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Exploring the European Medicine Agency's new mandate

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1. The COVID-19 pandemic has been devastating to economies, societies, and lives worldwide. The Member States were caught off guard by the sheer dimension and the speed at which the virus initially spread. Each country started stockpiling whatever was needed to address the outbreak, from personal protective equipment (PPE) to

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medical ventilators.[1] The logic of being part of a Union was quickly set aside, limits to cross-border movements were reintroduced, and ignoring years of market globalization policies, EU countries adopted autarchic and inward-looking measures. When reality caught up with State policies, self-centered measures were seen to be inefficient: shortages of PPE across the continent were a standard feature. Despite having closed borders, the virus had spread everywhere.

The outbreak outstripped Member States' capabilities and has shown EU countries' deficiencies in health crisis management and the EU's lack of competencies on the subject.[2] The mechanisms at the disposal of the EU have not been able to ignite a timely common EU-level response or guarantee initial solidarity among the Member States,[3] giving them the way to adopt unilateral measures. The absence of a rationalized system in the collection and evaluation of data concerning public health crises, and deficiencies in the crisis management systems, have undermined Member States' ability to adopt well thought political decisions in regard to an EU-wide response and further strained national healthcare systems, already deprived of proper funding due to the last financial crisis.[4]

These shortcomings could be considered endemic to the EU and strictly linked to Member States' wish to limit Union's competencies in health-related matters. To the surprise of many citizens the EU has limited competencies within the realm of health, having a supporting, coordinating, or supplementing competence on health policies.[5] The

[1] M. GATTI, *La risposta europea all'emergenza da COVID-19,* in P. MANZINI, M. VELLANO (eds.), *Unione Europea 2020: I dodici mesi che hanno segnato l'integrazione europea*, Milano, 2021, pp. 40-41.

[2] E. MAZZONI, *Towards a European Health Union: Lessons learned, future challenges*, 2021, p. 6, www.i-com.it/wp-content/uploads/2021/05/Policy-brief_-Towards-a-European-Health-Union.pdf.

[3] G. DI FEDERICO, *L'assistenza sanitaria transfrontaliera alla prova della pandemia*, in P. MANZINI, M. VELLANO (eds.), *op. cit.*, p. 73.

[4] G. DI FEDERICO, *Stuck in the Middle With You...Wondering What it is I should Do. Some Considerations on EU's Response to COVID-19*, in *rivista.eurojus.it*, vol. 3, 2020, p. 61. On the constraints put on national healthcare systems see M. E. FOLDES, *Health policy and health systems: a growing relevance for the EU in the context of the economic crisis*, in *Journal of European Integration*, vol. 38, n. 3, 2016, pp. 295-309.

[5] Art. 6, l. (a) TFEU. See also P. DE PASQUALE, *Le competenze dell'Unione europea in materia di sanità pubblica e la pandemia di Covid-19*, in *DPCE online*, vol. 43, n.

Member States remain the leading actor, also having exclusive competence in healthcare.[6] This competence allocation, indeed, had seen the Member States adopt their policies, often mismatched with those of their neighbours, which ultimately generated an inadequate response that undermined European citizens' wellbeing.[7]

EU countries' inability to coordinate COVID-19 policies sparked a renewed debate between policymakers, academics, and commentators about health competencies allocation between the Member States and the EU. It has been argued that the EU should reform its legal framework while staying inside the boundaries of Art. 168 TFEU.[8] Others have been calling for a bolder approach, emphasizing the necessity of reforming the EU health competencies.[9]

2, 2020, pp. 2295-2308; E. BROOKS, R. GEYERB, *The development of EU health policy and the Covid-19 pandemic: trends and implications*, in *Journal of European Integration*, vol. 42, n. 8, 2020, pp. 1057-1076.

[6] Art. 168 TFEU. It has to be mentioned that the Union had a considerable impact on health law nonetheless (D. S. MARTINSEN, R. SCHRAMA, *Networked Health Care Governance in the European Union*, in *Journal of Health Politics, Policy and Law*, vol. 46, n. 1, 2021, pp. 93-116; S. L. GREER ET AL., *Everything you always wanted to know about European Union health policies but were afraid to ask*, II ed.., London, European Observatory on Health Systems and Policies, 2019, pp. 63-93, 119-125, 132-135; A. DE RUIJTER, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care*, Oxford, 2019, pp. 1-15, primarily through internal market development. In the wake of the financial crisis, European health policies even extended to the MSs healthcare systems, imposing financial constraints on healthcare national budgets, leading to the adoption of fiscal governance mechanisms able to control budgetary decisions of MSs and supervise their structural reforms (see M. E. FOLDES, *op. cit.*; M. HENSHER ET AL., *Health care and the future of economic growth: exploring alternative perspectives*, in *Health Economics, Policy and Law,* vol. 15, n. 4, 2020, pp. 419-439).

[7] A. ALEMANNO, *Towards a European Health Union: Time to Level Up*, in *European Journal of Risk Regulation*, vol. 11, 2020, pp. 722-723.

[8] Art. 168. See also S. GREER, A. DE RUIJTER, *EU health law and policy in and after the COVID-19 crisis*, in *European Journal of Public Health,* vol. 30, n. 4, 2020, pp. 623-624, same position by A. DE RUIJTER, R. BEETSMA, B. BURGOON, F. NICOLI, F. VANDENBROUCKE, *EU solidarity in fighting COVID-19: state of play, obstacles, citizens' attitudes and ways forward*, 2020, www.voxeu.org/article/eu-solidarity-fighting-covid-19. See also M. GUY, *Beyond COVID-19: Towards a European Health Union*, in *European Journal of Risk Regulation*, vol. 11, n. 4, 2020, pp. 757-765.

[9] V. DELHOMME, *Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health*, in *European Journal of Risk Regulation*, vol. 11, n. 4, 2020, p. 748. See also G. BAZZAN, *Exploring Integration Trajectories for a European Health Union*, in *European Journal of Risk Regulation*, vol. 11, n. 4, 2020, pp. 736-746; O. BARTLETT, *COVID-19, the European Health Union and the*

In this state of affairs, EU citizens asked for greater involvement from the Union in managing health crises, with sixty-eight per cent of citizens wishing the EU had more competencies than those it currently has.[10] This meant European involvement in health policies had to be rethought. This buildup pushed the European Commission (EC) to propose on 11 November 2020 the European Health Union (EHU).[11]

The EHU aims to change how the EU and the Member States deal with health crisis management, enhancing their coordination on health issues, with the ultimate aim of preventing future chaotic scenes like the ones we witnessed at the beginning of the pandemic. A fundamental part of this structure is the mandate extensions of the European Centre for Disease Prevention and Control (ECDC) and the European Medicine Agency (EMA), as well as the establishment of one commission service, the newly established Health Emergency Preparedness and Response Authority (HERA). Each one of these is capable of addressing health crises from a different angle, hopefully offering a comprehensive crisis management system when combined.

The paper will exclusively focus on the EMA, of which the extended mandate has just come into force.[12] As regards the extended mandate of the ECDC, the European Parliament and Council reached a provisional agreement in November 2021. Today, both legislators endorsed the

CJEU: Lessons from the Case Law on the Banking Union, in *European Journal of Risk Regulation*, vol. 11, n. 4, 2020, pp. 781-789.

[10] European Parliament, *Public Opinion in Times Of Covid-19. A Public Opinion Survey Commissioned by the European Parliament First Results*, www.europarl.europa.eu/at-your-service/files/be-heard/eurobarometer/2020/public_opinion_in_the_eu_in_time_of_coronavirus_crisis_2/en-covid19-survey2-key-findings.pdf.

[11] Communication from the Commission 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 of 11 November 2020; European Commission, *European Health Union: Protecting the health of Europeans and collectively responding to cross-border health crises*, www.ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en.

[12] Regulation (EU) 2022/123 of the European Parliament and of the Council, of 25 January 2022, on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices entered into force on 1 February 2022 and is applicable from 1 March 2022. However, besides Art. 30, Chapter 4 on medical devices will apply as of 2 February 2023.

text; however, a plenary vote is scheduled for later in 2022.[13] The HERA, meanwhile, has come into being;[14] nonetheless, as Directorate-General does not raise the same questions associated with European agencies. Therefore, for the purpose of this paper, the planned extension of the mandate of ECDC and the new position of the HERA will not be further developed.

The paper draws on insights from European institutional law to examine the new mandate of the European Medicine Agency in this contested competence area. More specifically, the paper is situated within the existing literature on the agencification of the EU executive.[15] It will explore whether the concept of EU agencies as in-betweeners could be helpful in making sense of the EMA's extended mandate.[16] Moreover, it will show that by aiming at solving topical issues brought about by the pandemic, the EHU showcased old questions concerning EU agencies and the competence allocation on health.

2. The European Medicine Agency was established in 1993,[17] and it has been considered the "culmination of thirty years of pharmaceutical

[13] European Parliament, *Legislative train schedule - Extension of the mandate of the European Centre for Disease Prevention and Control (ECDC)*, 20 April 2022, www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-ecdc-mandate-extension.

[14] Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union, Brussels, COM (2021) 576, of 16 September 2021; Commission decision, of 16 November 2021, establishing the Health Emergency Preparedness and Response Authority, C (2021) 6712, of 16 November 2021.

[15] See D. CURTIN, *Holding (quasi-) Autonomous EU Administrative Actors to Public Account*, in *European Law Journal*, vol. 13, n. 4, 2007, pp. 523-541; M. CHAMON, *EU Agencies: Legal and Political Limits to the Transformation of the EU Administration*, Oxford, 2016; C. TOVO, *Le agenzie decentrate dell'Unione Europea,* Napoli, 2016; J. ALBERTI, *Le agenzie dell'Unione Europea*, Milano, 2018. On accountability issues see M. BUSUIOC, *European Agencies: Law and Practice of Accountability*, Oxford, 2013. Meanwhile, on "The definition of accountability" see M. BOVENS, *New Forms of Accountability and EU-Governance*, in *Comparative European Politics*, vol. 5, n. 1, 2007, pp. 104-120.

[16] See M. EVERSON, C. MONDA, E. VOS (eds.), *European Agencies in between institutions and Member States,* Alphen aan den Rijn, 2014.

[17] Regulation (EEC) 2309/93, of 22 July 1993, laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary

legislation"[18] that can be traced back to the Thalidomide tragedy of the 1960s.[19] The latter pushed the Community to adopt the first piece of pharmaceutical legislation, Council Directive 65/65/EEC,[20] which set in motion a fruitful cycle of reforms within the pharmaceutical sector that ultimately led to the establishment of the EMA.[21]

Since beginning operations in 1995, the EMA has been slowly but constantly acquiring more competencies. Today, the Agency is competent for the marketing authorization, supervision and pharmacovigilance of medicinal products for human and veterinary use. Moreover, it facilitates the development and access to medicines while providing scientific advice and protocol assistance for rare medical

use and establishing a European Agency for the Evaluation of Medicinal Products, Art. 1.

[18] M. GROENLEER, *The Autonomy of European Union Agencies – A Comparative Study of Institutional Developments,* Delft, 2009, p. 143. On the establishment of the Agency see regulation (EEC) 2309/93, Art. 1.

[19] On the Thalidomide tragedy see W. MCBRIDE, *Thalidomide and Congenital Abnormalities*, in *Lancet*, vol. 278, n. 7216, 1961.

[20] Directive 65/65/EEC established that medicinal product had to be authorized before being placed on the market (Art. 3). Such authorization had to require specific criteria assessing the safety and efficacy of the pharmaceuticals (Art. 4). By defining market entry conditions for medicines, Council Directive 65/65/EEC harmonized marketing authorization requirements across MSs (E. VOS, *Institutional Frameworks of Community Health and Safety Regulation – Committess, Agencies and Private Bodies,* Oxford, Hart Publishing, 1999, p. 207).

[21] The criteria set out by Council Directive 65/65/EEC were further developed by Council Directive 75/318/EEC, which harmonized particulars and documents (Art. 3(4) accompanying applications for marketing authorization. Meanwhile, Council Directive 75/319/EEC introduced at Art. 4 (and following) the community procedure and established at Art. 8 the Committee on Proprietary Medicinal Products. In 1981, Council Directive 81/851/EEC adopted similar requirements and procedures in regard to veterinary medicinal products. At Art. 16 it also established the Committee on Veterinary Medicinal Products. The limitations of the community procedure were addressed by Council Directive 83/570/EEC, which introduced the multi-state procedure and reduced the threshold of contemporaneous marketing authorization from five to two. In 1986, Directive 87/22/EEC introduced the concentration procedure, meanwhile Directive 87/21/EEC defined clear rules for copies of branded medicines, also known as "generics". Lastly, in 1989, Directives 65/65/EEC and 75/319/EEC were extended to medicinal products based on blood constituents (Directive 89/381/EEC) as well as to homeopathic medicinal products (Directive 92/73/EEC). First guidelines on good manufacturing practices were published, and harmonized rules were adopted for labelling, advertising, prescriptions and distribution of medicinal products (Directive 92 /27/EEC).

diseases,[22] traditional herbal medicines,[23] medicines for children's therapeutic needs,[24] and advanced therapy medicinal products.[25]

As a decentralized European agency, it has its legal personality, has been set up for an indefinite period, and is distinct from the EU institutions. Furthermore, like most European Agencies, it operates on a network-based structure. It relies on a network composed of National competent authorities (NCAs), within which all Agencies are equal. However, when it comes to the EMA, it has to be highlighted that the Agency has increased its stature over time, to the point that it can be seen *de facto* above NCAs; hence the nickname *primus inter pares*.[26]

2.1. Amid the pandemic, the European Medicine Agency played a vital role in the EU's response to the pandemic. The Agency has helped the Commission carry out its strategy for COVID-19 vaccines.[27] Indeed, it resorted to the Conditional Marketing Authorisation

[22] Regulation (EC) 141/2000 of the European Parliament and of the Council, of 16 December 1999, on orphan medicinal products, Art. 1.
[23] Directive 2004/24/EC of the European Parliament and of the Council, of 31 March 2004.
[24] Regulation (EC) 1901/2006 of the European Parliament and of the Council, of 12 December 2006, on medicinal products for paediatric use, Art. 3.
[25] Regulation (EC) 1394/2007 of the European Parliament and of the Council, of 13 November 2007, on advanced therapy medicinal products, Art. 1.
[26] It does not only apply to the EMA. Other European Agencies can today be seen as *primus inter pares*, such as EFSA (E. VOS, *European agencies and the composite EU executive*, in M. EVERSON, C. MONDA, E. VOS (eds.), *op. cit.*, p. 23).
[27] European Commission, *EU Vaccines Strategy*, www.ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccinesstrategy. On the topic of vaccines procurements see P. Manzini, *Brevi note sulla controversia relativa alla fornitura del vaccino AstraZeneca*, in *I Post di AISDUE*, *Coronavirus e diritto dell'Unione*, n. 1, 2021. Moreover, for further insights on the role of the European Commission amid the pandemic see European Commission, *Recovery plan for Europe*, www.ec.europa.eu/info/strategy/recovery-plan-europe_en; European Council, *COVID-19: the EU's response to the economic fallout*, consilium.europa.eu/en/policies/coronavirus/covid-19-economy/; Communication from the Commission: Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak, COM (2020) 1863 of 19 March 2020, p. 5 ss.; C. PESCE, *Pandemic Emergency Purchase Programme (PEPP): contenuti, finalità e basi giuridiche dell'azione monetaria UE*, in *I Post di AISDUE*, *Coronavirus e diritto dell'Unione*, n. 5, 2020; A. PITRONE, *Covid-19. Uno strumento di diritto dell'Unione europea per l'occupazione (SURE)*, in *I Post di AISDUE*, *Coronavirus e diritto dell'Unione*, n. 8, 2020.

(CMA),[28] which greatly benefitted the Member States' manoeuvre by cutting vaccine authorization times and enabled them to respond promptly to the pandemic.[29]

The CMA had sped up the procedure for approval of vaccines while thoroughly ensuring that all requirements were fully assessed in terms of efficacy, quality, and safety. A key element in speeding up the assessment was *rolling reviews*:[30] a simultaneous process enabling the Agency to assess data for promising drugs or vaccines as soon as they become available instead of waiting until all trials had been concluded.[31] Furthermore, being tasked with pharmacovigilance, the EMA better understood the disease and swiftly adjusted its recommendations to protect public health.[32] Moreover, by being an authoritative and influential body detached from politics, EMA's work helped national governments combat vaccine hesitancy.[33]

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[28] 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) 726/2004 of the European Parliament and of the Council; European Medicine Agency, *Conditional marketing authorisation*, www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation.

[29] Indeed, under normal circumstances, any vaccine developer that wishes to put a vaccine on the EU market has to complete its clinical trials and submit a marketing authorization to the EMA (regulation (EC) 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, Articles 1, 3).

[30] European Medicine Agency, *COVID-19 vaccines: development, evaluation, approval and monitoring*, www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-development-evaluation-approval-monitoring#accelerated-evaluation.

[31] See approved treatments at European Medicine Agency, *EMA's response to Covid-19 pandemic in 2021*, www.ema.europa.eu/en/documents/other/one-year-first-covid-19-vaccine-approval-eu_en.pdf.

[32] For example, EMA's contraindication for Vaxzevria (commonly known as AstraZeneca vaccine) in "people who have had thrombosis with thrombocytopenia syndrome after previously receiving this vaccine" (European Medicine Agency, *Annual Report 2020*, *op. cit.*, p. 13. On the Vaxzevria issue see European Medicine Agency, *Vaxzevria: further advice on blood clots and low blood platelets*, www.ema.europa.eu/en/news/vaxzevria-further-advice-blood-clots-low.

[33] J. SIVELÄ, panel *Vaccine hesitancy and uptake: From research and practices to implementation*, EU Health Policy Platform, [webinar on Vaccine hesitancy and uptake in the EU Joint Action on Vaccination], EUHPP, 14 February 2022.

However, it has to be highlighted that the Agency did not have the competencies to survey national readiness and initiate a common response in times of emergency, undermining the possibility of an effective joint response from the Member States.[34] Furthermore, according to the EC, the COVID-19 pandemic has displayed EMA's lack of a solid system to monitor and mitigate shortages of medical products and devices and a solid framework for crisis response. A lack of medicinal products may lead to adverse effects on a patient's health, resulting in severe reactions if unsuitable medicinal products have been used as a substitute for unavailable pharmaceuticals. Moreover, a lack of medical devices may exacerbate already dire situations, and the unavailability of PPE may put healthcare workers at risk while doing their job. Hence, the EMA's extended mandate aims to resolve those issues.

2.2. The EMA's extended mandate can be seen as part of a trend which saw the establishment or reinforcement of European Agencies as the answer to a European crisis.[35] Indeed, exogenous shocks have functioned as the trigger for deeper integration. While exposing endogenous deficiencies in the EU's integrated policy regimes,[36] these crises eventually intertwined with social and cultural environments, shaped political debates, and induced European integration within the crisis-affected area. This cause-and-effect situation has even led academics to refer to it as European integration through one crisis at a time.[37]

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[34] ECDC, *Strategic and performance analysis of ECDC response to the COVID-19 pandemic*, *op. cit.,* p. 20.

[35] See M. EVERSON, E. VOS, *EU Agencies and the Politicized Administration*, in J. POLLAK, P. SLOMINSKI (eds.), *The Role of EU Agencies in the Eurozone and Migration Crisis*, Cham, 2021; E. HEIMS, *Building EU Regulatory Capacity: The Work of Under-Resourced Agencies in the European Union*, Cham, 2019, Chapter 4; E. VOS, *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, in *Journal of Consumer Policy*, vol. 23, 2000, pp. 233-234.

[36] V. J. D'ERMAN, A. VERDUN, *Introduction: Integration Through Crises*, in *Review of European and Russian Affairs*, vol. 12, n. 1, 2018, pp. 3-4.

[37] H. DEGNER, *Public Attention, Governmental Bargaining, and Supranational Activism: Explaining European Integration in Response to Crises*, in *Journal of Common Market Studies*, vol. 57, n. 2, 2019, pp. 242-259.

This pattern, followed in the wake of the pandemic, has been seen across various EU policy fields, promoting agencification and European integration.[38] Today, greater integration within the pharmaceutical and infectious diseases sectors has been considered essential to address future transboundary health crises. Hence, the new mandates proposed for the EMA and the ECDC.

However, it has to be mentioned that relying on European agencies is shown to be complicated. Those bodies lack an institutional place within the treaties, a legal deficit that keeps affecting their existence and functioning. Indeed, European agencies exist and operate on the basis of their founding regulation but lack a legal basis within the treaties, which led to questioning their establishment and institutional place within the Union. For example, political science sees European Agencies as part of a direct administration, in which EU policies are implemented at the EU level.[39] Nevertheless, agencies may also be seen as in-betweeners, "beholden both to EU institutions and the Member States", assisting the EC while being part of networks of national counterparts.[40] Indeed, their hybrid structure, which sees representatives of the EU and the MS composing the steering body of

[38] The Bovine spongiform encephalopathy crisis of 1996, which sparked renewed calls for a clear-cut division between politics and science (E. VOS, *EU Food Safety* Regulation, cit., pp. 233-234), led to the establishment of the European Food Safety Authority, tasked with providing scientific advice on food safety (K. VINCENT, *'Mad Cows' and Eurocrats—Community Responses to the BSE Crisis*, in *European Law Journal*, vol. 10, n. 5, 2004, pp. 499-517). In 1999, the Erika disaster led to the establishment of a common maritime security structure, hence the European Maritime Safety Agency (E. HEIMS, *Building EU Regulatory Capacity: The Work of Under-Resourced Agencies in the European Union*, Cham, Palgrave Macmillan, 2019, pp. 85-86). Moreover, the unfolding of the SARS-CoV-1 outbreak (2003) pushed the EU and European countries to address health threats from infectious diseases, establishing the ECDC (E. BROOKS, R. GEYERB, *op. cit.*, pp. 1057-1076). Furthermore, in the aftermath of the financial crisis of 2007 the European Supervisory Authorities (EBA, EIOPA, and ESMA) were established (M. EVERSON, E. VOS, *op. cit*., p. 23). In 2015, amid the migration crisis, FRONTEX saw an expansion of its competencies (V. MEISSNER, *The European Border and Coast Guard Agency Frontex After the Migration Crisis: Towards a 'Superagency'?*, in J. POLLAK, P. SLOMINSKI (eds.), *op. cit.*).

[39] M. EGENBERG, J. TRONDAL, *Researching European Union Agencies: What Have We Learnt (and Where Do We Go from Here)?*, in *Journal of Common Market Studies*, vol. 55, n. 4, 2017, pp. 681-684.

[40] M. EVERSON, E. VOS, *op. cit.*, p. 27. See also M. EVERSON, C. MONDA, E. VOS (eds.), *op. cit.*

European Agencies, further validates the viewpoint of Agencies as in-betweeners.[41]

Moreover, lacking a place within the treaties has also affected European Agencies' capacity to operate within the EU. Their action, in fact, had been circumscribed by the *Meroni* ruling, in which the European Court of Justice (ECJ) adopted a restrictive approach to the delegation of powers to European Agencies, allowing only clearly defined executive powers and excluding all cases in which discretionary powers were involved.[42] According to the ECJ, conferring delegated powers to bodies not foreseen by the Treaty of Rome would have undermined the balance of powers between EU institutions.

Furthermore, when it comes to European health agencies, such as the EMA, further issues come into play. Their operations must abide by the competence allocation set by the treaties. A situation that raises more questions considering that EMA has acquired *de facto* decision-making powers. Also, as an in-betweener, the Agency may serve both the EU and the Member States; therefore, unclarities remain regarding whom EMA's accountability lies when implementing EU health law. In pursuing its competencies, questions arise on whom the EMA is or should be accountable.

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[41] *Ibidem*, p. 24.

[42] According to the Court, a delegation of discretionary powers would have produced an actual transfer of locus responsibility from EU institutions to European agencies, and thus incompatible with the principle of conferral and the Treaty (judgment of the Court of 13 June 1958, case C-9/56, *Meroni & Co., Industrie Metallurgiche SpA v High Authority of the European Coal and Steel Community*). On the topic see M. CHAMON, *EU Agencies: between Meroni and Romano or the devil and the deep blue sea*, in *Common Market Law Review*, vol. 48, n. 4, 2011, pp. 1055–1075. The *Meroni doctrine* has been "updated" via the *ESMA-short selling case* (Judgment of the Court of 22 January 2014, case C-270/12, United Kingdom of Great Britain and Northern Ireland v European Parliament and Council of the European Union, para 83 ff.). The ruling acknowledges the possibility of EU institutions delegating powers to European Agencies, in accordance with *Meroni*, as long as the conferral of powers does not involve discretionary powers and control systems are in place to check the delegation. See E. VOS, *EU agencies on the move: challenges ahead*, in *Swedish Institute for European Policy Studies*, vol. 1, 2018, pp. 27-33; G. LO SCHIAVO, *Judicial Re-Thinking on the Delegation of Powers to European Agencies under EU Law? Comment on Case C-270/12 UK v. Council*, in *German Law Journal*, vol. 16, n. 2, 2015, pp. 315-336; M. SCHOLTEN, M. VAN RIJSBERGEN, *'Parliament' and The ESMA-Short Selling Case Erecting a New Delegation Doctrine in the EU upon the Meroni-Romano Remnants'*, in *Legal Issues of Economic Integration*, vol. 41, n. 4, 2014, pp. 389-406.

3. The EMA's extended mandate addresses, first and foremost, the need for a coordinated Union approach in crisis management while aiming at preventing shortages of medicinal products and medical devices during a public health emergency.[43] Indeed, mismatched supply and demand could trigger trade restrictions among the Member States and impact the functioning of the internal market, therefore escalating the consequences for public health. To prevent those outcomes, regulation (EU) 2022/123 awards a more decisive role to the EMA in managing public health crises and aims to formalize the *ad-hoc* mechanisms put in place during the COVID-19 pandemic.[44] As such, the EMA will establish within its structure the Executive Steering Group on Shortages and Safety of Medicinal Products (the *Medicine Shortages Steering Group* – MSSG)[45] and the Executive Steering Group on Shortages of Medical Devices (the *Medical Device Shortages Steering Group* – MDSSG).[46] These internal bodies will monitor and mitigate shortages of medicinal products and medical devices. These new competencies are quite a step forward, given that before, the Agency had only been tasked with monitoring the safety of medicines.

Moreover, to enhance EMA's surveillance, the Agency will develop an information technology platform, the European shortages monitoring platform (ESMP), to monitor and report on shortages

[43] Regulation (EU) 2022/123, Art. 1 l. (a) (b).

[44] For example, the EMA's new structure will broaden the scope of the COVID-19 EMA pandemic Task Force (COVID-ETF). Instead of being limited to coordinating regulatory action on the development, authorization, and safety monitoring of COVID-19 treatments and vaccines, the Agency will monitor and mitigate all medicinal products. It will also set up an Emergency Task Force to develop medical countermeasures to diseases that pose a threat to public health, shifting away from its current core on the COVID-19 pandemic (for more on COVID-ETF see EUROPEAN MEDICINE AGENCY, *EMA's governance during COVID-19 pandemic*, www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/emas-governance-during-covid-19)

[45] Regulation (EU) 2022/123, Articles 3-14.

[46] *Ibidem*, Articles 21-30. The MDSSG in monitoring the supply and demand for medical devices will cooperate with the Medical Devices Coordination Group (regulation (EU) 2017/745, Art. 103), and the HSC or any other relevant advisory committee (Art. 23 (1). Also, in respect to the MDSSG, the EMA will set up the secretariat for the "expert panels" on medical devices (as designated by regulation (EU) 2017/745, Art. 106 (1), entitled to present their scientific opinions, views, and advice on the matter (Art. 30).

attaining critical medicinal products.[47] By 2025, the platform should be the only portal for collecting data and information from companies and the Member States on critical medicines shortages, supply, and demand.[48]

Lastly, to develop medical countermeasures capable of addressing the dangers postured to public health at an early stage and in a harmonized way, the new regulation assigns the Agency the task of facilitating the research and development of medicinal products which have the potential to treat, prevent or diagnose diseases that cause public health emergencies, in line with the objectives of the EHU. To ensure those results, and therefore high-quality, safe, and productive medicinal products, within EMA's structure will be expressly set up an Emergency Task Force (ETF) capable of providing advice on such medicinal products.[49] Thereby, Agency's competencies moved from evaluating the safety of medicines to offering advice on medicines and coordinating studies to monitor vaccine effectiveness and safety.

Before moving on, it should be clarified that the MSSG and the MDSSG have been established following the same blueprint. As such, besides the different subjects of monitorization and mitigation, what will be said on MSSG's composition and tasks, can be mainly considered valid, *mutatis mutandis*, to the MDSSG.

3.1. Increased demand for medicinal products, exacerbated by the COVID-19 pandemic, has led to further shortages, undermining healthcare systems. Aiming to address these issues amid a crisis, the MSSG has been set up to monitor and mitigate shortages of critical medicinal products and manage major events.

To be prepared for a health emergency and therefore be capable of tackling shortages and safety of medicinal products, EMA will, in collaboration with the Member States, monitor any event that is likely to lead to a public health emergency or major event. If required by the circumstances, the EMA has to cooperate with the ECDC and other relevant European Agencies.[50]

[47] Regulation (EU) 2022/123, Art. 1 l. (c), Art. 13.
[48] *Ibidem*, Art. 13 (5) l. (h).
[49] *Ibidem,* Art. 1 l. (d), Articles 15-20.
[50] *Ibidem*, Art. 4 (1).

Whenever the EMA considers that "an actual or imminent major event needs to be addressed", it will raise the issue with the MSSG,[51] which will closely follow shortages and safety concerns of medicinal products.[52] In carrying out these tasks, the internal body will establish a list of main critical medicinal products highly need it in a public health emergency or major event (updated annually or whenever required).[53] The list will be adapted to each critical situation affecting the EU.[54] Moreover, the work of the MSSG will be assisted by the ESMP. Also, if needed, the Agency is entitled to request at Member States information concerning medicinal products not yet available on the ESMP.[55] European countries will have to comply with the demands of the EMA by the deadline set out by the Agency itself.[56] Similar powers can be carried out with respect to marketing authorisation holders.[57]

In the event of a positive evaluation from the MSSG, the EC may recognise the existence of a major event or a public health emergency.[58] If the Commission recognises one of these situations, the MSSG must evaluate the need for "urgent and coordinated action with regard to the quality, safety, and efficacy of the medicinal products concerned".[59] Moreover, it will issue recommendations to the EC and the Member States on any response it considers helpful, which should be taken at the European level on the medicinal products under scrutiny.[60] Consequently, the Agency will publish on its web portal the information concerning the shortages affecting critical medicinal products needed to address the crisis.[61]

3.1.1. As indicated above, the MSSG will be an organ of EMA. It will be composed of one representative from the Agency, one from the

[51] *Ibidem*, Art. 4 (3).
[52] *Ibidem*, Art. 4 (1).
[53] *Ibidem*, Art. 6 (1).
[54] *Ibidem*, Art. 6 (2).
[55] *Ibidem,* Art. 11.
[56] *Ibidem,* Art. 11.
[57] *Ibidem,* Art. 10.
[58] *Ibidem*, Art. 4 (3).
[59] *Ibidem*, Art. 5 (1).
[60] *Ibidem*, Art. 5 (2).
[61] *Ibidem*, Art. 6 (6).

EC, and one from each Member State.[62] The MSSG will meet regularly, whenever required by the circumstances, and when the EMA has raised an issue of concern with the MSSG or when the Commission has recognised a major event in accordance with Article 4(3).[63] The working of the MSSG, moreover, will be supported by national competent authorities representatives for medicinal products, who will be the single point of contact (SPOC) between the national and European levels in relation to shortages of medicinal products.[64]

Interestingly, the MSSG and the MDSSG have been established as coordination bodies between the EC, the Member States, and the EMA. Nonetheless, they have been placed under the administration of the EMA, something that has never happened before. For example, a similar coordination body – the Coordination Group for Mutual Recognition and Decentralized Procedures – has been established outside the EMA's structure.[65] Moreover, the EMA has been granted the ability to put forward its representative within these internal bodies. This is a novelty when compared with previous experiences. For example, neither the Committees nor the working groups have one representative of the EMA.[66] At best, in one of those committees, the

[62] *Ibidem*, Art. 3 (2).
[63] Regulation (EU) 2022/123*,* Art. 3 (1).
[64] *Ibidem,* Art. 3 (6).
[65] European Medicine Agency, Coordination Group for Mutual Recognition and Decentralised Procedures-Human (CMDh), www.ema.europa.eu/en/committees/working-parties-other-groups/coordination-group-mutual-recognition-decentralised-procedures-human-cmdh.
[66] The Pharmacovigilance Risk Assessment Committee (PRAC) has one representative from each MS plus one from EEA-EFTA countries, and eight from the EC (Pharmacovigilance Risk Assessment Committee, EMA/PRAC/567515/2012 rev. 3 of 11 October 2021). The members of the Committee for Orphan Medicinal Products are nominated by MS, EEA-EFTA countries, and the EC (Committee for Orphan Medicinal Products (COMP), EMA/COMP/8212/00 rev. 6 of 11 October 2021). In some cases, besides the members nominated by the MSs and EEA-EFTA countries, the Committee itself may appoint five experts drawn up by a list of candidates redacted by the MSs or the Agency. This is the case with the Committee for Medicinal Products for Human Use (Committee for Medicinal Products for Human Use, EMA/366005/2021 of 11 October 2021), the Committee for Medicinal Products for Veterinary Use (Committee for Veterinary Medicinal Products, EMA/CVMP/422/04 - rev 4 of 07 January 2022), and the Committee on Herbal Medicinal Products (HMPC Rules of procedure, EMA/HMPC/139800/2004 rev. 5 of 11 October 2021). Meanwhile, the Committee for Advanced Therapies (Committee for Advanced Therapies (CAT), EMA/CAT/454446/2008 rev. 4 of 11 October 2021)

EC could choose some members based on a recommendation from the EMA (this is the case of the Committee for Orphan Medicinal Products). As such, their odd construction puts them apart from similar entities. This peculiarity raises further questions about who will be the representative. And what does it mean to have a representative of the Agency within those bodies? Indeed, by having a steering body composed of a representative of the EMA and the Member States, the MSSG and the MDSSG appear to replicate the hybrid organizational structure that characterized European agencies, further sustaining the viewpoint of European Agencies as in-betweeners.

What this development means in practice remains to be seen. It shows the stature EMA has acquired through time and the greater relevance that has been given to health in the aftermath of the COVID-19 pandemic.

3.1.2. The SPOC network was established as a pilot program in 2019.[67] Set up within the framework of the HMA/EMA Task Force on the availability of authorized medicines for human and veterinary use

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and the Paediatric Committee (Rules of procedure of the Paediatric Committee (PDCO), EMA/348440/2008 rev. 3 of 11 October 2021) have members are appointed by the Committee for Medicinal Products for Human Use, the MS, and the EC. Both the Coordination Group for Mutual Recognition and Decentralised Procedures Human and the Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products do not have one (EUROPEAN MEDICINE AGENCY, *Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)*, www.ema.europa.eu/en/committees/working-parties-other-groups/coordination-group-mutual-recognition-decentralised-procedures-human-cmdh; European Medicine Agency, *Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products (CMDv)*, www.ema.europa.eu/en/committees/working-parties-other-groups/coordination-group-mutual-recognition-decentralised-procedures-veterinary-medicinal-products-cmdv. The same can be said for Patients' and Consumers' Working Party (PCWP) (Mandate, objectives and composition of the Patients and Consumers Working Party (PCWP), EMA/563123/2018 rev. 4 of 10 May 2019, p. 3), the Healthcare Professionals' Working Party (HCPWP) (Mandate, objectives and composition of the Healthcare Professionals Working Party (HCPWP), EMA/109592/2018, rev. 2 of 10 May 2019, p. 3), and the Scientific Advice Working Party (Mandate, objectives and rules of procedure of the Scientific Advice Working Party (SAWP), EMEA/CHMP/SAWP/69686/04 rev. 16 of 12 November 2021, p. 7).

[67] European Medicine Agency, *Availability of medicines*, www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines#eu-level-coordination-on-medicines-availability-section.

(TF AAM),[68] the network aims at improving information sharing between Member States, EMA, and the EC on shortages of medicinal products for human and veterinary use, as well as at coordinating actions on preventing and managing foreseeable shortages.[69]

Therefore, the EMA's extended mandate has updated the SPOC network, which will now support the MSSG within and outside crisis situations. Those modifications, however, seem to have changed the relationship between the EMA and the HMA. In the pre-reform period, the SPOC worked under the umbrella of a cooperation framework, the HMA/EMA TF AAM. Both Member States and the EU, as such, oversaw the network and shared political accountability over it.

Today, due to the changed mandate, the SPOC network seems to be *de facto* shifting under the sole umbrella of the EMA. As framed in Regulation (EU) 2022/123, the SPOC network is tasked to support the MSSG in its operations. In this situation, possible diminished Member States' accountability is troublesome due to the competence at issue, that is, health-related matters. Despite boundaries in the Treaties limiting the EU's involvement, those have not stopped the Union's intervention in health. The same can be said for the EMA, which has even *de facto* acquired "risk management responsabilities".[70] European health agencies have been operating within an undefined matter: EU health law.[71] Which, until lately, saw questioned its mere existence.[72] As such, it has been difficult to grasp to what extent the EMA has acted

[68] EMA and the Heads of Medicines Agencies (HMA) established an HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use in December 2016 to "provide strategic support, advice for coordination and concerted approach to the Network on the availability of the medicinal products authorised in the EU" (HEADS OF MEDICINE AGENCIES, *HMA/EMA Task Force on Availability of Authorised Medicines for Human and Veterinary use (TF AAM),* www.hma.eu/about-hma/working-groups/hma/ema-joint-task-force-on-availability-of-authorised-medicines-for-human-and-veterinary-use-tf-aam.html.

[69] European Medicine Agency, *Availability of medicines*, *op. cit.*

[70] M. BUSUIOC, *op. cit.* p. 216.

[71] T. K. HERVEY, J. V. MCHALE, *European Union Health Law*, Cambridge, Cambridge University Press, 2015, pp. 10-29.

[72] The existence of EU health law as a separate discipline has been questioned many times. For some, in particular, these social policies were subservient to the EU internal market law, thus strictly dependent on it (F. W. SCHARPF, *Economic integration, democracy and the welfare state*, in *Journal of European Public Policy,* vol. 4, n. 1, 1997, pp. 18-36).

within or without the EU-Member States competence allocation. Or whether it acted in respect or defiance of the *Meroni* doctrine.

The question of respect for these boundaries appears to re-propose itself in the context of EMA's extended mandate. Indeed, about the competence allocation, we see that at the centre of a monitoring network, under the EMA, there is a steering group (the MSSG) around which seems to gravitate those SPOCs, that in turn, appear to be less entrenched with the Member States. And while greater involvement at European and national levels falls perfectly in line with the viewpoint of European Agencies as in-betweeners, which furthers the hybrid character of agencies as part of the composite EU executive, this should not come at the expense of proper accountability systems. As long as there is no competence reallocation on health-related matters, Member States' political accountability might be required or preserved. Meanwhile, concerning the delegation of powers, the MSSG (and the MDSSG) can issue recommendations that appear to go beyond risk analysis that move into risk management, which implies a certain degree of discretionary powers and thus blurs away the division between science and politics.[73] However, this issue calls for further research into European agencies in light of the changes the ESMA short-selling case brought.

3.1.3. The EMA, by design, has risk analysis functions, while it does not have decision-making power. It issues recommendations to the EC on pharmaceutical matters, based on which the Commission takes its decisions (binding on third parties). However, the EC's practice of *rubber-stamping* the Agency's opinion within its decisions has, *de facto,* endowed the Agency with risk management functions.[74] Therefore, it has vested EMA's recommendation with the ability to be binding on third parties and implicitly induced the EC to restrain from overseeing EMA's work.[75]

In *Artegodan v Commission*, the ECJ has found a way to examine EMA's recommendations whenever these have been passively received

[73] See section 3.1.3.
[74] M. BUSUIOC, *op. cit.* pp. 202-220.
[75] *Ibidem.*

by the EC and produced effects on third parties.[76] The Court, indeed, has refrained from second-guessing scientific opinions, but it started evaluating the reasoning process of the scientific committee.[77] Nonetheless, it has acknowledged its limits, not having the capabilities to fully assess EMA's opinions, which the EC should have overseen.

Similar accountability issues appear to present themselves in the context of the extended mandate, precisely when looking at the MSSG's task of reporting on shortages of medicinal products.[78] Indeed, if those entitled to oversee MSSG's activities refrain from doing so, non-binding acts may go unchecked.

By Article 8, as long as a public health emergency, or a major event as referred to in Article 4(3), keeps on going, the MSSG has to regularly report the results of the monitoring to the Commission and the single points of contact. It should also signal any actual or potential shortages of medicinal products. Moreover, whenever requested by the EC or one or more SPOC, the MSSG should provide further data and forecasts backing its findings and conclusions.[79] This arrangement could raise the question of lack of accountability in the event of misleading or fallacious reports on which those entitled to request further information do not ask them. And, on these reports, the MSSG produces its recommendations.

For example, according to Art. 8(3), the MSSG should provide recommendations on measures "to prevent or mitigate actual or potential shortages of medicinal products".[80] Those are based on the reports mentioned above. As such, because the MSSG appear not

[76] Judgment of the Court of 26 November 2002, joined cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00, T-141/00, *Artegodan GmbH and Others v Commission*.
[77] M. BUSUIOC, *op. cit.* pp. 213-220.
[78] Regulation (EU) 2022/123, Art. 8.
[79] *Ibidem,* Art. 8 (2). It is worth noting that the raw data can be made accessible to other actors within the supply chain for medicinal products. However, to be that the case, the availability needs to be appropriate, in accordance with competition law, and aim to prevent or mitigate shortages of medicinal products.
[80] It should also provide recommendations on measures "to ensure preparedness for dealing with actual or potential shortages of medicinal products caused by public health emergencies or major events" (Art. 8, para 4); "to prevent or mitigate actual or potential shortages of medicinal products in the context of a public health emergency or major event" (Art. 8, para 5).

required to publish the data backing their conclusions, and the data is available only for those entitled to ask for it, recommendations could be proposed by the MSSG without any oversight. This could mean that the MSSG could be (accidentally) overcounting or undercounting the shortages of a certain medicinal product (in the case of the MDSSG of a specific medical device). The MSSG would consequently publish its recommendation highlighting which measures the Commission, Member States, marketing authorization holders, and other entities should take to address the shortages of a particular product.[81] It has, therefore, the potential to influence the position of a product within the EU market. Indeed, oversimplifying it, if a medicinal product is deemed critical to the ongoing health crisis and its stock is considered insufficient, a recommendation on the need to replenish it, based on fallacious or misleading reports, would boost the sale of it across the Member States, with positive gains for those undertakings able to supply it, and ripple effects across the market.

Also, it should be noted that the MSSG could issue these recommendations on its initiative or at the request of the EC or the Member States.[82] Moreover, when requested by the Commission, the MSSG may also coordinate measures taken by NCAs and further stakeholders in a push to address actual or potential shortages.[83] Therefore, the MSSG may coordinate third-party measures to prevent or mitigate the needs of medicinal products based on its recommendations, which might have escaped any oversight.

Article 14 does not seem to address this lack of oversight. Indeed, according to the latter, the Agency should provide information regarding the work of the MSSG. However, it does not specify what needs to be made available. Moreover, according to Art. 14(2), recommendations referred to in Article 8(3)(4) should be documented and made available to the public. Nonetheless, this does not refer to the data or the forecast backing these provisions. Furthermore, while the EMA has adopted an overall transparency policy on its working, enabling third parties to access its documents, clinical trials, minutes of

[81] Especially the EC, according to Art. 12 (1), should move in accordance with information from and recommendations of the MSSG.
[82] Regulation (EU) 2022/123, Art. 8 (4).
[83] *Ibidem*, Art. 8 (5).

meetings and workshops,[84] this remedy shows itself as an *ex post* control, not avoiding the issuing of the recommendation, which could have a direct effect on the internal market.

The issue under scrutiny appears to be less problematic in the case of the MDSSG. According to Art. 24(2), those entitled to request data and forecasts of the MDSSG's reports are the EC, the Member States, and the SPOC, which, in this case, are "manufacturers of medical devices, or their authorised representatives, importers and notified bodies, for the medical devices included on the public health emergency critical devices list".[85] Therefore, the plethora of those entitled to hold accountable the EMA is more comprehensive, spanning from institutional figures to undertakings in the supply chain. The risk of unchecked reports still exists, but the probability of that happening should be lower. Those differences in the SPOC network could be traced back to the primary competence the EMA had until now: pharmacovigilance. Indeed, having only recently acquired – via Regulation (EU) 2022/123 – a mandate considering medical devices, this development seems to transpire in the role assigned to undertakings in the SPOC network.

The new mandate has just come into effect. As such, it has to be seen the extent to which these reports will be scrutinized by those entitled to, or how dutifully they will be followed by stakeholders, such as marketing authorization holders and representatives of healthcare professionals and patients. However, it has to be reported that the Commission has already shown a poor track record in overseeing EMA' opinions. A behaviour that enabled the EMA, formally without the capability of issuing binding acts, to *de facto* acquire decision-making power and therefore be able to have a legal effect on third parties.

3.2. In a push to increase EMA's surveillance of medicinal products, as already stated, the Agency has been tasked to establish the European Shortages Monitoring Platform. The latter will be used to "facilitate the collection of information on shortages of, supply of, and demand for

[84] European Medicines Agency policy on access to documents, EMA/729522/2016, 04 November 2018.
[85] Regulation (EU) 2022/123, Art. 25 (2), l. (a).

medicinal products".[86] By 2025, the ESMP should become the sole portal for the collected data. Nevertheless, part of the HERA's mission seems to overlap with the ESMP.

Indeed, according to Art. 2(2) l. (a) of Commission Decision C(2021) 6712:

> "2. HERA shall be responsible for the following tasks:
> (a) assessment of health threats and intelligence gathering relevant to medical countermeasures […]".

Decision C(2021) 6712 does not set out a definition for what "medical countermeasures" comprise, and the Proposal for a Council Regulation 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 is still in the making.[87] However, the definition commonly assigned to "medical countermeasures" easily comprises medicinal products. Therefore, the overlapping of EMA's and HERA's competencies raises a few questions: by operating within a niche sector, should the ESMP have been conducted to the broader mandate of the HERA? Especially given the fact that the latter has been specifically set up to improve Member States' preparedness and response to serious cross-border health threats, and in which a shortages monitoring platform sounds appropriate.

Also, the HERA board should deliver opinions on particular issues, such as:

> "(i) threat assessment, modeling, and forecasts of medical countermeasures;
> (ii) monitoring the supply and demand of medical countermeasures;

[86] *Ibidem*, Art. 13 (1).
[87] Proposal for a Council Regulation 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) 577final of 16 September 2021.

> (iii) procuring and deploying medical countermeasures […]"[88].

Therefore, given that the MSSG will issue its recommendations on possible shortages of medicinal products, what happens if a contradiction arises between these opinions? It must be mentioned that both ECDC's and EMA's representatives may participate at HERA's board meetings, however, only as observers, as the board will be composed exclusively of Member States representatives.[89]

This issue, moreover, opens up further questions regarding the division between science and politics. Indeed, European Agencies – such as the EMA – have been set up to have reliable and independent opinions on scientific matters. This meant excluding the political factor from the equation. However, by endowing these tasks to HERA, which is part of the Commission as Director-General, the separation between science and politics seems to blur away. In other words, it could be asked if, by awarding these wide-ranging competencies to HERA, the EC has been circumscribing the division between science and politics, thereby centralising competencies otherwise assigned to an independent body (such as EMA). Another point of view may see an *escamotage* by the EC to indirectly exert some form of control on EMA's operations regarding this specific task.

3.3. Besides monitoring and mitigating shortages and safety of medicinal products as well as medical devices, the extended mandate assigns a new task to the EMA, which is the task of facilitating the research and development of medicinal products. The Agency will establish the Emergency Task Force (ETF) to manage it.[90]

The ETF will be composed of stakeholders of the EMA and national competent authorities for medicinal products. In particular, the former will be represented by individuals from scientific committees and

[88] Commission Decision, of 16 September 2021, establishing the Health Emergency Preparedness and Response Authority, C (2021) 6712 of 16 February 2021, Art. 6 (5).
[89] *Ibidem*, Art. 6 (1) (3).
[90] Regulation (EU) 2022/123, Art. 15.

working parties (such as the PCWP and HCPWP)[91] of the Agency. Further members will be brought in by the coordination group established per Article 27 of Directive 2001/83/EC, and by the Clinical Trials Coordination and Advisory Group established following Article 85 of Regulation (E) no. 536/2014. External experts could be appointed to the ETF depending on the circumstances.[92] The ETF will be chaired by a representative of the Agency and co-chaired by the Committee for Medicinal Products for Human Use (CHPM) chair. [93]

During a public health emergency, the ETF will – in connection with the scientific committees, working parties, and scientific advisory groups of the Agency – provide scientific advice and review "the available scientific data on medicinal products that have the potential to address the health crisis".[94] These reviews will be constantly updated throughout the health crisis.[95] Moreover, in the pursuit of these reviews, as in the case of the MSSG and the MDSSG, the ETF has been empowered to request additional information and data from marketing authorization holders.[96] Based on the information at hand, the EFT, whenever asked by one or more Member States, or the EC, will provide recommendations to the CHPM on the use of medicinal products and the use and distribution of an unauthorized medicinal product. On these recommendations, the CHPM will adopt its opinion on the conditions to be imposed on the medicinal product concerned.[97]

[91] The Patients and Consumers Working Party (PCWP) "provides recommendations to the EMA and its Human Scientific Committees on matters of direct or indirect interest to patients in relation to medicines for human use and monitor the overall interactions between EMA and patients and consumers" (Mandate, objectives and composition of the Patients and Consumers Working Party (PCWP), *op. cit.*, p. 1). Meanwhile, the Healthcare Professionals Working Party (HCPWP) "provides recommendations to EMA and its Human Scientific Committees on matters of direct or indirect interest to healthcare professionals in relation to medicines for human use and monitor the overall interactions between EMA and healthcare professionals" (Mandate, objectives and composition of the Healthcare Professionals Working Party (HCPWP), *op. cit.*, p. 1).
[92] Regulation (EU) 2022/123, Art. 15 (3).
[93] *Ivi*.
[94] *Ibidem*, Art. 15 (2).
[95] *Ibidem*, Art. 18.
[96] *Ibidem*, Art. 18 (1) (2).
[97] *Ibidem*, Art. 18 (3) (4).

Furthermore, the ETF will hand over advice on clinical trials for medicinal products with the capacity to treat, prevent or diagnose the disease causing the health crisis.[98] In particular, the ETF should advice developers' clinical trial applications who have engaged in an accelerated scientific advice process.[99] Given the relevance to the ongoing public health emergency, whenever one of those successfully receives a marketing authorisation, the Agency must publish clinical data supporting the application.[100]

Lastly, concerning the ETF, special attention has to be reserved for Article 20, Regulation (EU) 2022/123. The Article calls for the setting up of an IT platform to support the work of the ETF during a public health emergency. The system should be helpful in the collection of "information and health data generated outside of clinical studies, that facilitate interoperability with other existing IT tools and with IT tools under development, and provide adequate support to national competent authorities".[101] The IT platform should be able to "coordinate monitoring studies on the use, effectiveness, and safety of medicinal products intended to treat, prevent or diagnose diseases related to a public health emergency".[102] Moreover, it should facilitate data sharing across public stakeholders, such as Member States and Union bodies. Those aims quite resemble the Data Analysis and Real World Interrogation Network (DARWIN EU), set up within the context of the HMA - EMA Joint Big Data task force.[103] Indeed, DARWIN EU aims at setting up a "coordination centre to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the European Union".[104] The system should allow EMA and NCAs to access and use the data whenever needed.

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[98] *Ibidem*, Art. 15 (2).
[99] *Ibidem*, Art. 16.
[100] *Ibidem*, Art. 17.
[101] *Ibidem*, Art. 20.
[102] *Ibidem*.
[103] HMA-EMA Joint Big Data Taskforce - Phase II report: "Evolving Data-Driven Regulation", EMA/584203/2019, 20 January 2020, pp. 27-29.
[104] European Medicine Agency, *Data Analysis and Real World Interrogation Network (DARWIN EU)*, www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-real-world-interrogation-network-darwin-eu.

As in the case of the ESMP and HERA's mission, both IT platforms appear to overlap. The ETF IT platform works within the stricter boundaries of medicinal products used within the ongoing public health emergency. Meanwhile, DARWIN EU lays down the foundations of an EU system on health data, which could be comprised of the niche sector of the ETF IT platform. Even though Art. 20 explicitly assess the need for the ETF IT platform to be interoperable with existing IT tools or those under development; this specification could have been avoided by reconducting under one system multiple IT platforms. In a push to quickly set up parts of the EHU, it appears efficiency and economics have lost out against the desire to capitalize on the political will of greater integration on health matters.

4. Like those that preceded it, the current health crisis has been a driver of European integration. The dimension of it, and the impact it had and still has on the Member States, pushed the Union to enhance its involvement in health significantly. Therefore, wishing to assess part of the EHU put forward in the wake of the pandemic, the present study was designed to determine the changes introduced by Regulation (EU) 2022/123 and what can be deduced from the new tasks assigned to the European Medicine Agency.

The paper has shown that by placing under the EMA's administration the MSSG and the MDSSG, this odd construction appears to further validate EMA as *primus inter pares*. Their composition, which sees representatives from all parties involved in the monitorization and mitigation of shortages, seems to enhance the EMA's role within the EU's shared administration. Meanwhile, looking at European agencies as in-betweeners, the paper has shown that the hybrid structure that characterized Agencies' management boards seems to be replicated elsewhere, namely in the MSSG and the MDSSG, which raises further questions on Agencies' institutional place within the EU structure, and which role should Member States have when it comes to bodies operating within health matters.

It was also shown that the practice of *copy-pasting* EMA's opinion by the European Commission, and therefore the abdication of overseeing EMA's opinions if replied within the context of the MSSG, appears to re-propose accountability issues regarding EMA's *de facto*

decision-making power. The same problems seem to be drawing less attention in the case of the MDSSG, given the broader spectrum of parties able to oversee its work.

Lastly, the paper has found possible overlapping situations between the ESMP system and HERA's tasks and between EMA's latest IT systems, the EFT IT platform, and DARWIN EU (established in coordination with HMA). These situations could raise questions about a possible conflict between systems and the soundness of their establishment.

In general, the evidence from this paper highlights what greater EU involvement could hold in the future. Entrusting the EMA with more significant competencies in monitoring and mitigating shortages of medicinal products and medical devices and a new task in clinical trials appears to strengthen and rationalize European crisis management capabilities. The extended mandate gives the Agency – in collaboration with the Member States – the ability to monitor any event that may lead to a public emergency. However, it does not address shortages of medicines and medical devices as structural ones, which the pandemic has strained. Indeed, the system has been envisioned as an ongoing crisis scheme that will not run daily. As such, it will not enable the EMA to practically address shortages linked to non-crisis situations. This choice could be considered a consequence of the competence allocation on health and the desire of Member States to keep their prerogatives on health-related matters outside health crises.

The current findings add to a growing body of literature on European Agencies, highlighting the ever-greater role that has been assigned to those entities, which still lack a formal institutional place within the EU framework.

Moreover, with regard to European involvement in health, the paper has shown that as we advance, given the complicated competence allocation on the matter, serious discussions should be held on the future development of European involvement in health and which role bestowed upon European Agencies. On this, Mario Draghi's speech at the European Parliament on 3 May 2022 should be recalled. The Italian Prime Minister has emphasized the need to rethink current European Institutions, which cannot serve today's European citizens. According to him, the EU should move towards a "pragmatic federalism that

embraces [...] all spheres hit by the transformations taking place".[105] On this, positive signals come from the European Parliament, which on the 9 June 2022 adopted a resolution asking EU leaders to establish a constitutional convention to reopen the EU treaties.[106]

In envisioning EU's future involvement in health, a role has been played by the Conference on the Future of Europe, which closed its workings on 9 May 2022. In regard to health, European citizens have been vocal about what they wish from the EU. According to the latest documents, four main proposals have come forward: establishing a new framework pushing for healthy food and a healthy lifestyle; a reinforced healthcare system; a broader understanding of health; and equal access to health for all.[107] How those proposals will be addressed by those entitled to, possible changes to the treaties might be unavoidable. This is especially true for healthcare, where any increased role of the EU beyond supporting, coordinating, or supplementing State policies could require a change in the Treaties.

[105] Italian Government-Presidency of the Council of Ministers, *Prime Minister Mario Draghi's address to the European Parliament*, 03 May 2022, www.governo.it/en/articolo/prime-minister-mario-draghi-s-address-european-parliament/19748.
[106] M. DE LA BAUME, *European Parliament presses EU leaders to convene treaty change convention*, 09 June 2022, www.politico.eu/article/meps-adopt-proposal-for-treaty-changeeuropean-convention.
[107] Conference on the Future of Europe, *Conference on the Future of Europe – Report of the final outcome*, 09 May 2022, pp. 49-52.