this right.⁷⁸

⁷² F. CAMILLERI, Compulsory vaccinations for children: Balancing the competing human rights at stake, in Netherlands Quarterly of Human Rights, 2019, p. 245 ss.

⁷³ Calvelli and Ciglio v Italy, App no. 32967/96 (ECtHR, January 17, 2002), para. 49.

⁷⁴ Tyrer v. United Kingdom (Appl. No. 5856/72, Judgment of 25 April 1978, Series A no. 26). See R. LAWSON, The ECHR at 70: A Living Instrument in Precarious Present-day Conditions, in *leidenlawblog* (2020), https://www.leidenlawblog.nl/articles/the-echr-at-70-a-living-instrument-in-precarious-present-day-conditions.

⁷⁵ Research Report. Bioethics and the case-law of the Court, Council of Europe/European Court of Human Rights,
2012,

https://www.coe.int/t/dg3/healthbioethic/texts and documents/Bioethics and caselaw Court EN.pdf. See also T. Murphy, G. O Cunn, Works in Progress: New Technologies and the European Court of Human Rights, in Human Rights Law Review, 2010, p. 601 ss.

⁷⁶ Acmanne and others v. Belgium, Application n. 10435/83, 10 December 1984.

⁷⁷ Application no. 24429/03.

⁷⁸ Para. 33 of the judgment reads as follows "Compulsory vaccination – as an involuntary medical treatment – amounts to an interference with the right to respect for one's private life, which includes a person's physical and psychological integrity" (Para. 33)".

Therefore, the key issue is to evaluate whether such interference is justified under the exemption clause ex Art. 8, Para. 2,⁷⁹ or under the derogation clause (Art. 15),⁸⁰ whereas the States enjoy a wide margin of appreciation.

Analogies can be found with case law on non-psychiatric, mandatory medical treatments: in the case *X and others v. Austria* (1979), the Court claimed the applicant's compulsory blood testing was justified by the public interest in determining paternity.⁸¹

It bears recalling that Art. 8, Para. 2, contemplates derogation according to the well-known three-step test, an interference by a State – demanding compulsory vaccination – can be justified if i) it is provided by law; ii) it is *necessary* in a democratic society and iii) it pursues a legitimate aim (such as the protection of public health).⁸²

Since the norms on compulsory vaccinations are usually envisaged by a law, it must be assessed whether they are *necessary* in a democratic society and whether they *pursue* a legitimate aim.

The notion of necessity in a democratic society is, therefore, crucial in evaluating the legitimacy of an interference by a State in the private sphere. In *Dudgeon v. the United Kingdom* (1981),⁸³ the Court argued that the notion of necessity in a democratic society implies "the existence of a 'pressing social need' for the interference in question" (Para. 51). It is up to domestic authorities – that enjoy a wide margin of appreciation – to assess the pressing social need in each case (Para. 52).

In *Solomakhin v Ukraine*, the Court has highlighted two additional criteria to assess the necessity of a compulsory vaccination policy:⁸⁴ the first is the protection of public health from the spread of an infectious disease; the second is the suitability of the individual for vaccination. In this framework, one State must evaluate the suitability of the applicant for a vaccination and must take the necessary precautions before the medical intervention (Para. 36).

⁷⁹ Art. 8, Para. 2, ECHR, provides that "There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic wellbeing of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

⁸⁰ Article 15 (derogation in time of emergency) of the ECHR states that "In time of war or other public emergency threatening the life of the nation any High Contracting Party may take measures derogating from its obligations under this Convention to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with its other obligations under international law.

^{2.} No derogation from Article 2 [right to life], except in respect of deaths resulting from lawful acts of war, or from Articles 3 [prohibition of torture and inhuman or degrading treatment or punishment], 4 (paragraph 1) [prohibition of slavery and servitude] and 7 [no punishment without law] shall be made under this provision.

^{3.} Any High Contracting Party availing itself of this right of derogation shall keep the Secretary General of the Council of Europe fully informed of the measures which it has taken and the reasons therefor. It shall also inform the Secretary General of the Council of Europe when such measures have ceased to operate and the provisions of the Convention are again being fully executed."

⁸¹ A. KRASSER, Compulsory Vaccination in a Fundamental Rights Perspective: Lessons from the ECtHR, in ICL Journal, 2021, p. 207 ss.

⁸² See D. HARRIS, M. O'BOYLE, C. WABRICK, Law of the European Convention on Human Rights (London, Dublin, Edinburgh, 2018, p. 335.

⁸³ Case of Dudgeon v. the United Kingdom (Application no. 7525/76), Judgment, Strasbourg, 22 October 1981.

⁸⁴ S. KATSONI, What Does the Vavříčka Judgement Tell Us About the Compatibility of Compulsory COVID-19 Vaccinations with the ECHR?, in Völkerrechtsblog, 21.04.2021, https://voelkerrechtsblog.org/what-does-the-vavricka-judgement-tell-us-about-the-compatibility-of-compulsory-covid-19-vaccinations-with-the-echr/.

As to the proportionality, on sensitive issues, such as beginning and end of life, States enjoy a wider margin of appreciation in an inversely proportional measure to the lack of consensus on a given matter.

In the case *Boffa and others v San Marino* (1998)⁸⁵ the Court highlighted that the interference related to a compulsory vaccination of minors against Hepatitis B respected the conditions for a valid derogation *ex* art. 8, Para. 2, due to "the need to protect the health of the public and of the persons concerned" (Para. 8-9);

In the case of *Jehovah's Witnesses of Moscow v. Russia* the Court stated that there is a specific reference to compulsory vaccination in case of an epidemic and that "the right to private life could in principle be limited for the protection of third parties" (Para. 36-37).

According to this line of thought of the Court, an eventual vaccination campaign against COVID-19 would pursue a legitimate aim.

In the 'key case' Vavřička v. the Czech Republic (2021),86 the Court clearly highlighted its position on the issue of mandatory vaccinations.

The judgment is quite relevant to the debate in European countries on compulsory vaccination policies on COVID-19, since it provides a useful legal basis for any legislator to guarantee an appropriate balance between individual rights and protection of public health. ⁸⁷ Apart from COVID-19 vaccines, CoE's Member States are clearly divided on the issue of mandatory vaccinations, although the judges of the Court highlighted a European *favor* towards compulsory vaccination, 'due to a decrease in voluntary vaccination and a resulting decrease in herd immunity' (Para. 278).

In its judgment of 21 April 2021, the Grand Chamber of the ECtHR took a clear stance on the topic of vaccinations: a State policy which envisages a compulsory vaccination for minors is not in breach of the ECHR. The majority of the judges found the Czech Republic's vaccination legislation to be "fully consistent with the rationale of protecting the health of the population" (Para. 306), and falling within the wide margin of appreciation provided to Member States on health issues (Para. 274).

The policy struck a fair balance between the protection of children against serious diseases and the protection of families from the consequences of their refusal.

The judgment is based upon an in-depth investigation that considers first a comparative analysis of the constitutional jurisprudence of COE's Member States (such as Italy, France, Hungary, Slovenia), that are basically in favour of a compulsory vaccination.

Then, the Court highlights "the general consensus among the Contracting Parties, strongly supported by the specialized international bodies, that vaccination is one of the most successful and cost-effective health interventions and that each State should aim to achieve the highest possible level of vaccination among its population" (Para. 277); at the same time the Court excludes that there is a consensus about which is the best vaccine strategy which

⁸⁵ Boffa and Others v. San Marino, Application n. 26536/95, 15 January 1998.

⁸⁶ In this case, the applications were lodged with the European Court of Human Rights by five families – belonging to the 'no vax movement' between 2013 and 2015. The applicants challenged a violation of Articles 8, 9, 2, 6, 13 and 14, as well as of Article 2 of Protocol 1, to the ECHR. However, the Court asserted the inadmissibility of their claims under Articles 9, 2, 6, 13 and 14 (paras. 338 and 347) and decided to assess their applications only under Article 8 (right to respect for private life). After this initial assessment, the Court did not deem it necessary to assess their claims also under Art. 2 of Protocol 1 (right to education) (Para. 345).

⁸⁷ I.Y. NUGRAHA, J. MONTERO REGULES, M. VRANCKEN, Vavříčka and Others v. The Czech Republic, in American Journal of International Law, 2022, p. 579 ss.

makes it possible to protect most of the population from a given infectious disease. Para. 278 reads as follow "the Court notes that there is no consensus over a single model".

The role of solidarity and as a consequence the collective dimension of health was then reiterated: social solidarity towards the most vulnerable requires the rest of the population to assume a 'minimum risk' in the form of vaccination.⁸⁸

The Court then considered that the interference with the right to private life was fully justified under Art. 8, Para. 2, ECHR. The derogation is, indeed, envisaged by a law, it has the legitimate goal of protecting public health in its double dimension (as an individual and as a collective right); it is within the margin of appreciation of States, which is wide in this case for several reasons.

First, there are different positions on vaccination policies; then such an approach has limited impact given that is has only envisaged indirect sanctions rather than a direct obligation. Furthermore, the States are in the better position to evaluate their priorities, the use of resources and their social needs (a decrease in voluntary vaccinations constitutes a pressing social need, as explained in paras. 283-284).

Finally, the Law respects the principle of proportionality because it foresees exceptions (for medical reasons, on religious grounds) and forms of flexibility (the possibility to choose the type of vaccine and when to vaccinate the children as "it cannot be regarded as disproportionate for a State to require those for whom vaccination represents a remote risk to health to accept this universally practised protective measure as a matter of legal duty and in the name of social solidarity for the sake of the small number of vulnerable children who are unable to benefit from vaccination specific calendar") (Para. 306).

The Court evaluated that compulsory vaccination for children was established as a response to a 'pressing social need', given that the Czech authorities were bound by a positive obligation under the right to health to ensure adequate immunisation coverage. According to the experts who provided advice to the authorities, this aim could only be achieved if vaccination were a duty, and not a mere recommendation. Therefore, if voluntary vaccination programmes do not suffice to achieve herd immunity, mandatory schemes may become necessary to protect the best interests of children, both individually and as a group. The interference with the applicants' right was also considered proportionate on the basis of numerous elements providing reasons related to the lack of trust in science and religious belief

The concept of the superior interest of the child⁸⁹ was also raised by the Court: who decides what is the best interest of a child? The immunisation against infectious disease is undoubtedly in the best interest of a minor, since it also allows him/her to be admitted at a *kindergarten*.⁹⁰

Against this backdrop, it is worth recalling that according to Art. 24, Para. 1, of the UN Convention on the Rights of the Child, "States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health ... States Parties shall strive to ensure

⁸⁸ On the duty of solidarity in the context of a pandemic, M. YEH, Solidarity in Pandemics, Mandatory Vaccination, and Public Health Ethics, in American Journal of Public Health, 2022, p. 255 ss.

⁸⁹ The principle of "the best interest of the child" is implemented in Art. 3, Para. 1, of the UN Convention on the Rights of the Child (1989) (CRC), which provides that "in all actions concerning children, whether undertaken by public or private social welfare institutions, a court of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration."

⁹⁰ On the concept of best interest of the minor in Vavricka, D. ARCHARD, J. BRIERLEY, E. CAVE, Compulsory Childhood Vaccination: Human Rights, Solidarity, and Best Interests, in Medical Law Review, 2021, p. 716 ss.

that no child is deprived of his or her right of access to ... health care services". Para. 2, then affirms that "States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures: (a) To diminish infant and child mortality; (b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care; (c) To combat disease ..., including within the framework of primary health care".

According to General comment No. 15, "the realisation of this right entails the universal availability of immunisation against the common childhood diseases". 91

The Czech legislation on compulsory vaccination denies permission to enroll not vaccinated children in both private and public schools making enrollment contingent upon the presentation of a certificate of vaccination. The law does not envisage an obligation to undergo vaccination, but it has imposed a sanction for who refuses.

According to the applicants' view, "it was not justified to refuse access to nursery schools as a form of punishment for the fact that the children were not vaccinated" (Para. 178). It was a fundamental issue for the applicant *Novotná*, who wanted to pursue a specific educational model.

In practical terms, it implied a significant burden upon the families that should have taken care by themselves of the education of their children at preschool level. It is worth underlying, however, that *kindergarten* or maternal school is not mandatory in the Czech Republic.

The applicants complained that the Czech legislation violated a series of Articles of the ECHR, namely Article 8 (right to respect for private and family life) and Article 9 (freedom of thought, conscience and religion) of the Convention, and Article 2 of Protocol No. 1 (right to education) to the Convention. With reference to the last point, the Court did not recognize the necessity to analyze the issue of the compatibility between compulsory vaccination and right to education, since it retained that the issue had already been successfully dealt within Art. 8 ECHR (Para. 345).

The decision of the Court to abstain from discussing the relationship between private life and right to education was highly criticized by Judge Lemmens in his partly concurring and partly dissenting opinion.⁹²

The argumentations of the applicants were based on the concept according to which the vaccinations are an issue that concerns the respect for physical and moral integrity; they recalled in particular, the principles of the primacy of the human being over the exclusive interest of science and society (Art. 2 of the Biomedicine Convention) and of informed consent (Art. 5 of the Biomedicine Convention) which envisages the right to refuse a medical treatment.

8. Vaccines and freedom of thought, conscience and religion

The issue of conscientious objection to vaccination that is, the refusal to comply with certain vaccination requirements because of personal moral or religious views (as opposed to refusal

⁹¹ General comment No. 15 by the United Nations Committee on the Rights of the Child in relation to the right of the child to the enjoyment of the highest attainable standard of health, published on 17 April 2013 (CRC/C/GC/15)

⁹² Partly Concurring and Partly Dissenting Opinion of Judge Lemmens, Para. 3.

motivated by concerns around safety or effectiveness of vaccines) has been discussed in recent years.

A precise stance by the scientific community in recognizing the importance of vaccines as an instrument of protection of public health and of the balance between health, benefits and risks: vaccinations are, indeed, one of the most efficient and less costly interventions in the health field.

In Vavricka, the Court specifically excluded the applicability of Art. 9 at the case under examination, establishing that "personal views on compulsory vaccination based on wholly subjective assumptions about its necessity and suitability did not constitute a "belief" within the meaning of Article 9 of the Convention" (Para. 315). In particular, the judges stated "[...] the Court finds that his critical opinion on vaccination is not such as to constitute a conviction or belief of sufficient cogency, seriousness, cohesion and importance to attract the guarantees of Article 9" (Para. 335).

The Court confirmed that the emphasis on freedom of conscience must be limited to particular individual situations (as for instance, previous adverse reactions, that induce an individual to refuse the vaccination in itself); it cannot comprehend a position that is generally critical towards vaccination and vaccination policies which induce the individual to sustain that are an hazard for the health of the whole population.

The refusal to vaccinate raises also the issues of conscious objection (*Boffa and Others v. Saint-Marin*); the judged clearly stated on this point that "compulsory vaccination – if applied to everyone irrespective of their beliefs – does not constitute interference with the exercise of freedoms guaranteed by Art. 9".

According to the interpretation of Art. 9 of the ECHR, the 'convictions' must not be confused with the conscience or with mere personal ideas. It is about "firmly held beliefs or opinions to which the activity of conscience leads". 93

The UN Commission on Human Rights has recognized that conscious objection "derives from principles and reasons of conscience, including profound convictions, arising from religious, moral, ethical, humanitarian or similar motives" (Res 1998/77).

In Italy, Art. 32 of the Constitution is clear on the issue of compulsory vaccinations; the right to health is considered not exclusively as an individual right but also as an interest of the collectivity; according to the Constitutional Court, it allows to impose a health treatment if it is directed not only to improve or to preserve the individual health, but also to preserve the state of health of the others. Against this backdrop, collective health prevails over individual health. According to the judges of the Constitutional Court the measures envisaged by the Legislative Decree represent a choice of the domestic legislator. The obligation to vaccinate is a 'reasonable' choice founded on the duty of solidarity to prevent and to limit the spread of serious infectious diseases. The Italian Constitutional Court in 2018 challenged the validity of a decree-law adopted as an urgency measure due to the worrying drop of vaccination rate in children, which increased the number of vaccinations for children from four to ten.

The goal of vaccinations – the prevention of the spread of infectious diseases – is in itself a legitimate purpose that must be pursued through measures as indulgent as possible, balancing the protection of health, the respect for private life and freedom or religion. However, in case of a public health emergency, such as COVID-19, the protection of public health must always prevail over the considerations or interests of the single persons.

Constitutional Court, judgment n. 5/2018, 22 November 2017, https://www.camera.it/temiap/2018/08/03/OCD177-3677.pdf.

⁹³ https://www.echr.coe.int/Documents/Guide_Art_9_ENG.pdf.

While in the case of euthanasia and assisted suicide, the decision of an individual, namely the terminally ill person, to die does not have relevance to third parties, the situation is different in case of vaccination. The deliberate choice of an individual not to vaccinate himself/herself or his/her children does have an impact of public health in its collective dimension.

9. Concluding Remarks

As public discussions on COVID-19 vaccines have multiplied at the end of 2021, and a few States have waveringly leaned towards compulsory vaccinations policies, the Court's judgement in *Vavříčka* could not have been any timelier, since it provides useful guidelines on the circumstances under which compulsory COVID-19 vaccinations can be deemed as compatible with the European Convention on Human Rights.

In the Vavřička' s judgement, the Court did not leave room for generalizations. Instead, it highlighted that its analysis concerned the 'standard and routine vaccination of children against diseases that are well known to medical science' (Para. 158), and that 'in the present case, which specifically concerns the compulsory nature of child vaccination, that margin should be a wide one' (Para. 280). However, despite such pronouncements, the Court's analysis shed more light into the formerly established criteria on the assessment of compulsory vaccinations' necessity in a democratic society and provides clearer guidelines on the compatibility of compulsory COVID-19 vaccinations with the ECHR.

Throughout its ruling, the ECtHR has expressed its view about the "vaccination duty" to protect against contagious diseases which "could pose a serious risk to health", a characterization that could easily apply to COVID-19.

What emerges from the judgement in the *Vavřička* case is that there is a scientific consensus on the efficacy of vaccines, although there are different positions on the issue of obligatoriness of COVID-19 vaccines (even though the instrument of the EU COVID Certificate is already a form of indirect enforcement). Indeed, a citizen that wants to have access to particular services, such as travelling through airplanes or trains, or having access to restaurants or cinemas, must either show to have a Green Pass or must present a valid anti COVID-19 test.

In general terms, according to the judges of Strasbourg in *Vavřička* the decision whether to impose or not compulsory vaccination against COVID-19 perfectly fits within the wide margin of appreciation States enjoy in the sector of public health (Para. 285), in choosing the means by which "to attain the highest possible degree of vaccine coverage".

The margin of appreciation of States in 'sensitive domains', such as life sciences, public health, end of life, access to artificial procreation technologies is, indeed, inversely proportional to the differences amongst Member States.

The Court was clear on this point: if a policy of voluntary vaccination is not sufficient to achieve and maintain herd immunity, or herd immunity is not relevant due to the nature of the disease (e.g. tetanus), "domestic authorities may reasonably introduce a compulsory vaccination policy in order to achieve an appropriate level of protection against serious diseases" (Para. 288); therefore, compulsory vaccination against COVID-19 can be deemed as a 'reasonable response' to a public health emergency. In light of: i) the ECtHR case law on mandatory medical treatments; ii) the *Vavřička*'s case, iii) the rejection by the Court of the request of interim measures, one can conclude that States policies requesting a compulsory

vaccination against COVID-19 are perfectly compatible with the ECHR. Indeed, the public dimension of the protection of public health prevails over the individual dimension of the right to health.

Furthermore, it is worth recalling that Article 15 of the ECHR explicitly envisages the possibility to derogate from some ECHR provisions "[i]n time of war or other public emergency threatening the life of the nation," with the exception of peremptory norms (*jus cogens*), such as the right to life, the prohibition of torture and inhuman or degrading treatment or punishment, the prohibition of slavery and servitude.⁹⁵

Art. 15 ECHR was triggered due to the COVID-19 pandemic – that exemplifies the notion of 'public emergency threatening the life of a nation' – by Albania, Armenia, Estonia, Georgia, Latvia, North Macedonia.⁹⁶

On the basis of the above mentioned considerations, one can conclude that legislative measures imposing a duty of vaccination against COVID-19 (or any other infectious disease that threatens public health) are in line with the ECHR. However, the vaccination must be considered safe by the scientific community and a mechanism of compensation must be available in case of injuries caused by the vaccine.

⁹⁵ A. GREENE, Separating Normalcy from Emergency: The Jurisprudence of Article 15 of the European Convention on Human Rights, in German Law Journal, 2019, p. 1764 ss.

https://www.coe.int/en/web/conventions/derogations-covid-19. Alan Greene, "States should declare a State of Emergency using Article 15 ECHR to confront the Coronavirus Pandemic", *Strasbourg Observer*, 2020, https://strasbourgobservers.com/2020/04/01/states-should-declare-a-state-of-emergency-using-article-15-echr-to-confront-the-coronavirus-pandemic/.