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The Lingering Impact of the Pandemic over EU Legislation

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1. *Public health in the European integration process*. – The Treaty of Rome did not include health as a building block of the EEC. However, the European integration process has progressively necessitated specific legislation on it. This seems due to the awareness, more and more felt, of a strictly interconnection between the management of public health and the regulatory framework of the internal market. Indeed, the recognition of health as part of the objectives of the European integration process started with the progressive establishment of the internal market. The greater degree of integration brought about by the internal market triggered new debates related to the freedoms of movement of goods, capital, services and people. As a matter of fact, both drugs and medical equipment constitute commodities and are, therefore, subject to the rules on the free circulation in the internal market. Furthermore, medical doctors themselves can benefit of the rights deriving from the free movement of workers or of the rules protecting the freedom to provide services, depending on whether they are self-employed or not. On the other hand, European citizens have the right to benefit from health care in another Member State.

It is for these reasons that starting from the Single European Act of 1986 the EEC - and nowadays the EU - established a requirement for European policies to guarantee a high level of health protection which laid to the foundations for a European public health policy and the public health field of competence subsequently shaped in Article 129 TEC, in Article 35 of the Charter of Fundamental Rights of the European Union (CFREU) and, finally, in Article 168 TFEU. The latter specifies the Union's competence in the field of public health. It also is the legal basis of a wide range of EU health initiatives and measures. Furthermore, Article 114 TFEU may be considered an indirect legal basis to adopt legislative acts in the field concerned since it empowers the Union to harmonize national legislations with a view to the completion of the internal market, especially in the same field, specifically referred to in that rule. Finally, precisely for reasons connected with public health, Member States may derogate from the rules established by the Treaties for the functioning of the internal market. They can therefore adopt measures, including discriminatory ones, which hinder the free movement of goods, persons, or services.

2. *Public health vs healthcare*. – In general terms, the EU health policy can be structured around two pillars. The first is public health. It includes all organised measures – whether public or private – to prevent disease, promote health and prolong life among the population. Its activities' purpose is to provide conditions in which people can be healthy. It focuses on entire populations, not on individual patients or diseases. As a result, it is concerned with the total system and not only the eradication of a particular disease. The three main public health functions are: (i) to gauge and monitor the health of communities and populations at risk to identify health problems and priorities; (ii) to establish public policies designed to solve identified local and national health problems

and priorities; (iii) to guarantee that all populations have access to appropriate and cost-effective care, including health promotion and disease prevention services.

The second pillar is healthcare. It is the core business of health systems, although the latter are also responsible for some public-health activities, such as immunisation and screening. It can be conceptualised as a set of provisions, services and initiatives aimed at promoting, preventing or treating health. It is provided through a range of different systems run at individual national levels. It includes organisation of health systems in each Member State, financing of health services for citizens, organisation of access to these services as well as education and employment conditions of medical staff. The inclusion (or not) of healthcare stands out as one of the main differences in the approaches to public health at national level. In the EU most health care services are excluded from the public health remit, in order to have specific policy space for population-based services, which are typically underfunded and have low visibility. This approach makes sense given the historical foundations of the health systems of the Member States and their strong roots in the principles of universal access.

3. *The most relevant EU regulatory framework on public health concerning Covid-19.* – The protection of human health constitutes a horizontal application clause provided for in Article 168.1 TFEU which affirms that in the definition and implementation of all actions and policies of the Union, the choice that guarantees a high level of protection of human health must be evaluated and pursued.

As mentioned above, Member States have conferred on the Union a competing competence in matters of common safety problems in public health, although only in relation to some sectors. More specifically, common rules can be adopted to determine safety parameters for organs, blood, and blood products; common parameters of quality and safety of medicines and devices for medical use as well as measures to protect public health in the veterinary and phytosanitary sector. The Union, on the other hand, has the competence to carry out actions of mere support, coordination, and completion in the field of protection and improvement of human health. To this end, Article 168.1, TFEU affirms that the Union «shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas». Furthermore, para. 5 establishes that the EU institutions «may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health».

This type of competence does not call into question the primary role of the Member States in the field at issue. As stated in Article 168.2 TFEU: «The Union shall encourage cooperation between the Member States in the areas [of public health] … and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas [of public health] ... The

Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation». As a result, public health falls within the competence of the Member States. The latter regulate, finance, organise and manage the provision of health and care services. The actions undertaken by the Union, on the other hand, have the aim of integrating national policies, without overlapping or replacing them.

Supporting competence activity seems to be a difficult exercise. The Union is often in a critical position as it could do too much and/or not do enough. This is because these two opposite attitudes can be simultaneous. The integrational one has led the European Court of Justice, making a link between health, the improvement of the internal market and the principle of free movement, to develop case law favorable to Union intervention and patients' rights. On the other hand, the regulating one relies on the principle of subsidiarity – affirmed in Article 5.3 TEU – which applies to areas of non-exclusive competence of the Union, shared between the latter and the Member States. Under this principle, «the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, …, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level». In other words, the Union can only intervene whether its actions are more effective than those carried out by Member States. Theoretically, the action of the Union is essentially limited to facilitating cooperation between Member States and coordinating their one. Practically, the Commission has a very broad view of its competence, often justifying its proposals by the deepening of the internal market or the cross-border dimension of a subject.

As stated in Article 168.7 TFEU the «Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them …». This provision is believed to add little to the formal division of powers enshrined in the Treaties, such that its constraining power on Union action may be considered primarily political rather than legal. Doctrine explaining Member States reluctance to cede sovereignty over healthcare systems to the Union generally points out the latter's economic significance and socio-political implications – as well as the prominence recognised to health – as distinct from other aspects of social policy. An apparently logical consequence of this state of the art is that the Union's response seemed initially constrained by the framework in question, which developed 'because the Member States wanted it so'.

Substantially, the current framing of Article 168, par. 7 TFEU appears, exclusively, an impediment to the action of the Union in combatting future pandemics similar to COVID-19. Indeed, the rule inhibits the Union's ability to provide either comprehensive solutions to a complex and evolving situation, or a corrective to national policies governing the responses to the pandemic. This would be in contrast with a vision of Member State competence regarding national health policy and healthcare system organisation being questioned by wider Union action, especially in relation with Union-

level fiscal policy and coordination of national economic policies. The framing of the rule at issue has been considered as a mere elaboration of the extent of Member State competence. In other words, it has been deduced as a clarification of the exclusive competence of Member States. However, the 'downgrade' of the action of the Union, just 'respecting' Member State responsibilities, could also be interpreted both «to leave open more room for [Union] involvement ...», and to introduce «a delicate and sophisticated balance between the [Union] and national competences in health care».

These 'delicate and sophisticated balance' and juxtaposition of the 'statements of national autonomy' provided for in Article 168.7 TFEU can be explained referring to Union fiscal policy reforms. It appears coherent to affirm that Member States would have responsibility for the allocation of resources within national healthcare systems. This activity may also be considered as a Union activity affecting the financial resources assigned to the same Member States. This seems to confirm a long-standing consideration that «explicit stipulations ... and implicit understanding of the subsidiarity principle ... proved not to be the 'guarantees' of no [Union] interference in national health care services that they were often held to be». This allows a further evaluation of the interrelation between Union and national competence on public health, which would be considered as an interconnected relationship, now demonstrated referring to the Union fiscal policy.

The Union has relevant powers to deploy its own resources, such as through its structural funding. In other words, it has competence to fund collaborative research into vaccines, treatments, new medical equipment and devices as well as behavioural research into effective disease containment strategies. Since 2007, it also has competence, under the 'solidarity clause' provided for in Article 222 TFEU, if its Member States so desire, to pool resources under a Civil Protection Mechanism. The latter, since March 2019 has been strengthened by 'RescEU', with the aim to centralise Union capacities, allowing the Union to use its internal funds, pre-committed national funds and Union co-financed Member States' capacities at the disposal of Union efforts to respond to a major emergency. This gives Union competence, for instance, to fund: (i) epidemiological research into the spread of COVID-19; (ii) behavioural research into effective disease containment strategies; and social science research into the social, economic, political, legal and cultural consequences of COVID-19; (iii) to organise a European medical corps and a distinctive COVID-19 public procurement scheme.

The Union has the power to allow Member States to use resources in response to COVID-19 that are likely to disrupt competition in the internal market. For instance, they can give state aid to key industries. The Commission has also proposed the disapplication of the normal 'one time, last time' principle. It is permitting national measures: (i) ensuring access to liquidity and finance; (ii) preserving employment; (iii) facilitating COVID-19-relevant research and development; (iv) supporting the construction and upgrading of testing facilities of COVID-19 relevant products; (v) expanding production capacity for products needed to respond to the outbreak.

One must also observe that Article 35 of the Charter of Fundamental Rights of the European Union states that «everyone 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».

4. *The impact of Decision 1082/2013/EU*. – Decision 1082/2013/EU is the EU's current legal framework for serious cross-border threats to health. Among other things, it represents the basis for Joint Procurement Agreements for medical countermeasures, which have allowed Member States to procure medicines, personal protective and medical equipment in past outbreaks and the COVID-19 pandemic. Within its scope, Member States are required to present their preparedness and response plans for review by the European Commission in 3-year intervals. However, at the beginning of the COVID-19 pandemic, many of the national plans were inadequate and poorly updated. They basically left Member States grappling with overwhelmed health systems, while also highlighting gaps within the Decision framework and the lack of legal instruments at the disposal of the Commission to ensure Member State compliance. The deficiencies unveiled by the pandemic were manifesting the need for a new Regulation – based on Article 168.2 TFEU – foresing a stronger and more comprehensive legal framework for the Union to prepare and respond to serious cross border threats and public health emergencies. This includes: (i) strengthened preparedness planning at EU level; (ii) rules for a flexible and more integrated EU-level surveillance system; (iii) increased capacity of the EU and its Member States for risk assessments and targeted action; (iv) the development of a binding EU pandemic preparedness plan. This would allow the Commission to recognise and declare a future health emergency at EU level and thereby trigger the adoption of common measures and specific response mechanisms.

Decision 1082/2013/EU on serious cross-border health threats is one amongst many crisis management mechanisms adopted by the EU over the past two decades. Through it, the EU should supervise the coordination of Member States responses to cross- border health threats. Actually, the Decision seems too light on Member States' duties to coordinate in a situation where human lives are at stakes. However, in the current system of distribution of competences, it is not conceivable – nor desirable – for a supranational EU authority to make decisions on health crises at the expense of Member States. One solution to this dilemma could be to temporarily extend the Health Security Committee (HSC) coordinating powers when a 'State of Emergency' is triggered (Articles 12-13-14 of the 2013 Decision). Currently, the legal consequences of the State of Emergency are limited to authorising the European Medicine Agency to approve strategic medicine or vaccines quicker than usual. Doctrine has recommended a revision of the temporary mechanism of 'enhanced coordination' which would operate from the HSC and the Member States, with the Commission's technical assistance and the ECDC expertise, in order to negotiate binding coordination measures. It has been affirmed that enlarging the HSC powers has the virtue of respecting the intergovernmental nature of this domain, and the letter of Article 168 by maintaining decision-making powers to the Member States, while introducing a temporary mechanism of binding coordination in case of crisis. It has also been proposed that the role and functioning of the HSC during crises should be clarified to avoid any confusion, as seen during the COVID-19 pandemic. The new model should provide for the possibility of setting up crisis units or nominating crisis

coordinators – within the EU as well as the Member States – who could work together continuously and be ready to do so in case of crisis. This would ease the coordination of national responses and improve communication amongst Member States, the Commission and the ECDC. The new model should also have regional crisis units since health threats can also spread spatially without affecting all Member States.

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