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## VALUING HEALTH: COST-BENEFIT ANALYSIS OF THE EU COVID CERTIFICATE

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*"The world of cost and benefits (which includes taking note of the badness of nasty actions and violations of freedom and rights) is quite a different decisional universe from the sledgehammer reasoning of consequence-independent duties and obligations"*

Amartya Sen, *The Discipline of Cost-Benefit Analysis*  
in *Rationality and Freedom*, 553, 561 (2002)

### Abstract

Although emergency still rages around the world, governments promise to make social life better. But what price should we pay for really doing so?

In this article I explore the economic effects of public policy on health certification. To do so, I take the paradigmatic case of the EU Regulation on the Covid Certificate where restoring the economy through free movement of goods and people reveals some significant costs for the latter. Cost-benefit analysis is applied to health certification policies to this end.

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## Sintesi

Nonostante l'emergenza imperversi ancora in tutto il mondo, i governi promettono di migliorare molti aspetti della vita sociale. Ma a quale prezzo?

In questo articolo esploro gli effetti economici delle politiche pubbliche sulla certificazione sanitaria. A questo scopo, prendo in esame il paradigmatico caso del regolamento UE sul certificato Covid, dove il rilancio dell'economia attraverso la libera circolazione di beni e persone rivela alcuni costi significativi per quest'ultime. L'analisi costi-benefici sarà applicata alle recenti politiche europee sulla certificazione sanitaria.

**Keywords:** Health certifications, Public Regulation, Economy, Social Effects, Cost-Benefit Analysis.

**Summary:** 1. Introduction – 2. Goals – 3. Legal Bases – 4. Costs – 5. Options – 6. Uncertainty – 7. Precaution – 8. Proportionality (Introduction) 9. Freedom of Movement – 10. Proportionality (discussion) – 10.1 Suitability – 10.2. Necessity – 10.3. Cost-Benefit Analysis – 11. The cost of Discriminating – 12. Valuing Health

## 1. Introduction

Governments around the world are implementing new measures restricting people's civil and economic liberties as a result of the boom in infections caused by variants of the virus. Surprisingly, the mandatory negative test requirement and measures such as quarantine and self-isolation have been reinstated despite widespread vaccination. And yet, only a few months ago, many governments were appealing to their citizens to take up vaccination, promising it would bring restrictions to an end. In many parts of the world, public policies for lifting or at least loosening restrictions have required vaccination certificates for domestic travel and access to many public services.

The policies of the European Union (EU) are a paradigmatic case. These policies have resulted in the EU Regulation on the Digital COVID

Certificate (hereinafter "Covid Certificate"), which empowers Member States to issue a certificate for travel in the Schengen area without further restrictions on their citizens.

Although it aims at regulating public health, the Covid Certificate has a significant impact in economic terms. Regulating access to key public services in most EU countries such as flights, trains, universities, schools, and much more, the Covid Certificate is expected to have a significant impact on the economy and especially on the market of the sectors targeted by its measures.

The Covid Certificate was designed to restore economic momentum by giving back the freedom of movement to people and goods as a cornerstone of the EU. To do so, it has leveraged health by exploiting the market for health certifications based mainly on vaccination status, as I shall demonstrate in this article.

## **2. Goals**

My goal here is to explore the economic effects of European regulatory policies on the Covid Certificate, focusing on cost-benefit analysis for undertakings and individuals. What's wrong with doing that?

At first glance, it is not wrong at all. Yet, if we look at the regulatory mechanisms that govern the issuing of health certificates, we understand that it concerns the valuation of people's health. Thus, while restoring the economy in many sectors is the benefit of public regulation, certifying people's health is its cost.

Whereas, on the one hand, this article assesses the economic effects of health certification, on the other, it should also assess its legitimacy in terms of protecting the fundamental rights at stake (health).

To begin with, let us look at the European Covid Certificate Regulation for an overview of the Parliament's and the Council's main reasons and objectives on the issue of health certification.

### 3. Legal bases

To deepen the legal basis of the Covid Certificate we will thus look at Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 (hereinafter the Regulation) because it provides a legal framework in Europe for the issuance, verification and acceptance of COVID certificates<sup>1</sup>.

Though it may seem rather obvious, the first question we should ask is: why this Regulation on COVID-19 certificates? Ostensibly, the reason is to ensure free movement, one of the fundamental principles of the European Union.<sup>2</sup> We can read how, according to Article 1 of the Regulation, the main objectives of this legislation are to “facilitate the [Covid Certificate] holders’ exercise of their right to free movement” and to “contribute to facilitating the gradual lifting of restrictions to free movement” implemented by governments during the pandemic.

But not only. In fact, more fundamentally, the Regulation on Covid Certificate aims at “[f]acilitating freedom of movement” as “one of the key preconditions for *starting an economic recovery*”. We can read so in Recital (12) of the EU Regulation<sup>3</sup>. No secrets. Yes, freedom of movement is considered by the EU Regulation as a useful tool for the economy. And this given that it is intended as an essential “precondition” for the resumption of undertaking and people activities.

### 4. Costs

Exchanging goods and people is a cornerstone of the EU. No one can cast doubt on that. Once again, no problem. (Apparently).

Recall what we said in the Introduction on the costs and benefits of such an EU regulatory policy. Starting an economic recovery. But, what is the cost? Especially in emergencies like a pandemic. Of course, health.

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<sup>1</sup> 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 to facilitate free movement during the COVID-19 pandemic (Text with EEA relevance), PE/25/2021/REV/1, OJ L 211, 15.6.2021, 1-22, <http://data.europa.eu/eli/reg/2021/953/oj>.

<sup>2</sup> See A Alemanno and L Bialasiewicz “Certifying Health: The Unequal Legal Geographies of COVID-19 Certificates” (2021) 12 European Journal of Risk Regulation 273.

<sup>3</sup> Regulation (EU) 2021/953, *supra* note 1, Recital (12), last phrase (*emphasis mine*).

Obviously, each of us cannot get the Covid Certificate for free. Perhaps, we did not really wonder what it costs to move freely during a health emergency. Perhaps we didn't think about it when we were at the vaccination centre. Perhaps, we're still not thinking about it now that we're getting a booster.

Arguably, this is not a monetary cost. Not narrowly speaking. But it is still a cost. And I shall argue why that it is so. To be sure, I believe that the cost-benefit analysis of public regulation based on health certificates should take this into account now and in the near future<sup>4</sup>.

Indeed, what is the economic value of exchanging two fundamental rights such as freedom of movement and health? Regulators should take costs into account when asking people for duties in the public interest. It has certainly assessed the pros and cons of mandatory vaccination, especially in terms of tort liability. Did you finally decide to make it mandatory? No. But the policy makers nudged it through a regulatory approach based on health certification. Once again, we should consider the cost. Clearly the cost of being subjected to a health treatment such as vaccination. This is a cost.

Yet the EU Regulation does not make the vaccine the only tool (cost) for obtaining the Covid Certificate, but provides three different options. Let's see what they are.

## 5. Options

Article 3 of the EU Regulation lays down that the Covid Certificate framework allows for the following three types of document:

(a) a certificate confirming that the holder<sup>5</sup> has received a COVID-19 vaccine in the Member State issuing the certificate;

(b) a certificate confirming that the holder received a test in a healthcare centre and it proved negative<sup>6</sup>;

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<sup>4</sup> See C.R. Sunstein, *Valuing Life: Humanizing the Regulatory State*, The University of Chicago Press, Chicago and London, 2014.

<sup>5</sup> According to Art. 2(1), the holder is "a person to whom an interoperable certificate containing information about that person's COVID-19 vaccination, test result or recovery has been issued in accordance with this Regulation".

(c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection.

Even if the Covid Certificate framework provides three options, the possibility of choosing among them in fact exists only on paper. Vaccination is the only concrete way of obtaining the health certificates. Let's be clear, the negative test certificate is valid for a very short period (from 24 to a maximum of 48 hours, depending on whether a rapid antigen or PCR test was performed). Contracting COVID is an involuntary event – apart from a few exceptional cases which attracted attention in the press<sup>7</sup>; all the more so, since it is hard to believe that people would deliberately be infected to receive the certificate.

It is thus more likely that people will choose to be vaccinated, as this guarantees a Covid Certificate valid for at least 9 months<sup>8</sup>. That this is true is no secret. The Regulation shows that the European Parliament and the Council has taken a clear stance in favour of a large-scale vaccination campaign. Vaccination is promoted by European policies. Let's look at some of the main legislations approved by Member States.

Vaccination as the main regulatory choice is supported by public policies. EU governments have regulated people's movements on their national territories through mass vaccination campaigns and are still doing so. By enforcing the Covid Certificate Regulation, legislative and administrative measures have placed restrictions on unvaccinated people, forbidding access to key public and private services as well as to social life. Italy, France, and Germany are paradigmatic cases.

The Italian government, by strengthening the legislation of the Covid Certificate through Decree-law No. 52 of 22 April 2021 on the *certificato*

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<sup>6</sup> See Art. 2(4) of the Regulation, *supra* note 1.

<sup>7</sup> V Dardari "Bolzano, il medico denuncia: 'COVID party per ammalarsi e avere il Green pass'", Il Giornale, 19 November 2021, <https://www.ilgiornale.it/news/cronache/bolzano-medico-denuncia-covid-party-ammalarsi-e-avere-green-1990398.html>

<sup>8</sup> See European Commission "EU Digital COVID Certificate", [https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate\\_en](https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en). See also European Centre for Disease Prevention and Control "Questions and answers on COVID-19: Vaccines" <https://www.ecdc.europa.eu/en/covid-19/questions-answers/questions-and-answers-vaccines>.

*verde*, banned unvaccinated people from entering theatres, schools, universities, trains and even hospitals.<sup>9</sup>

The French government has introduced a *passé sanitaire* whereby unvaccinated people are banned from entering major public places.<sup>10</sup>

Germany introduced the *digitalen Impfnachweis* as a mandatory requirement for entering public places except in situations with a low risk of infection or where the pressure on the health system is low<sup>11</sup>.

These are just a few examples of how EU governments have implemented their risk regulation strategies since the Covid Certificate was introduced. But it is enough for my goal here. They clearly show what I said before when I discuss the cost-benefit analysis of European policies. Recall that restoring economy through Covid Certificate is the benefit of EU regulators. But also recall certifying people's health is the cost that we shall pay for it. Recall too that without it we have no access to public and private services nor to social life.

That's a significant cost because it imposes a sacrifice on a fundamental right such as people's health. But it is not the only one. Further costs lie in certifying health, and I will look at some of them below.

## 6. Uncertainty

Look at the pandemic. The worsening of the emergency due to the spread of variants of the virus and the consequent boom in contagion are leading most policy makers to unroll new and more stringent measures. Thus, the initial policies on the Covid Certificate have been reconsidered almost everywhere in Europe<sup>12</sup>. As a result, regulators in most Member States

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<sup>9</sup> Decree-law No. 52 of 22 April 2021, converted, with amendments, by law No. 87 of 17 June 2021, and other Decrees of the President of the Council of Ministers (DPCM). See also Decree-law No. 221 of 24 December 2021 that reduced the certificate's validity from 9 to 6 months.

<sup>10</sup> LOI n° 2021-1040 du 5 août 2021 relative à la gestion de la crise sanitaire, <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043909676>. For a *point de situation* see the French government on *Passe Sanitaire* at <https://www.gouvernement.fr/info-coronavirus/pass-sanitaire>.

<sup>11</sup> Bundesministerium für Gesundheit, "Fragen und Antworten zum digitalen Impfnachweis," <https://www.bundesgesundheitsministerium.de/coronavirus/faq-covid-19-impfung/faq-digitaler-impfnachweis.html>.

<sup>12</sup> For the introduction of further health measures for obtaining the COVID certificate, see A Giuffrida and J Henley "Italy to tighten COVID rules for unvaccinated with 'super green pass'," *The Guardian*, 24 November

have reassessed the rights relating to the Covid Certificate (and implicitly of vaccination status)<sup>13</sup>.

The currently requirements for obtaining the Covid Certificate are no longer sufficient, as most regulators have enacted or are planning to enact further measures such as requiring proof of a negative PCR or rapid antigen test (taken 24/48 before arrival) in order to enter the country as well as to exercise key civil and economic liberties. Still other restrictive measures like quarantine and self-isolation have been reintroduced<sup>14</sup>. To take an example, the Italian government has recently introduced new rules in addition to those governing the Covid Certificate (the so-called super green pass), as well as a vaccine mandate for over-50s<sup>15</sup>.

When Covid certificate is not enough on its own or its duration is shortened or the shots needed to get it are increased, all these things have further costs. In other words, this new legal framework reveals costs of uncertainty.

Recall when I emphasised that EU policy makers were betting on the Covid Certificate to restore the economy through the resumption of free movement of people and goods in the Member States. To this end, they leveraged vaccines. While vaccines may have saved lives, they have proved ineffective in preventing the spread of the virus. As a result, stringent new measures have been (re)introduced. To people those measures cost, perhaps in terms of reliability above all. Of sacrifices later. Regulators should consider them in the near future.

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2021, <https://www.theguardian.com/world/2021/nov/24/italy-poised-to-tighten-rules-for-unvaccinated-with-super-green-pass>.

<sup>13</sup> For the latest restrictive measures in France, see A Sandford "COVID: Omicron variant prompts France to drastically restrict travel to and from UK", 17 December 2021, *Euronews*, <https://www.euronews.com/2021/12/16/france-to-tighten-entry-requirements-for-uk-arrivals-over-omicron-covid-variant>.

<sup>14</sup> On new and recent restrictions in EU Member States, see "COVID in Europe: A complete list of travel restrictions for every European country", <https://www.euronews.com/travel/2021/12/08/what-s-the-latest-on-european-travel-restrictions>.

<sup>15</sup>The measures were introduced by Decree-Law No. 1 of 7 January 2022, "Urgent measures to deal with the COVID-19 emergency, particularly in workplaces, schools and higher education institutions". (22G00002) (OJ General Series No. 4 of 07-01-2022), entered into force on 8 January 2022. For the main changes see <https://www.leggioggi.it/2022/01/10/super-green-pass-guida-completa/#Cose>.

## 7. Precaution

In the next two sections I shall analyse two basic principles of European law: precaution and proportionality. The first seeks to clarify whether and how regulation through health certificates complies with the best version of this principle; and if so, what economic effects it produces. The second aims to explain whether and how proportionate the regulations are in economic terms compared with other measures deemed equally effective in tackling the emergency.

Regarding the first, we can refer to the European Court of justice (ECJ)'s jurisprudence<sup>16</sup>. According to the case-law, the precautionary principle requires that competent authorities adopt appropriate administrative measures to prevent specific potential health risks. The ECJ's approach maintains that an appropriate application of the precautionary principle presupposes the identification of hypothetically harmful effects for health flowing from the contested administrative measure, combined with comprehensive assessment of the risks to health based on the most reliable scientific data available<sup>17</sup>.

If we read Recital (13) of the EU Regulation on Covid Certificate, this states that "in line with the precautionary principle [...] restrictions could be waived in particular for vaccinated persons" as vaccination breaks "the transmission chain"<sup>18</sup>.

I believe that this is an application of the "strong version" of the precautionary principle, given that Recital (13) of the Regulation specifies that scientific evidence on the effects of vaccination is still not consistently conclusive with regard to its effectiveness in preventing virus transmission among vaccinated persons.

But I contend that the application here of a strong form of the principle should be criticised. But in this case not because it suggests that

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<sup>16</sup> The jurisprudence of the European Court of Justice (ECJ) played a prominent role in elevating the precautionary principle to the status of a general principle of EU law. Some ECJ judgments in health matters are seminal in this regard. See above all ECJ Case T-13/99 *Pfizer Animal Health SA v Council* [2002] ECR II-3305; Cases T-74, 76, 83-85, 132, 137 and 141/00 *Artegodan GmbH v Commission* [2002] ECR II-4945.

<sup>17</sup> ECJ Case C-77/09 *Gowan* [2010] ECR I-13533, paras 73–78. In the same sense, see also Case C-157/96 *National Farmers' Union* [1998], ECR I-2211, para 63; Case C-180/96 *United Kingdom v. Commission* [1998], ECR I-2729, para 99; Case C-236/01 *Monsanto Agricoltura Italia* [2003], ECR II-8105, para 111.

<sup>18</sup> Regulation (EU) 2021/953, Recital (13) *supra*, note 1.

regulation is required whenever there is a potential risk to health, even if the supporting evidence is conjectural and the economic costs of administrative regulation are high<sup>19</sup>. In this emergency the health risks associated with the virus exist and are (more or less) high, although statistically this applies mainly to a certain range of age groups of people (the elderly overall).

Rather, the strong application of this principle does not work with the risks referred to in the EU Recital Regulation (13), namely breaking the chain of transmission of infection. Hence, applying it in this way entails high costs. If there are no scientific or statistical findings that the vaccine blocks the chain of contagion (strong version), regulators take the risk of taking costly measures (high costs).

To whom does it cost? For people, of course. To consider further these costs for people, let us turn to the second principle.

## **8. Proportionality (introduction)**

My main goal here is to challenge the EU policies on the Covid Certificate because they do not respect the principle of proportionality. Disproportionate measures impose costs on people.

Let's see why they are disproportionate. Recall the discussion about the (three) options (Section 5). Even if the Covid Certificate Regulation purports to give people freedom of choice in obtaining the certificate, this is not in fact the case because it is only available after vaccination. EU policies set vaccination as an implicitly preferred option for obtaining the Covid Certificate, as governments' campaigns on vaccines would indicate. To be clear, I do not deny that vaccines save lives. What I dispute is making them the basis for obtaining the Covid Certificate, which is disproportionate if compared to other less costly measures for people (in

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<sup>19</sup> In this sense, see the seminal work of CR Sunstein, *Laws of Fear. Beyond the Precautionary Principle* (Cambridge, Cambridge University Press 2005); CR Sunstein, "Beyond the Precautionary Principle" (2003) 151 *University of Pennsylvania Law Review* 1003 (from which I will quote). Sunstein enunciated a number of behavioural elements – such as loss aversion, probability neglect and neglect of the impact of one-off interventions – that might trigger people to blind themselves to certain aspects of the risk situation and focus on a particular subset of the hazards involved.

terms of sacrifices) that would have better ensured the balance between public health and free movement.

By the way, we need to talk about freedom of movement before discussing proportionality principle as the EU regulation refers to the restoration of the movement of goods and people as the prerequisite for economic recovery.

## 9. Freedom of movement

Freedom of movement is a cornerstone of the European Union and a fundamental right of European citizens<sup>20</sup>, and I feel that it still is despite the pandemic.

According to the Treaty on the Functioning of the European Union (TFEU), every citizen has the fundamental right to move and reside freely within the territory of the Member States, subject only to the limitations laid down in the Treaties and the measures adopted to give them effect. The Charter of Fundamental Rights of the European Union (CFREU) and the European Convention on Human Rights (ECHR) likewise guarantee every citizen the right to freely move within the territory of the Member States. In addition, the right to freedom of movement is specifically regulated by Directive 2004/38/EC of the European Parliament and of the Council, which also lays down the detailed procedures for exercising it<sup>21</sup>.

Member States may restrict freedom of movement for public health reasons, according to EU law<sup>22</sup>. During the recent pandemic, EU governments took several health measures involving mandatory requirements for quarantine, self-isolation and testing for infection,

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<sup>20</sup> See P Craig, G de Búrca, *EU Law: Text, Cases, and Materials* (Oxford, Oxford University Press, 6th edn, 2015), p. 15, 744, 784, 796, pp. 966-70, 972-3, p. 976. See also E Baldoni, "The Free Movement of Persons in the European Union: A Legal-historical Overview", Pioneur Working Paper No. 2, 2003, pp. 10.

<sup>21</sup> Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68, OJ L 158, 30.4.2004, pp. 77-123, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004L0038>.

<sup>22</sup> For an overview of the principles mediating conflicts between free movement and public goods, see D Chalmers, G Davies and G Monti, *European Union Law* (Cambridge, Cambridge University Press, 4<sup>th</sup> edn, 2019), pp. 827-849.

thereby restricting people's right to move and reside freely within the territories of the Member States.<sup>23</sup>

To coordinate governmental constraints imposed by the emergency, the Council adopted Recommendation (EU) 2020/1475<sup>24</sup>. It provides some coordinates for risk regulation in the EU by establishing common criteria for the implementation of travel bans, defining geographical areas with different colour codes according to the level of risk for the spread of the virus in these areas, and applying proportionate measures for people travelling there. Furthermore, in order to strengthen governments' decision-making process, the European Centre for Disease Prevention and Control (ECDC) publishes weekly maps based on data relating to the number of cases occurring in the Member States, as well as testing and positivity rates reported by geographical region.<sup>25</sup>

I have said that Member States may restrict the freedom of movement of persons for reasons of public health as long as they do so within the limits of the fundamental principles of the EU. Accordingly, the fundamental right to free movement can be restricted only for specific and limited reasons of public interest; that is to say, in the current emergency, the protection of public health – for the time being, irrespective of what is meant by public health.

To understand if this requirement is met, we shall consider whether restrictions on free movement for public health purposes comply with one of the key elements of the EU legal system, the principle of proportionality. And more specifically, we will look at how this principle applies to the Covid Certificate.

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<sup>23</sup> For an analysis of the measures introduced by EU member states affecting the free movement of people during the pandemic see D Duic and V Sudar, "The Impact of COVID-19 on the Free Movement of Persons in the EU" (2021) 5 EU and Comparative Law Issues and Challenges Series, pp. 30-56.

<sup>24</sup> Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic (Text with EEA relevance) OJ L 337, 14.10.2020, pp. 3-9 ELI: <http://data.europa.eu/eli/reco/2020/1475/oj>.

<sup>25</sup> See ECDC, "Maps in support of the Council Recommendation on a coordinated approach to travel measures in the EU", <https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement>.

## 10. Proportionality (discussion)

The principle of proportionality as a means of balancing fundamental rights is enshrined in one of the most important conventions on people's rights: the ECHR. The Convention states that limits to the exercise of these rights are allowed if restrictions are prescribed by law and are necessary in a democratic society, particularly in order to protect public health. Proportionality, which applies both to the actions of Member States and those of the European institutions, appears to be particularly relevant to EU citizens' right to freedom of movement after the introduction of the Covid Certificate.

The scholarly literature<sup>26</sup> and case-law<sup>27</sup> provide a significant frame of reference, establishing the conditions for determining the proportionality of a measure. In particular, the ECJ assesses proportionality on the basis of a measure's necessity, suitability, and balance or proportionality *stricto sensu*, as it is called by scholars<sup>28</sup>.

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<sup>26</sup> See G de Búrca, "The Principle of Proportionality and its Application in EC Law" (1993) 13 Yearbook of European Law 105; A Sandulli, "Eccesso di potere e controllo di proporzionalità. Profili comparati" (1995) Rivista Trimestrale di Diritto Pubblico 329; N Emiliou, *The Principle of Proportionality in European Law* (Kluwer, 1996); G Gerapetritis, *Proportionality in Administrative Law* (Sakkoulas, 1997); D-U Galetta, *Principio di proporzionalità e sindacato giurisdizionale nel diritto amministrativo* (Giuffrè, 1998); E Ellis (ed), *The Principle of Proportionality in the Laws of Europe* (Hart, 1999); J Jans, "Proportionality Revisited" (2000) 27 Legal Issues of Economic Integration 239; U Bernitz and J Nergelius, *General Principles of European Community Law* (Kluwer, 2000); E Castorina, "Diritto alla sicurezza, riserva di legge e principio di proporzionalità: le premesse per una "Democrazia europea" (2003) Rivista Italiana di Diritto Pubblico Comunitario 301; D-U Galetta, "La proporzionalità quale principio generale dell'ordinamento" (2006) Giornale di Diritto Amministrativo 1106; T Tridimas, *The General Principles of EU Law* (Oxford University Press, 2<sup>nd</sup> edn, 2006) ch 3; J Schwarze, *European Administrative Law* (Sweet & Maxwell, revised edn, 2006) ch 5; A Stone Sweet and J Mathews, "Proportionality Balancing and Global Constitutionalism" (2008) 47 Columbia Journal of Transnational Law 73; TI Harbo, "The Function of the Proportionality Principle in EU Law" (2010) 16 European Law Journal 158; P Craig, *EU Administrative Law*, 2<sup>nd</sup> edn (Oxford University Press, 2012) 590-640; A Barak, *Proportionality: Constitutional Rights and their Limitations* (Cambridge University Press, 2012); M Klatt and M Meister, *The Constitutional Structure of Proportionality* (Oxford, Oxford University Press, 2012); W Sauter, "Proportionality in EU Law: A Balancing Act?" (2013) 15 Cambridge Yearbook of European Legal Studies 439; B Pirker, "Proportionality Analysis and Models of Judicial Review: A Theoretical and Comparative Study" (Groningen, Europa Law Publishing, 2013).

<sup>27</sup> European Court of Justice (ECJ) case-law has acknowledged that proportionality is a general principle of EU law since the *Fedesa* judgement. See Case C-331/88 *The Queen v Minister of Agriculture, Fisheries and Food and Secretary of State for Health, ex parte: Fedesa and others* [1990] ECR I-4023, where the ECJ stated as follows: "[i]n accordance with the principle of proportionality, which is one of the general principles of Community law, the lawfulness of the prohibition of an economic activity is subject to the condition that the prohibitory measures are appropriate and necessary in order to achieve the objectives legitimately pursued by the legislation in question".

<sup>28</sup> In the literature of EU administrative law, there is no unanimous consensus on whether this principle also encompasses so-called proportionality *stricto sensu*. See P Craig, *EU Administrative Law*, *supra*, note 22, 591-92, and also 601-4. See also W van Gerven, "The Effect of Proportionality on the Actions of Member States of the European Community: National Viewpoints from Continental Europe" in Ellis (ed), *The Principle of Proportionality in the Laws of Europe*, *supra*, note 22, 37-38. According to Craig "[t]he normal judicial formulation of proportionality is cast in terms of suitability and necessity. Moreover, the EU courts will not always address what is generally known as the *stricto sensu* proportionality inquiry". Notwithstanding, Craig argues "[t]here are nonetheless two reasons for resisting this conclusion". For these two reasons, see pp. 601-2 and the EU case-law cited therein.

When applying the principle of proportionality to administrative measures relating to the Covid Certificate, we must thus test their necessity, suitability and proportionality *stricto sensu*<sup>29</sup>. We have clarified the aims for introducing the Covid Certificate: the EU policies refer to the resumption of economic through free movement of good and persons.

This public policy objective during the pandemic calls for closer scrutiny. For the Covid Certificate to ensure that socio-economic activities can be resumed safely, we would have to assume that there is sufficient scientific evidence to prove that certificate holders are not capable of transmitting the virus, or at least that they are less likely to do so according to a certain risk threshold. Public health is thus the key to explaining the policy behind the Covid Certificate and its goals.

Turning to the three legal components of the principle of proportionality, we must first assess a measure's suitability for achieving its aims. Thus, when determining the suitability of these certificates, we must consider whether there is scientific evidence that they are appropriate measures for meeting the objectives pursued.

We then consider the measure's necessity in relation to the proposed aims. In other words, we assess whether such certificates are the least restrictive measure<sup>30</sup>, compared to other possible ones, for people and their rights.

Still more importantly, my goal here is to assess proportionality *stricto sensu*<sup>31</sup>, whereby measures should not be manifestly disproportionate in terms of balancing costs and benefits<sup>32</sup>. In the case of the Covid Certificate, this means that the fundamental right of freedom of movement cannot be unreasonably or disproportionately affected simply in order to achieve the aims pursued by EU policies.

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<sup>29</sup> See recently E Paris "Applying the Proportionality Principle to COVID-19 Certificates" (2021) 12 European Journal of Risk Regulation 287.

<sup>30</sup> W Sauter, "Proportionality in EU law: a balancing act?" *supra*, note 22.

<sup>31</sup> See P Craig, *EU Administrative Law*, *supra* note 22, 601-2, where the author clarifies the relevance of proportionality *stricto sensu*. "The third limb is relevant where the court has found that the measure was both suited and necessary to achieve the desired end, but the applicant argues that the burden placed on it by the measure should nonetheless be regarded as disproportionate to the benefits secured".

<sup>32</sup> See E Paris "Applying the Proportionality Principle to COVID-19 Certificates", *supra* note 25, 292.

### **10.1. Suitability**

As regards suitability, the scientific framework of knowledge about the effectiveness of vaccines in curbing infection is such that we must be very cautious in claiming that the Covid Certificate is a suitable measure. Consequently, its appropriateness should be questioned.

By contrast, as we can see from current epidemiological data showing the boom in infections due to variants, though vaccination has contributed to reducing the harmful effects of the disease, it has proved ineffective in preventing the virus's spread.

In this light, the Covid Certificate does not pass the suitability test, bearing in mind that the policy's purpose is to safely restore the freedom of movement as a sine qua non for the recovery of the economy within the Member States' territories – and this is exactly what the data on the high number of infections throughout Europe contradict.

### **10.2. Necessity**

As regards necessity, it seems quite clear from the foregoing arguments that the vaccination requirement – as the only concretely feasible way for people to obtain the Covid Certificate, is not the least restrictive of all available measure.

This is neither the time nor the occasion to discuss this aspect. But the fact remains that a vaccine is a medical treatment, while wearing a protective mask and complying with certain social distancing measures – however intrusive they may be to personal freedom – is not, as everyone can see.

For clarity, let us look again at this important issue. The latest epidemiological data show that vaccines, though they have been used quite effectively throughout Europe, have not done more than other measures to prevent the spread of infection.

We might ask what happened as a result of this unexpected failure. Surprisingly (or unsurprisingly, depending on one's point of view), EU governments have introduced further intrusive measures without looking

at whether people are vaccinated or not. This is tantamount to saying, are you going to travel? Don't worry about your Covid Certificate, you won't need it anymore. Rather, you will need to have a negative test, wear an FFP2 protective mask, keep your distance from everyone else and much more.

I do not dispute that vaccines save lives. But as the data show, whether or not they prevent contagion is a different matter.

I also want to draw attention to another, related, issue. Making vaccination the basis for obtaining a Covid Certificate poses a risk because it could promote opportunistic behaviour by those who feel legitimised by a kind of government "licence" to behave irresponsibly and endanger others' health by paying less attention to precautionary and mitigation measures.

Another concern is that public policies based mainly on vaccines could exclude people who do not agree with such health treatments from social life.

These are costs imposed on people by public regulation.

### **10.3. Cost-benefit analysis**

What we have said so far also has to do with proportionality *stricto sensu*. Cost-benefit analysis suggests that we cannot ask people to be vaccinated in order to move freely when we have less intrusive and equally effective measures at our disposal. Many people may be ethically, culturally or religiously opposed to vaccination, but this does not mean that they should be excluded from social life. Still this is a cost. Not surprisingly, there have been – and continue to be – protests in all European countries against indirectly mandatory vaccination<sup>33</sup>.

There is another cost, no less important than those we have examined so far.

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<sup>33</sup> See A Brezar, "New COVID measures and restrictions spark protests across Europe, inciting anger", EuroNews, 20 December 2021, <https://www.euronews.com/2021/12/19/new-covid-measures-and-restrictions-spark-protests-across-europe-inciting-anger>.

Placing vaccines at the heart of Covid Certificate policies and perhaps in the future for other health certificates entails a particular risk. The risk is that such a policy may promote opportunistic behaviour by those who feel legitimised by a kind of government “licence” to be irresponsible for the health of others, reducing the threshold of attention to mitigation and social distancing measures. This is a bit like what happens with mandatory road accident insurance, where the driver may be incentivised to drive less cautiously knowing that in case of an accident he can always rely on the coverage of his policy.

Recent empirical work, not yet published, which I have had the pleasure of reading as a scientific reviewer, shows that in a sample of vaccinated people most of them were nudged to take the vaccine not so much because of the risks associated with the virus but rather in order to obtain the Covid Certificate to access the main public and private services as well as to other social life places.

## 11. The cost of discriminating

To conclude, I want to focus on another cost of European policies on health certification. I am quite concerned that the EU’s Covid Certificate policies may pose a risk of discriminating against people because of their health status, that is to say, of making a “distinction” between those who are vaccinated and those who are not. Determining who can enjoy civil liberties and who cannot, or at least distinguishing between those who cannot be restricted and those who can, could depend on health status<sup>34</sup>.

Vaccinating should be for the purpose of preserving one’s health, rather than as a way of allowing or prohibiting access to social life. And yet, looking at Recital (7) of the Regulation on Covid Certificate, we

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<sup>34</sup> On this argument, see the two seminal works by M Foucault, *Security, Territory, Population: Lectures at the Collège de France, 1977-78* (Palgrave Macmillan 2007), where he defines biopolitical governmentality as “a matter of organizing circulation, eliminating its dangerous elements, making a division between good and bad circulation, and maximizing the good circulation by diminishing the bad”, and Id, *The Birth of Biopolitics: Lectures at the Collège de France, 1978-79* (Palgrave Macmillan 2008). Recently, see K Berker, “Biosecurity: securing circulations from the microbe to the macrocosm” *The Geographical Journal* (2015) 181(4), 357-365, which explores different modes of circulation that are significant for biosecurity: trade and travel, microbes, information and capital; she states that “circulation itself has (e)merged as a space of security and form of power; a life-generative force; an informatic projection; and an opportunity for capital accumulation”.

realise that EU public policies make this concern a reality. The recital reads as follows: “[t]he free movement of persons who [...] do not pose a significant risk to public health, for example because they are immune to and cannot transmit SARS-CoV-2, should not be restricted, as such restrictions would not be necessary to achieve the objective of safeguarding public health”<sup>35</sup>.

This rule raises at least two concerns. The first regards the preference for the health status of the “immunised” (i.e., vaccinated) person. The second relates to the concept of “safeguarding public health”.

I have explained my point of view on the first issue, and here it is sufficient to say that vaccination is not more effective than other less intrusive and costly measures in reducing the risk of transmitting the infection.

## 12. Valuing Health

The second point would require an in-depth discussion which is beyond the scope of this paper. But we can at least look at the problem by asking a question. What does “achieving the objective of safeguarding public health” in fact mean?

My point here is that it is not clear who should be protected, from what, and how. Does public health mean everyone’s health or not?

Does public health mean the health of each person or does it mean an objective parameter, a standard, indicating the state of health of a community such as the population of a country?

If so, who decides that this standard is appropriate for each of us?

We know that the main aim of the World Health Organisation (WHO) is “to bring all populations to the highest possible level of health”<sup>36</sup>. But who decides what is the highest level of health for a person rather than for a population?

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<sup>35</sup> Regulation (EU) 2021/953, Recital (7) *supra*, note 1.

<sup>36</sup> Constitution of the World Health Organization, 22 July 1946, 14 UNTS 185, Art 1. The WHO’s Constitution provides expansive legal authority in the field of global health standard-setting, starting with the mandate of Art. 1: the “attainment by all peoples of the highest possible level of health”, [https://www.who.int/governance/eb/who\\_constitution\\_en.pdf](https://www.who.int/governance/eb/who_constitution_en.pdf).

Lastly, how can we measure in cost-benefit terms the therapeutic treatment required of a person, as in the case of the vaccination of a population, in order to ensure a high level of public health?

These issues point to the urgent need for in-depth discussion and pose challenges to consolidated definitions in the legal domain that ought to be faced in the near future.