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ARTICLE

The EU Vaccines Strategy: A Missed Opportunity for EU Public Health?

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Abstract

The response to the COVID-19 crisis implied an unprecedented involvement of the European Union (EU) executive in public health matters. In June 2020, the Member States agreed upon a joint EU Vaccines Strategy, whereby the European Commission was enabled to negotiate, support and allocate vaccine doses on their behalf. Entailing political and redistributive choices, the Commission's centralised procurement presents some innovative patterns when compared to traditional EU executive action. This paper will focus on the institutionalisation of such patterns within the legal framework of the Health Emergency Preparedness and Response Authority (HERA). Did EU administrative law offer appropriate tools for this process? Or did the EU merely formalise the procedural and organisational schemes set up during the crisis? Answers to these questions will contribute to a fuller understanding of the administrative dimension of the new European Health Union and shed light on some recent evolutions of the EU administrative system.

Keywords: EU administrative system; EU Vaccines Strategy; Health Emergency Preparedness and Response Authority (HERA)

I. Introduction

The early stages of the COVID-19 pandemic brought about an institutional shock for the European Union (EU),[1] as national governments undertook uncoordinated containment measures and imposed export bans on strategic goods (eg personal protective equipment)[2] in breach of the EU principle of solidarity.[3] The systemic reach of the crisis triggered several interventions by the European executive. The European Commission tackled illegal export bans by starting infringement procedures and drafted a joint roadmap to coordinate national risk regulations.[4] Once the Member States turned to cooperation,

[1] E Jones, RD Kelemen and S Meunier, "Failing Forward? Crises and Patterns of European Integration" (2021) 28(10) Journal of European Public Policy 1519.

[2] A Alemanno, "The European Response to COVID-19: From Regulatory Emulation to Regulatory Coordination?" (2020) 11(2) European Journal of Risk Regulation 307; SL Greer, A De Ruijter and E Brooks, "The Covid-19 Pandemic: Failing Forward in Public Health" in M Riddervold, J Trondal and A Newsome (eds), *The Palgrave Handbook of European Union Crises* (London, Palgrave 2020).

[3] Arts 2, 222 TFUE and 35 CFREU. See A de Ruijter, RMWJ Beetsma, B Burgoon, F Nicoli and F Vandenbroucke, "EU Solidarity, and Policy in Fighting Infectious Diseases: State of Play, Obstacles, Citizen Preferences and Ways Forward" (2020) Amsterdam Centre for European Studies Research Paper 2020/06.

[4] Commission, "Joint European Roadmap towards Lifting COVID-19 Containment Measures" 2020/C 126/01.

the political agenda for a "stronger European Health Union"[5] came forward. The Commission rolled out a new spending programme ("EU4Health")[6] and a package of legislative proposals to introduce a new European emergency regulation and to boost the mandates of the EU health agencies (the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC)).[7] One main initiative in this sense was represented by the EU Vaccines Strategy. On 17 June 2020, the Commission and the Health Ministers of the twenty-seven Member States agreed upon an intergovernmental agreement[8] establishing a joint approach for vaccine procurement,[9] then formalised by a Commission Decision.[10] According to this agreement, the Commission was enabled to negotiate, support the development of and finally allocate "safe and affordable" vaccine doses on behalf of the participating Member States. The joint procurement schemes set up during the pandemic were afterwards institutionalised within the legal framework of the Health Emergency Preparedness and Response Authority (HERA),[11] a new Commission body in charge of health risk prevention and management.

The new "European Health Union" project is a sign of an unprecedented EU commitment to public health,[12] whose action in this field has been historically limited due to the weak competencies conferred by Article 168 TFEU.[13] The EU's scarce involvement in health issues can be explained by the EU having developed over time as a market-making regulatory polity,[14] thus leaving the Member States to face the consequences of economic integration in terms of redistributive policies, including healthcare.[15] In this context, the main

[5] Commission, "State of the Union 2020 – President von der Leyen's speech" (16 September 2020) <https://ec.europa.eu/info/strategy/strategic-planning/state-union-addresses/state-union-2020_en>.

[6] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ("EU4Health Programme") for the period 2021–2027 and repealing Regulation (EU) No 282/2014 [2021] OJ L 107/1.

[7] Commission, "Communication from the Commission of 11 November 2020 to the European Parliament, the Council, the European Economic, and Social Committee, and the Committee of the Regions. Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats" COM (2020) 724 final.

[8] This procedure was subsequently formalised by the Council Regulation (EU) n. 2020/521 on 14 April 2020, which amended Art 4(5)(b) of the Council Regulation (EU) 2016/369 on 15 March 2016. According to this article, the European Commission negotiates public procurements on behalf of the Member States on the basis of previous intergovernmental agreements (Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak [2020] OJ L 117/3).

[9] Commission, "Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank of 17 June 2020. EU strategy for Covid-19 vaccines" COM (2020) 245 final.

[10] Commission, "Commission Decision of 18 June 2020 approving the agreement with member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures" C (2020) 4192 final.

[11] Commission, "Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority" COM (2021) 6712 final.

[12] AM Pacces and M Weimer, "From Diversity to Coordination: A European Approach to COVID-19" (2020) 11 European Journal of Risk Regulation 283.

[13] According to Art 2(5) TFEU, the EU's competence in public health is only "complementary".

[14] SL Greer and H Jarman, "What Is EU Public Health and Why? Explaining the Scope and Organization of Public Health in the European Union" (2021) 46(1) Journal of Health Politics, Policy and Law 23; G Majone, "The European Community as a Regulatory State" (1996) 5 Collected Courses of the Academy of European Law 321–419. Moreover, the EU is a particular regulatory polity, since it is keener on deregulation through European courts rather than regulatory protections and market-compensating programmes (FW Scharpf, "The Asymmetry of European Integration, or Why the EU Cannot Be a 'Social Market Economy'" (2010) 8(2) Socio-Economic Review 211–50; S Hix, "The European Union as a Polity (I)" in KE Jørgensen, MA Pollack and B Rosamond (eds), *Handbook of European Union Politics* (New York, Sage 2007) pp 141–58).

[15] P Genschel and M Jachtenfuchs (eds), *Beyond the Regulatory Polity? The European Integration of Core State Powers* (Oxford, Oxford University Press 2014); M Zürn and S Leibfried, "Reconfiguring the National Constellation" (2005) 13(1) European Review 1–36; SL Greer, "Health, Federalism and the European Union: Lessons from Comparative Federalism about the European Union" (2021) 16(1) Health Economics, Policy and Law 90.

EU health functions[16] have been regulatory and aimed at market harmonisation under Article 114 TFEU,[17] whereas the mandate of Article 168 TFEU allowed only for some marginal initiatives like information-sharing platforms and joint research and development programmes.[18] Despite the renovated EU interest in public health, even the European Health Union initiatives seem to stick with such patterns of the EU health policy. The Commission's legislative proposals do not entail a structural rethinking of the "root causes" of the COVID-19 crisis, such as economic inequalities among healthcare systems, but rather reinforce the existing EU health policy, as implemented through technocratic agencies and intergovernmental cooperation mechanisms.[19]

Against this backdrop, the EU Vaccines Strategy appears to be the most innovative building block of the rising European Health Union. The EU executive carried out some administrative activities that clash with the traditional vision of EU public health as a market-orientated policy, as the Commission was required to make some active choices on the purchase and redistribution of scarce resources, affecting directly Member States' healthcare systems.[20] Given these novel traits, it is worth posing some questions regarding the institutionalisation of the EU Vaccines Strategy through the HERA framework. Did EU administrative law offer tools capable of taking into consideration the innovative patterns of the Strategy? Or did the Commission merely formalise the procedural and organisational schemes established by the intergovernmental agreement during the crisis?[21] The former hypothesis would imply that HERA's legal framework turned out to be capable of facing the critical aspects raised by the new role of the Commission, whereas according to the latter the institutionalisation of the Strategy would have only acknowledged the arrangements set up by intergovernmental consensus with no consideration for the innovative patterns of the Strategy.[22]

[16] For a functional analysis of the EU administrative system, see H Hofmann, GC Rowe and A Turk, *Administrative Law and Policy of the European Union* (Oxford, Oxford University Press 2011).

[17] An example is provided by Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L 88/45 and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67.

[18] See SL Greer, "The Three Faces of European Union Health Policy. Policy, Markets, and Austerity" (2014) 33(1) Policy and Society 13; K Purnhagen, A de Ruijter, M Flear, T Hervey and A Herwig, "More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak" (2020) 11(2) European Journal of Risk Regulation 297; M Klamert, "Public Health Policy" in H Hofmann, GC Rowe and A Türk (eds), *Specialized Administrative Law of the European Union: A Sectoral Review* (Oxford, Oxford University Press 2018), ch 15, p 404.

[19] A Alemanno, "Towards a European Health Union: Time to Level Up" (2020) 11(4) European Journal of Risk Regulation 721–25, p 724; A de Ruijter, "What Do We Actually Mean by a European Health Union?" (2020) 26(3) Eurohealth 30–31; A de Ruijter and E Brooks, "The European Health Union: Strengthening the EU's Health Powers?" (2022) 28(3) Eurohealth 47–49.

[20] E Brooks and R Geyer, "The Development of EU Health Policy and the Covid-19 Pandemic: Trends and Implications" (2020) 42(8) Journal of European Integration 1057–76. To this extent, these functions are complementary to the export controls conducted by the Commission in the same timeframe.

[21] "The Commission faces a choice: should it capitalize on the issue salience provided by Covid-19 to openly proclaim its stake and role in health, to politicize its proposals by involving the European Parliament in budget allocation and priority-setting, and to flesh out an ambitious agenda on health system strengthening, inequalities and health determinants, for instance? Or should it opt for a softer, more technocratic model of implementation, resting more heavily on the ECDC and EMA and channeling its health systems role via the EU4Health and the European Semester?" (E Brooks, A de Ruijter and SL Greer, "Covid-19 and European Union Health Policy: From Crisis to Collective Action" in B Vanhercke, S Spasova and B Fronteddu (eds), *Social Policy in the European Union: State of Play 2020* (Brussels, ETUI 2020) p 48).

[22] Look at the "failing forward" dynamics of European integration: E Jones, RD Kelemen and S Meunier, "Failing Forward? Crises and Patterns of European Integration" (2021) 28(10) Journal of European Public Policy 1519. A critique of this argument comes from M Rhodes, "'Failing Forward': A Critique in Light of Covid-19" (2021) 28(10) Journal of European Public Policy 1537.

To address these issues, Section II will preliminarily assess the novel traits of the Commission's strategy, as well as the characteristics of the joint procurement procedures. As these procedures were established *ex novo* during the crisis through an intergovernmental agreement, they turned out to be flawed in terms of effectiveness and democratic/social participation (see Section III). Section IV will therefore be dedicated to understanding how HERA's new legal framework has managed such criticalities: first, the effectiveness of HERA's action will be discussed (Section IV.1); a second subsection will dwell on the degree of participation granted in the decision-making processes (Section IV.2).

II. A tailor-made joint procurement procedure

1. The new role of the European Commission

According to the agreement of 17 June 2020, the Commission was enabled to negotiate on behalf of the Member States with pharmaceutical companies by signing the so-called Advance Purchase Agreements (APAs).[23] The APA provided that the Commission would have funded the development of anti-COVID-19 vaccines through the Emergency Support Instrument (ESI) funds[24] in return for their availability after their development and authorisation by the EMA. Once available, the Commission would have managed the allocation of vaccine stocks across the Member States based on their population. On their side, the national executives remained fully responsible for the purchase of the vaccine doses[25] and their final distribution to the population.[26] Even though every Member State adopted its own purchasing and distributive strategy, the actual availability of the vaccines relied upon the joint negotiation and allocation carried out by the Commission.

Leveraging the joint contractual power of the twenty-seven Member States to procure critical resources in international markets, the Commission assumed a role of political salience. The joint procurement initiative supported indeed the political interests of two groups of Member States: the "bigger" economies (and the wealthier healthcare systems), which could count on their own purchasing power; and the "smaller" ones, which required some shared solutions at the EU level to leverage a larger public demand and thus deal successfully with the negotiations. In April 2020, when Germany, Italy, France and the Netherlands established the "Inclusive Vaccines Alliance" (ie an autonomous joint group to negotiate separately for the AstraZeneca/Oxford vaccine), smaller Member States raised concerns about the risk of being cut off from the vaccines race.[27] The subsequent

[23] Hofmann et al, supra, note 16, ch 19, p 651. See also A Petti, "EU Covid-19 Purchase and Export Mechanism: A Framework for EU Operational Autonomy" (2022) 59(5) Common Market Law Review 1333–70; L Arroyo Jimenez and M Eliantonio, "Masks, Gloves, Exports Licences and Composite Procedures: Implementing Regulation 2020/402 and the Limelight of Accountability" (2020) 11(2) European Journal of Risk Regulation 382–89.

[24] The ESI fund amounted to €2.7 billion, capable of being supported by the Member States in case of need. Its function was to transfer part of the economic risks related to the vaccine research and development from the pharmaceutical companies to the public authorities. See Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union [2016] OJ L 70/1.

[25] Communication of 17 June 2020: "Once any of the vaccines supported proves successful, Member States will be able to acquire that vaccine directly from the producer on the basis of the conditions laid down in the APA. Allocation of access to vaccine doses between Member States would be according to a population-based distribution key."

[26] Commission, "Annex to the Commission Decision of 18 June 2020 on approving the agreement with the Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures" C (2020) 4192 final (Art 2).

[27] J Deutsch and S Wheaton, "How Europe Fell Behind on Vaccines. The EU Secured Some of the Lowest Prices in the World. At What Cost?" (*Politico*, 27 January 2021) <https://www.politico.eu/article/europe-coronavirus-vaccine-struggle-pfizer-biontech-astrazeneca/>.

Commission-led initiative of a European plan came as an all-encompassing alternative based on the principle of solidarity,[28] capable of avoiding fragmentation in vaccine availability within the Union.[29]

The political saliency of the Commission's strategy is intertwined with its redistributive reach. Although national executives remained in charge of purchasing the vaccine doses by themselves, the joint purchasing leverage and the population-based allocation foreseen by the Strategy brought about a redistributive effect that no doubt represents a novel trait for EU public health. As was said before, EU action in the area of public health has traditionally been regulatory in nature and aimed at setting up a competitive market of medical goods and services under Article 114 TFEU, without any consequences for the allocation of entitlements to these goods and services.[30] However, the Vaccines Strategy substantially differed from this in that it provided universal access to limited strategic resources,[31] as the centralized mechanisms allowed the Commission to pool the benefits of joint bargaining and level off any purchasing power imbalances among the Member States' healthcare systems, thereby ensuring the equitable availability of vaccine stocks.

2. *A compromised executive centralisation*

The Vaccines Strategy was not the first joint procurement initiative in the field of public health. Procurement agreements to purchase medical goods were already regulated by the Health Threat Decision in 2013,[32] and some mechanisms for their stockpiling and allocation in case of an emergency were already provided by the introduction of the so-called RescEU reserve within the framework of the EU Civil Protection Mechanism.[33] However, differently from these previous initiatives, the Vaccines Strategy was designed as a

[28] Arts 2 TFEU and 35 CFREU. See A de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford, Oxford University Press 2019); A de Ruijter, "The Impediment of Health Laws' Values in the Constitutional Setting of the EU" in TK Hervey, CA Young and L Bishop, *Research Handbook on EU Health Law and Policy* (Cheltenham, Edward Edgar Publishing 2017); TK Hervey and JV McHale, *European Union Health Law: Themes and Implications* (Cambridge, Cambridge University Press 2015).

[29] Moreover, the strategy allowed the Commission to design the values and purposes of an original European approach. Unlike the UK and the USA, the EU approach proved to be more cautious in assessing the security and quality of vaccines through the EMA, even though more controls had some repercussions on the rapid distribution of doses among the population. Anti-COVID-19 vaccines needed to be authorised by the EMA through the centralised procedure, as they contain a "new active substance" (see Art 3(1) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136/1). The EMA adopted a specific "conditional marketing authorisation" disciplined by the Commission Regulation (EC) No 507/2006 as a fast-track authorisation to speed up their approval (Commission Regulation (EC) 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council [2006] OJ L 92/6).

[30] Brooks et al, supra, note 21, p 29: "This means that it can support, for instance, the development of a new vaccine, but cannot ensure that such an innovation will be evenly enjoyed across the EU."

[31] T Daintith, "The Techniques of Government" in J Jowell and D Oliver, *The Changing Constitution* (Oxford, Oxford University Press 1994); G della Cananea, "The European Administration: *Imperium* and *Dominium*" in C Harlow, P Leino and G della Cananea, *Research Handbook on EU Administrative Law* (Cheltenham, Edward Elgar 2017).

[32] Art 5 Decision n. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC [2013] OJ L 293/1.

[33] Decision n. 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism [2013] OJ L 347/1. In 2019, this decision was amended to establish the RescEU reserve (Decision n. 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision n. 1313/2013/EU on a Union Civil Protection Mechanism [2019] OJ L 77I/1).

centralised mechanism despite the complementary role that the EU is supposed to assume in public health according to Article 168 TFEU.[34] The Vaccines Strategy did not merely support national strategies but integrated them within a joint procedure, as the APAs bound the participating Member States not to negotiate autonomous conditions with pharmaceutical companies.[35] As a result, Member States had to comply with the conditions established by the Commission for the development, production and allocation of "safe" and "affordable"[36] anti-COVID-19 vaccines without adopting their own national strategies.

As long as centralisation came through political bargaining, a compromise was found in terms of flexibility. According to the Decision of 18 June 2020, the participating Member States had the right (not the legal obligation) to purchase the vaccine doses reserved by the Commission. If a Member State had not intended to buy the allocated vaccines, those would have been distributed to the other Member States requiring them. Member States' right to buy vaccine doses would have turned into a legal obligation only by the provision of a specific clause in the preliminary agreement.[37] In this case, Member States could still rely on an opt-out option, whereby they would have been exempted from the obligation by notifying the Commission of their intentions within five working days of the Commission's communication. However, whenever a Member State chose the opt-out option, it would have been authorised to carry out separate negotiations only once the APA had been fully negotiated, to avoid any distortion of the centralised mechanism. As a result, although the purchasing mechanism was fully centralised, it allowed national welfare systems to make their own choices,[38] for which they remained completely reliable and independent. Nevertheless, the drawback of these flexibility provisions was that the effectiveness of the vaccine allocation *de facto* depended not only on the population-based criterion but also on the national purchasing choices.

Moreover, the governance of the Vaccines Strategy was characterised by a strong involvement of national experts in the agenda-setting and even in the negotiation with the pharmaceutical companies. The core decisions regarding the procurement procedures were taken by an *ad hoc* steering group composed of senior officials from all of the participating Member States and co-chaired by the Commission and a "Participating Member State with experience in the negotiations and production capacities for vaccines".[39] The negotiations of the vaccine doses themselves were indeed carried out by a "Joint Negotiation Team" composed of the representatives of six Member States participating in the steering group.[40]

[34] The intergovernmental agreement of 17 June 2020 indeed allowed the Commission to go a little beyond the strict constraints foreseen by the Treaties (see A Von Bogdandy and J Bast, "The European Union's Vertical Order of Competences: The Current Law and Proposals for Its Reform" (2002) 39 Common Market Law Review 239; S Weatherill, "Competence Creep and Competence Control" (2004) 23(1) Yearbook of European Law 1).

[35] Art 7, Annex to the Commission Decision of 18 June 2020.

[36] Communication of 17 June 2020: "The strategy has the following objectives: ensuring the quality, safety, and efficacy of vaccines; securing timely access to vaccines for the Member States and their population while leading the global solidarity effort; ensuring equitable access for all in the EU to an affordable vaccine as early as possible."

[37] Art. 3 and 4, Annex to the Commission Decision of 18 June 2020.

[38] J Deutsch, DM Herszenhorn and J Barigazzi, "Austria Threatens to Halt EU's 100M Vaccine Buy Until It Gets a Greater Share of Jabs. Austria Wants More Than Its Allotted Doses, Even Though Data Show It Is Not Among the Countries in Greatest Need" (*Politico*, 30 March 2021) <https://www.politico.eu/article/sebastian-kurz-austria-threatens-to-block-eu-option-to-buy-100-million-coronavirus-vaccine-doses-in-fight-over-distribution/>.

[39] Art 2, Commission Decision of 18 June 2020.

[40] The Joint negotiation team included experts from the four states of the "Inclusive Vaccines Alliance" (France, Germany, Italy and the Netherlands), with the additions of Poland, Spain and Sweden.

III. The incompleteness of the mechanism

The EU Vaccines Strategy introduced new patterns of joint action for the EU executive, as the Commission purchased and allocated vaccine doses through a centralised procedure, which turned out to have some redistributive consequences within a highly contested policy space. However, as the joint procurement procedure was set up during the crisis by intergovernmental consensus, its design turned out to be incomplete.

Firstly, the intergovernmental agreement did not provide precise mechanisms of compliance capable of enforcing the joint procedure in case a participating Member State flouted the rules. Indeed, the Strategy relied mainly on the general tendency of the participants to cooperate rather than on the Commission's concrete enforcement powers. The centralisation of the strategy seemed to be ensured mainly by the political pressure of the participating States, as long as they complied with the transparency duties regarding their decisions. Some evidence of this is provided by the controversy on the obligation not to negotiate separately.[41] This provision constituted the core of the centralised procedure, as it was designed to avoid the risk that the wealthier healthcare systems could start parallel negotiations, thus hampering the redistributive purposes of the joint strategy. In September 2020, however, the German health ministry signed a separate deal with Pfizer–BioNTech for 30 million extra doses of the Pfizer vaccine, declaring that "the EU cannot prohibit forever other EU countries from buying additional vaccine doses on their own".[42] Although the German side-deal constituted a clear violation of Article 7 (Annex to the Decision of 18 June 2020), the Commission refused to give any answer to the European Parliament about what enforcement procedures could be deployed.[43] Such institutional inertia could be explained by the uncertainty regarding the legal nature of the intergovernmental agreement, as it constituted an *ad hoc* basis outside the European acquis. In the end, as long as the procurement strategy was effective at reaching the goal of providing the Member States with vaccines, no action was deemed necessary against Germany.

A second criticised flaw is that the Strategy lacked appropriate procedures to foster participation by the stakeholders and the European Parliament.[44] As in the previous case, the lack of supervision stemmed from the nature of the Strategy as an emergency solution set up through *ad hoc* institutional arrangements. Several observers blamed the Commission for the absence of transparency in the negotiations with pharmaceutical

[41] Art 7, Annex to the Decision of 18 June 2020.

[42] G Fortuna, "Commission Takes Evasive Action Over Germany's Vaccine Side Deal" (*Euractiv*, 8 January 2021) <https://www.euractiv.com/section/coronavirus/news/commission-takes-evasive-action-over-germanys-vaccine-side-deal/>; J Deutsch and M Sugue, "Commission Lets Germany Off the Hook for Coronavirus Vaccine Solidarity Breach" (*Politico*, 8 January 2021) <https://www.politico.eu/article/germanys-coronavirus-vaccine-side-deal-at-odds-with-legally-binding-eu-pact/>.

[43] Parliamentary Questions, "Priority Question for Written Answer to the Commission. Subject: Germany Acting Outside the EU's Vaccine Strategy" (22 January 2022) <https://www.europarl.europa.eu/doceo/document/P-9-2021-000388_EN.html>.

[44] European Parliament, "European Parliament resolution of 21 October 2021 on EU transparency in the development, purchase, and distribution of COVID-19 vaccines" 2021/2678(RSP). The day after the Resolution, a group of Members of the European Parliament from the Greens/European Free Alliance group filed a case applied to the Court of Justice of the European Union stating an "implicit refusal" from the Commission to provide access to the contracts with vaccine manufacturers (see Summary of the application for annulment of 22 October 2021 in Case Margrete Auken, Tilly Metz, Jutta Paulus, Michèle Rivasi, And Kimberly Van Sparrentak v. European Commission <https://www.greens-efa.eu/en/article/press/access-to-information-five-greens-efa-meps-launch-legal-action-on-vaccine-contract-transparency>). See G Peseckyte, "MEPs vs Commission in Court Over Vaccine Contracts" (*Euractiv*, 29 October 2021) <https://www.euractiv.com/section/coronavirus/news/meps-vs-commission-in-court-over-vaccine-contracts/>.

companies,[45] as relevant information related to the ongoing negotiations, such as prices and timing, was not provided. Although documents or parts of documents (in the case of contracts) were made available on the Commission's website, their publication followed the end of negotiations. The Commission even decided not to disclose the identity of the national members of the Joint Negotiation Team to allow them to carry out their task "independently and without being subject to undue external influence or pressure".[46] The disclosure of the members of the negotiation board depended instead on the discretionary choices of the Member States participating in the team. The secrecy regarding the board negotiators raised some concerns about possible conflicts of interest in favour of pharmaceutical companies.[47]

Such flaws in the design of the joint procurement procedure derived from the emergency context in which it was conceived. The constrained legal basis for EU public health would not have allowed for such operational patterns, which were therefore established by a contingent intergovernmental agreement. However, in view of the institutionalisation of the Strategy within the legal framework of HERA, it is worth questioning whether the Commission seized the chance to overcome such deficits through a coherent set of rules, thereby capitalising on this experience to set up some integrated mechanisms of health risk management, or whether it merely replicated the patterns of the Strategy, opting for a "lowest common denominator" solution.

IV. HERA: a *sui generis* administrative body

Through HERA, the Commission aimed at establishing an administrative body in charge of the tasks informally carried out during the pandemic.[48] HERA is conceived to be the core of a long-term policy to boost EU capacities in preventing and managing future health crises.[49] For this purpose, its intervention will not be limited to the procurement of critical resources in case of an emergency; rather, its intervention will range from the coordination of national healthcare systems to the cooperation with national administrations and private companies to assess potential health threats and incentivise research and

[45] Thirty-nine civil society organisations requested that the European Commission and EU national governments ensured the maximum degree of transparency in the EU's exchanges, negotiations and deals with pharmaceutical companies over COVID-19 vaccines. See Y Natsis, "Transparency Is a Fundamental Pillar for the Success of the EU Vaccines Strategy" (*European Public Health Alliance*, 17 December 2020) <https://epha.org/transparency-is-a-fundamental-pillar-for-the-success-of-the-eu-vaccine-strategy/>. See also the report of the EU Ombudsman regarding the transparency issues raised by the health crisis management (European Ombudsman, "Overview of European Ombudsman's Initiative Looking into the COVID-19 Response of the EU Administration" (5 January 2021) <https://www.ombudsman.europa.eu/fi/news-document/en/136499>.

[46] E Wegener, "EU's Lack of Transparency Around Covid-19 Vaccine Negotiations Is Damaging Public Trust" (*Transparency International*, 14 January 2022) <https://ti-health.org/content/european-union-covid-19-vaccine-negotitaitons-contracts-transparency/>.

[47] See M Peigné, "EU's 'Secret' Vaccine Negotiators: Who's Dealing with Big Pharma?" (*EUobserver*, 4 November 2021) <https://euobserver.com/health-and-society/153412>.

[48] Recital 1, Proposal for a Council Regulation of 16 September 2021: "The *ad-hoc* measures taken by the Commission to restrict the spread of the COVID-19 pandemic were reactive and the Union was not sufficiently prepared to ensure efficient development, manufacturing, procurement, and distribution of crisis-relevant medical countermeasures, especially in the early phase of the COVID-19 pandemic."

[49] HERA will tackle "vulnerabilities and strategic dependencies within the Union related to … medical countermeasures" and foster health preparedness and responses on a global scale (Art 2, Commission Decision of 16 September 2021). See M Anderson, R Forman and E Mossialos, "Navigating the Role of the European Union (EU) Health Emergency Preparedness and Response Authority (HERA) in Europe and Beyond" (*The Lancet Regional Health*, 2021) <https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(21)00180-0/fulltext>.

development regarding medical countermeasures.[50] In case of a health emergency, HERA will purchase, stockpile and distribute medical countermeasures, re-shore production capacity to the EU and negotiate directly with manufacturers.[51]

Although one would have expected a European Health Union to be agency-driven,[52] its operational core has been designed as an internal department of the Commission. According to Recital 6, HERA is set up as a "Commission service", whose Head has the ranking of a Director-General (DG; Article 4). HERA is meant to be complementary to other Commission Directorate-Generals, such as the Directorate-General for Health and Food Safety (DG SANTE), the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) and the Directorate-General for European Civil Protection and Humanitarian Aid Operations (DG ECHO), as well as other Union structures and mechanisms. The choice not to delegate powers to pre-existing or new administrative agencies was regarded as a way to reduce the reach of the EU's initial ambitions in public health.[53] However, the hypothesis of a downsized project clashes with the considerable budget (€6 billion) bestowed upon it over six years in the multi-annual financial framework, which is highly comparable to its American counterpart, the US Biomedical Advanced Research and Development Authority (BARDA).[54] Rather, HERA should be considered as a new centralised method of policy delivery involving strategic decisions and EU budget management as distinct from administrative implementation through EU agencies.[55] HERA will operate as a cross-sectoral service participating in several spending programmes, such as EU4Health, Horizon Europe and the Union Civil Protection Mechanism, to address the vulnerabilities and strategic dependencies of the EU pharmaceutical market and also to strengthen health security coordination on a global scale. Such tasks entail margins of political discretion that would exceed EU agencies' delegated powers as envisaged by the Court of Justice.[56]

[50] ibid.

[51] JH Vela, "Brussels Playbook: Fortress Europe Weakens Asylum Rights – Holding Out for a HERA – Statues of Limitation" (*Politico*, 1 December 2021) <https://www.politico.eu/newsletter/brussels-playbook/fortress-europe-weakens-asylum-rights-holding-out-for-a-hera-statues-of-limitation/>. Such an operational "crisis mode" will be regulated by two proposals of Regulation: Commission, "Proposal for a Regulation of 11 November 2020 of the European Parliament and the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU" COM (2020) 727 final; Commission, "Proposal for a Council Regulation of 16 September 2021 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level" COM(2021) 577 final. On 17 December 2021, Member States reached a political agreement on the text of the Council Regulation (Council, "Council Regulation on the emergency framework regarding medical countermeasures – Political agreement of 17 December 2021" 2021/0294(NLE)).

[52] As an example, see, in this journal, O Bartlett, "COVID-19, the European Health Union, and the CJEU: Lessons from the Case Law on the Banking Union" (2020) 11(4) European Journal of Risk Regulation 781–89. In view of establishing a stronger European Health Union, the author analyses the possible approach of the Court of Justice of the European Union to the allocation of powers to EU health agencies.

[53] As many expected an agency to be built up, the institutionalisation of HERA as a service within the Commission seemed to downsize the initial premises. See J Deutsch, "Europe's 'Health Union' Prepares for Its First Feeble Steps. When It Comes to Health Policy, the European Commission Has Largely Wasted the Coronavirus Crisis" (*Politico*, 1 September 2021) <https://www.politico.eu/article/european-health-union-coronavirus-ema-hera-barda/>.

[54] J Deutsch, "HERA Isn't the Hero Parliament Wants – Or the Game-Changer Council Fears" (*Politico*, 17 September 2020) <https://www.politico.eu/article/hera-eu-commission-health-emergency-preparedness-response-authority/>.

[55] E Chiti, "The Agencification Process" in P Craig and G De Búrca (eds) *The Evolution of EU Law* (Oxford, Oxford University Press 2021) p 134.

[56] Case 9-56 *Meroni* [1958] ECLI:EU:C:1958:7; Case 98-80 *Romano* [1981] ECLI:EU:C:1981:104; Case C-270/12 *Short Selling* [2014] ECLI:EU:C:2014:18. On the delegation of powers to European agencies, see M Simoncini, "The Delegation of Powers to EU Agencies After the Financial Crisis" (2021) 6(3) European Papers – A Journal on Law and Integration 1485–503; M Scholten and M Rijsbergen, "The ESMA-Short Selling Case: Erecting a New

The fact that HERA represents an administrative *unicum* raises some crucial questions regarding the challenges posed by the institutionalisation of the provisional arrangements set up in the context of the Vaccines Strategy in terms of effectiveness and social/democratic participation in the decision-making processes.

1. The effectiveness of HERA's action

As was said before, the first concern regarding the Vaccines Strategy related to the effectiveness of the Commission's action. As the intergovernmental agreement provided an uncertain legal basis, compliance with the obligation not to negotiate separately relied on political pressure rather than specific powers, which could have been deployed if the EU had had more competencies in public health. In the aftermath of the crisis, however, the overall success of the EU response to the pandemic, and of the procurement strategy, created the impression that EU risk management could work even with no Treaty revision. As a result, the initial keenness to amend Article 168 TFEU[57] left room for tendency among almost all Member States to maintain their sovereignty in public health, as it represents a fundamental asset for national welfare systems.[58]

This intergovernmental retrenchment also affected HERA's functioning and internal organisation. The internal organisation of HERA largely reflects the provisional steering group set up during the implementation of the Vaccines Strategy,[59] as its organisational core – the HERA board[60] – is composed of one high-level representative from each Member State appointed by the Commission on the basis of national authorities' indications.[61] The Board shall "assist and advise" the Commission in the formulation of strategic decisions and deliver opinions on the tasks performed by the Authority. Moreover, the functioning of HERA is subject to the strict control of the Council when it activates its operational "crisis mode", which implies the deployment of significant powers by HERA. It is up to

Delegation Doctrine in the EU upon the Meroni–Romano Remnants" (2014) 41 Legal Issues of Economic Integration 389; E Chiti, "European Agencies' Rulemaking: Powers, Procedures and Assessment" (2013) 19(1) European Law Journal 93. See also M Everson and E Vos, "European Union Agencies" in M Riddervold, J Trondal and A Newsome (eds), *The Palgrave Handbook of European Union Crises* (London, Palgrave 2020) p 319: "Discretionary powers may be delegated to independent agencies where they have no redistributive consequences, or the subject-matter of regulation is value neutral in terms of general welfare losses." See also G Majone, "Independence vs. Accountability: European Non-Majoritarian Institutions and Democratic Government in Europe" (1994) EUI Working Papers – SPS.

[57] An appeal to a "joint European response" to revise the TFEU was indeed forwarded on 15 March 2020. The initiative, started by professors R. Castaldi and D. Innerarity, was supported by Romano Prodi, Enrico Letta and José Luis Rodrìguez Zapatero and others ("Prominent Europeans Call for EU Answer to Coronavirus Threat" (*Euractiv*, 15 March 2020) <https://www.euractiv.com/section/future-eu/opinion/prominent-europeans-call-for-a-european-answer-to-the-coronavirus-threat/>).

[58] As public health represents a "core state power" (Genschel and Jachtenfuchs, supra, note 15), Member States have been historically reluctant to cease their sovereignty in the field. See M McKee, E Mossialos and P Belcher, "The Influence of European Law on National Health Policy" (1996) 6 Journal of European Social Policy 263; M Anderson and E Mossialos, "Time to Strengthen Capacity in Infectious Disease Control at the European Level" (2020) 99 International Journal of Infectious Diseases 263; Deutsch, supra, note 54. Health management is considered to have some "state-building capacity", as health issues involve some forms of national solidarity to be carried out by the nation-state. See LO Gostin, *Public Health Law: Power, Duty, Restraint* (Berkeley, CA, University of California Press 2000); K Lenaerts and JA Gutierrez-Fons, "The Constitutional Allocation of Powers and General Principles of Law" (2010) 47 Common Market Law Review 1629.

[59] Art 2, Commission Decision of 18 June 2020.

[60] Art 6, Commission Decision of 16 September 2021.

[61] In addition, representatives of the ECDC, the EMA, the Emergency Response Coordination Centre, other Union decentralised and relevant executive agencies and other bodies relevant to public health emergencies may participate as observers.

a Council Regulation[62] to decide what measures HERA can deploy during a health crisis[63] and their duration, which is generally to be six months.[64] After the activation of the emergency framework, "crisis-mode" HERA should operate "in close coordination" with an intergovernmental Health Crisis Board constituted within the Commission to ensure coordination among the Council, the Commission, the relevant Union agencies and bodies and the Member States. During a crisis, the Commission is held to be accountable to the Health Crisis Board whenever it does not follow its opinions.[65]

However, although the Council's supervision turned out to be strengthened, the powers attributed to HERA seem to have decreased when compared to the provisions of the Strategy intergovernmental agreement. Article 7 of the Proposal of 16 September 2021, regarding the "procurement ... of crisis-relevant medical countermeasures and raw materials", does not even mention the obligation not to negotiate separately, a core procedural principle of the Strategy. The political agreement on the Draft Council Regulation of 17 December 2022 pushed forward the consensus-based nature of the procurement procedure by fully revising Article 7. The new version of the article remarks on the advisory role of the Health Crisis Board and the information duties of the Commission, and it makes it clear that the Member States "shall be free to participate in the procurement procedure, including through opt-out mechanisms and, in duly justified cases, through opt-in mechanisms". In fact, Article 12 of the Proposal of 11 November 2020 provides that "Member States, EFTA States, and Union candidate countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product" (paragraph 2, letter c). If the provision was also in the final regulation, the Commission would be enabled to start infringement procedures against those States that do not comply with the strategy. Even in this case, however, some concerns could be raised regarding the effectiveness of an ordinary infringement procedure in the course of a health emergency, and, anyway, no specific powers are attributed to supervise national authorities and assess eventual breaches in case a Member State flouted the obligation.

2. *Participation in the decision-making processes*

The second concern regarding the Vaccines Strategy was the scarce involvement of the European Parliament and groups of stakeholders in the joint negotiations. As the emergency required agile decision-making processes, executives took over the management of the crisis worldwide, and the EU was not an exception. Once HERA was charged with strategic decisions about Europeans' health, one would have expected that the new legislation would have provided some forms of social and democratic participation. However, as HERA's legal framework will rely on a Commission Decision and a Council Regulation under Article 122(1) TFEU,[66] the European Parliament has been *de facto* excluded by the

[62] Art 3, Proposal for a Council Regulation of 16 September 2021.

[63] The measure can be the surveillance, procurement and manufacture of medical countermeasures, emergency research plans, emergency funding and the use of Union-wide clinical trial networks and data-sharing platforms. See Arts 5–11 and 13, Proposal for a Council Regulation of 16 September 2021.

[64] If deemed necessary, however, the Commission shall ask the Council for their prolongation by submitting a report assessing the public health situation and the economic consequences of the public health crisis (Art 4, Proposal for a Council Regulation of 16 September 2021).

[65] Art 5, Proposal for a Council Regulation of 16 September 2021, as revised by the Political Agreement of 17 December 2021.

[66] Art 122 TFEU has also provided the legal basis for the EU economic policies to confront the crisis. See M Ioannidis, "Between Responsibility and Solidarity: COVID-19 and the Future of the European Economic Order" (2020) Max Planck Institute for Comparative Public Law & International Law (MPIL) Research Paper No. 2020(39); F Fabbrini, "The Legal Architecture of the Economic Responses to COVID-19: EMU Beyond the Pandemic" (2020) 60(1) Journal of Common Market Studies 186. In the past, Art 122 TFEU was used to establish the European financial stabilisation mechanism through Regulation n. 407/2010 (A de Gregorio Merino, "Legal

process of HERA's formation.[67] The Parliament will not even participate in HERA's internal governance, where a crucial role is played by the Council and the intergovernmental HERA Board. Although the Parliament will have the right to vote on HERA's budget, it will take part in the meetings of the HERA Board as an observer,[68] thus with little chance to influence HERA's decisions. Moreover, weak tools of political accountability[69] are provided by the Proposal of the Council Regulation. The Proposal mentions only an "in-depth review of the implementation of the operations of HERA" to be conducted by the Commission by 2025 to eventually revise HERA's mandate. Subsequently, the Commission will be required to report to the European Parliament, as well as the Council and the HERA Board, on the findings of such an operation.

Secondly, the institutional design of HERA does not overcome the concerns raised against the Vaccines Strategy regarding the lack of participation of interest groups and stakeholders (ie health non-governmental organisations). Such concerns also related to the shape of HERA governance, even more so that it will be entrusted to manage a huge amount of European funds. Neither the Commission Decision nor the Proposal of the Council Regulation focused on mechanisms capable of fostering some forms of participation and accountability. The amendments posed by the Political Agreement of 17 December 2021 seem to pay some more attention to transparency issues, as "[t]he Commission shall ensure transparency and provide all national representatives with equal access to information, to ensure that the decision-making process reflects the situation and the needs of all Member States". Moreover, the Draft Regulation introduces a new Article 5a ("Declaration of interest"), whereby the members of the Health Crisis Board as well as observers and external experts "shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests ... or any direct or indirect interests which might be considered prejudicial to their independence". However, the rationale underlying these amendments seems to ensure more intergovernmental control rather than fostering the participation of the stakeholders.

V. Conclusion

Although part of HERA's legal basis is currently pending approval, the findings of this analysis already allow us to draw some conclusions about the question posed at the beginning of this paper. The EU Vaccines Strategy constituted a tailor-made procedure aimed at tackling jointly the systemic consequences of the COVID-19 pandemic. On one side, the powers delegated to the EU executive by intergovernmental agreement required the Commission to take strategic decisions entailing redistributive effects within the Union. On the other, the joint Strategy presented some structural flaws, as its functioning was excessively consensus-dependent and it lacked provisions for democratic and social participation. In the wake of its institutionalisation, this paper aimed to understand whether HERA's

Developments in the Economic and Monetary Union During the Debt Crisis: The Mechanisms of Financial Assistance" (2012) 49(5) Common Market Law Review 1613).

[67] Art 122 (1) TFEU: "Without prejudice to any other procedures provided for in the Treaties, the Council, on a proposal from the Commission, may decide, in a spirit of solidarity between the Member States, upon the measures appropriate to the economic situation, in particular, if severe difficulties arise in the supply of certain products, notably in the area of energy."

[68] Art 6, Commission Decision of 16 September 2021.

[69] Here *accountability* has to be intended as "a relationship between an actor and a forum, in which the actor has an obligation to explain and to justify his or her conduct, the forum can pose questions and pass judgment, and the actor may face consequences". See M Bovens, "Analysing and Assessing Accountability: A Conceptual Framework" (2007) 13(4) European Law Journal 447; M Bovens, D Curtin and PT Hart, "Studying the Real World of EU Accountability: Framework and Design" in M Bovens, D Curtin and PT Hart (eds), *The Real World of EU Accountability: What Deficit?* (Oxford, Oxford University Press 2010) p 31.

new legal framework built up an effective and participated policy for the availability of medical supplies or maintained the contingent intergovernmental patterns of the Strategy, thus representing a "missed opportunity" to establish a stronger European Health Union.

The findings of this work seem to support the latter hypothesis. Indeed, HERA represents an *ad hoc* administrative arrangement, whose governance and functioning rely decisively on the consensus of the Council and the Member States. HERA will address medical supply and raw materials shortages in the long run, whereas it will be delegated some exceptional risk management powers by the Council in case of a health emergency. However, no specific supervisory powers and enforcement tools are provided to HERA, whose activities will remain dependent on the willingness of the Member States to cooperate. Although HERA's actions will require strategic decisions entailing redistributive consequences, the European Parliament has played no active role in the making of HERA, and its role in its governance will presumably also be marginal since it participates on the HERA Board only as an observer. Little attention has been also paid to stakeholders' participation. Even though some transparency flaws regarding the Strategy's negotiations were addressed by the Political Agreement of December 2021, such provisions are more aimed at guaranteeing national authorities' supervision than being functional in terms of social accountability.

Although the institutionalisation of HERA missed the chance of achieving a supranational and politically debated health policy, it reveals some innovative traits that deserve to be assessed even beyond the scope of this work. The Vaccines Strategy, then followed by HERA, turned out to establish an innovative method of policy delivery steered by the Commission. Indeed, both the provisional Strategy and HERA represent *ad hoc* executive arrangements relying on original patterns of cooperation between European and national executives. A normative approach to such phenomena could be used to understand what role law ought to play to ensure their effectiveness and, most of all, their control.

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