EU Health Union in a digital environment, between fight against fake medicines, shortage prevention, and data protection*

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Abstract:
Dopo la pandemia da Covid-19, l'EU ha dato avvio all'Unione Europea della Salute finalizzata a prevenire e rsipondere alle crisi sanitarie, assicurando disponibilità di dispositivi medici affidabili e innovativi e gestendo i dati sanitari. L'Unione Europea della Salute è strettamente interconnessa con lo sviluppo digitale, soprattutto per l'uso dell'intelligenza artificiale nell'offerta di servizi e prodotti

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sanitari, ma anche in riferimento alla digitalizzazione delle catene di approvvigionamento dei prodotti sanitari e alla raccolta, condivisione ed uso dei dati nello Spazio Europeo dei Dati Sanitari. I temi in parola sono significativamente influenzati dalla disciplina elaborata dalle Istituzioni dell'UE per i servizi digitali, in particolare il Digital Service Act (DSA) e l'AI Act (AIA). Assumendo le catene di approvvigionamento dei prodotti sanitari e la gestione dei dati come casi studio, il paper analizza l'impatto della digitalizzazione sull'Unione Europea della Salute alla luce della disciplina dei servizi digitali in termini di rischi e opportunità. Sotto il profilo dei rischi, il paper si focalizza sulla vendita on line dei farmaci fake (falsificati o contraffatti) e sul contributo del DSA all'identificazione e rimozione di tali prodotti. Il paper si focalizza, altresì, sui limiti riscontrati dai ricercatori nell'accesso ai dati sanitari sulle piattaforme on line e sugli obblighi imposti dall'art. 40 DSA. Per quanto riguarda le opportunità, il paper di focalizza sul potenziale uso dell'intelligenza artificiale nella gestione dell'approvvigionamento dei prodotti sanitari, per verificare il suo contributo in termini di efficienza e buon funzionamneto del sistema di prevenzione e gestione delle crisi creato dalla Commissione europea e dalle Agenzie. Il paper analizza, altresì, l'impatto dell'intelligenza artficiale sulla raccolta, condivisione e uso dei dati sanitari. Il paper giunge alla conclusione che solo una adeguata regolazione orientata alla prenzione e gestione del rischio e delle emergenze può realizzare il giusto bilanciamento tra pericoli e opportunità derivanti dalle nuove tecnologie nel settore sanitario. In questa prospettiva, la Commissione europea e le Agenzie sembrano il livello ottimale di standardizzazione per assicurare una digitalizzazione sicura ed efficace dello spazio digitale.

After the Covid-19 pandemic, the EU launched the European Health Union (EHU) aimed at preparing and responding to health crises, assuring availability of affordable and innovative medical supplies, and managing the health data. The EHU is strictly interconnected with the digital development, mainly as it concerns the Artificial Intelligence (AI) use in health service provision and medical good production, but also as it concerns the digitalization of medical product supply chains and of heath data collecting, sharing, and use in European Health Data Space. These issues are being significantly impacted by the discipline elaborated by the EU Institutions to regulate the sale of goods and services on the digital platforms, more specifically the by the Digital Service Act (DSA) [1]*and the Artificial Intelligence Act (AIA). Assuming the medical supply chains and data management as case-studies, the paper analyzes the digitalization impact on the EHU in the light of digital service rules in terms of risks and opportunities. As it concerns risks, fistly, the paper focuses on the phenomenon of the online sale of fake (falsified of counterfeit) medicines and on the contribution offered by DSA in the identification and remotion of such products. Secondly, the paper analyses the limits currently faced by the researchers to the access to the health data on online platforms and the obligations imposed by the Article 40 DSA. As it concerns opportunities, firstly, the paper analyzes the potential AI use in the supply management of medical goods, with specific attention to the joint procurement procedures and stockpile assessment and management, in order to verify its contribution in terms of effectiveness and well- functioning of the crisis preparedness, prevention, and management system created by the European Commissions and European agencies. Secondly, the paper analyzes the AI impact on the collecting, sharing, and use of health data. Paper arrives at the conclusion that only a proper regulation oriented to risk and crisis prevention and management could determine the right balance between threats and opportunities coming from new technologies in the health sector. In this perspective, the European Commission and EU Agencies' appears the "optimum standard-setting level" to improve an effective and sure health space digitalization.*

1. Introduction

After the Covid-19 pandemic, the EU launched the European Health Union (EHU) aimed at preparing and responding to health crises, assuring availability of affordable and innovative medical supplies, and managing the health data.
The EHU is strictly interconnected with the digital development, mainly as it concerns the Artificial Intelligence (AI) use in health service provision and medical good production. Nevertheless, there are other aspects in the relationship between EHU and digitalization that did not attract the legal doctrine interest until now, as the digitalization of medical product supply chains and of heath data collecting, sharing, and use in European Health Data Space. These issues are being significantly impacted by the discipline elaborated by the EU Institutions to regulate the sale of goods and services on the digital platforms, more specifically by the Digital Service Act (DSA)[2] and the Artificial Intelligence Act (AIA)[3].
Assuming the medical supply chains and data management as case-studies, the paper analyzes the digitalization impact on the EHU in the light of digital service rules in terms of risks and opportunities. As it concerns risks, fistly, the paper focuses on the phenomenon of the online sale of fake (falsified of counterfeit) medicines and on the contribution offered by DSA in the identification and remotion of such products. Secondly, the paper analyses the limits currently faced by the researchers in accessing health data on online platforms and the obligations imposed by the Article 40 DSA.
As it concerns opportunities, firstly, the paper analyzes the potential AI use in the supply management of medical goods, with specific attention to the joint procurement procedures and stockpile assessment and management, in order to verify its contribution in terms of effectiveness and well-functioning of the crisis preparedness, prevention, and management system created by the European Commissions and European agencies. Secondly, the paper analyzes the AI impact on the collecting, sharing, and use of health data.
Paper last end is to verify if the digital service discipline could increase the effectiveness of EHU, strengthening its ability to prevent, manage, and mitigate the future health emergencies.

2.1. DSA contribution to the European Health Union well-functioning: fight against fake medicines

Selling of falsified and counterfeit medicines is really frequent on the online platforms. Both the phenomena are disciplined by the EU regulation. Indeed, while the entry in-

[2] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act), OJ L 277, 27.10.2022, p. 1 ff.

[3] European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)).

to the legal supply chain of falsified medicinal products is prevented by the Directive 2011/62[4], that specifically treats the sale at a distance to the public[5], Council Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products[6] and its modifications and integrations[7] and Regulation 2017/1001 on the European Union trademark forbid intellectual property infringements also in medical sector[8].

With the Digital Service Act (DSA)[9], the EU equipped itself with a very important instrument imposing marketplaces to individuate and remove falsified and counterfeit drugs from their catalogues. DSA imposes to the online platforms duties of "content moderation", defined as "activities, whether automated or not, undertaken by providers of intermediary services, that are aimed, in particular, at detecting, identifying and addressing illegal content…, provided by recipients of the service, including measures taken that affect the availability, visibility, and accessibility of that illegal content…, such as demotion, demonetisation, disabling of access to, or removal thereof, or that affect the ability of the recipients of the service to provide that information, such as the termination or suspension of a recipient's account"[10]. An "illegal content" is "any information that, in itself or in relation to

[4] Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, *OJ* L 174, 1.7.2011, p. 74 ff., Article 1, §1, letter c): "Falsified medicinal product: Any medicinal product with a false representation of: (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or (c) its history, including the records and documents relating to the distribution channels used. This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights". So, falsified medicines are a portion of counterfeit medicines, that include also the medicines infringing EU patent and trademark discipline. According to the European Medical Agency, while falsified medicines are fake medicines that are designed to mimic real medicines, counterfeit medicines are medicines that do not comply with intellectual-property rights or that infringe trademark law https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/falsified-medicines-overview. As it concerns falsified medicines, see judgement of the European Court of Justice of 17 November 2022, Cause C-147/20, Novartis Pharma; 17 November 2022, Cause C-204/20, Bayer Intellectual Property GmbH v. Kohlpharma GmbH; 17 November 2022, C-224/20, Merck Sharp & Dohme BV v. Abacus Medicine A/S; As it concerns the medicine online sale, see judgement of the European Court of Justice of 1° October 2020, Cause C-649/18, A v. Daniel B e a.

[5] Article 1, § 20 establishes the conditions for sale of medical products at a distance to the public by means of information society services and incentivizes information campaigns aimed at the general public on the dangers of falsified medicinal products. See also Commission Implementing Regulation (EU) No 699/2014 of 24 June 2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity, *OJ* L 184, 25.6.2014, p. 5 ff.

[6] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version), *OJ* L 152, 16.6.2009, p. 1 ff.

[7] Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, *OJ* L 153, 11.6.2019, p. 1 ff.

[8] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (codification), *OJ* L 154, 16.6.2017, p. 1ff.

[9] Regulation (EU) 2022/2065, cit.

[10] Article 3, letter t). In general, on online platform duties under the DSA, see M.-E. Ancel, *Brefs propos introductifs – Le Digital Services Act dans le paysage normatif européen*, in *Revue des Affaires Européennes* 3, 2023, pp. 611 ff.; G. Caggiano, *La proposta di Digital Service Act per la regolazione dei servizi e delle piattaforme online nel diritto dell'Unione*

an activity, including the sale of products or the provision of services, is not in compliance with Union law or the law of any Member State (MS) which is in compliance with Union law, irrespective of the precise subject matter or nature of that law"[11]. Online marketplaces are also requested to trace their traders ("know your business customer")[12] and to organize their online interfaces in a way that allows traders to comply with their information obligations towards consumers[13]. They have also to assure that notices submitted by trusted flaggers, entities which have demonstrated particular expertise and competence, are given priority and are processed and decided upon without undue delay[14].

Being illegal goods, falsified or counterfeit (fake) medicines sold by online platforms could be considered as "illegal contents" justifying the adoption of the measures of moderation and removal indicated above and the application of notice and action measures established in the DSA, article 16 ff[15]. To the "very large online platforms" (VLOPs)[16] the DSA imposes further obligations to elaborate methods of risk identification, analysis, assessment, and mitigation[17].

European Commission adopted the first list of very large online platforms on 25 April 2023 including several marketplaces, as Alibaba Express and Amazon[18]. According to the articles 15 and 42 DSA, these platforms had to produce, by 6 November 2023, a transparency

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europea, in G. Caggiano, G. Contaldi, P. Manzini (a cura di), *Verso una legislazione europea su mercati e servizi digitali*, Bari, 2021, pp. 3 ff.; G. Morgese, *Moderazione e rimozione dei contenuti illegali online nel diritto dell'UE*, in *Federalismi*, 12 gennaio 2022, pp. 80 ff.; M. Rubechi, Nouveautés et défis du Digital Services Act dans l'espace juridique européen, in Revue des Affaires Européennes 3, 2023, pp. 683 ff.; G. M. Ruotolo, *La disciplina europea della responsabilità dei fornitori di servizi online tra regime pregresso, proposte di riforma e un rischio d*i bis in idem, G. Caggiano, G. Contaldi, P. Manzini (a cura di), *Verso una legislazione europea*, cit., pp. 59 ff.; M.I. Torres Cazorla, *Ensuring a Safe and Accountable Online Environment. The need for the Digital Services Act and its Historical Basis*, in *Revue des Affaires Européennes* 3, 2023, pp. 617 ff.

[11] Article 3, letter h).

[12] Article 30.

[13] Article 31.

[14] According to Article 22 DSA, the "trusted fluggers" shall be appointed by Digital Service Coordinators since 17 February 2024. R. Jahangir, *Building Trust in the Digital Service Act's Trusted Flaggers*, *Tech Policy Press*, FEB 23, 2024

[15] According to Article 16 DSA "Providers of hosting services shall put mechanisms in place to allow any individual or entity to notify them of the presence on their service of specific items of information that the individual or entity considers to be illegal content... Providers of hosting services shall process any notices that they receive…and take their decisions in respect of the information to which the notices relate, in a timely, diligent, non-arbitrary and objective manner".

[16] According to the article 33 "Online platforms and online search engines which have a number of average monthly active recipients of the service in the Union equal to or higher than 45 million" are designated as very large online platforms…The Commission shall, after having consulted the Member State of establishment or after taking into account the information provided by the Digital Services Coordinator of establishment, adopt a decision designating as a very large online platform or a very large online search engine for the purposes of this Regulation the online platform or the online search engine which has a number of average monthly active recipients of the service equal to or higher than the number referred to in paragraph 1 of this Article. The Commission shall take its decision on the basis of data reported by the provider of the online platform or of the online search engine pursuant to Article 24(2), or information requested pursuant to Article 24(3) or any other information available to the Commission".

[17] Art. 34-35 DSA.

[18] European Commission, *Press Release, Digital Services Act: Commission designates first set of Very Large Online Platforms and Search Engines,* Brussel, 25 April 2023. On 26 April 2024, European Commission designed also Shein as a VLOP.

report containing information about illegal orders, notices, and content moderation instruments. Well-conscious of the increasing selling of fake medicines on these platforms[19], on 6 November 2023 the European Commission announced an investigation wanting to know how AliExpress will "comply with obligations related to risk assessments and mitigation measures to protect consumers online, in particular with regard to the dissemination of illegal products online such as fake medicines"[20]. It was followed by a request of information sent on 18 January 2024 to AliExpress and other 16 VLOPs to provide more information on the measures they have taken to comply with the obligation to give access, without undue delay, to the data publicly accessible on their online interface to eligible researchers, in the conviction that researchers' access to publicly available data greatly contributes to the goals of the DSA for an ongoing monitoring of the presence of illegal content and goods on online platforms[21].

On 14 March 2024, on the basis of the preliminary investigation, including the analysis of the risk assessment report sent by AliExpress in August 2023, the information published in its Transparency Report and its replies to European Commission's formal requests for information, European Commission decided to open formal proceedings against AliExpress under Article 66 DSA. The proceedings will focus mainly on the compliance with the DSA obligations related to the assessment and mitigation of the systemic risks of dissemination of illegal content, as well as actual or foreseeable negative effects for consumer protection linked, in particular, to the lack of enforcement of AliExpress' terms of service prohibiting certain products posing risks for consumers' health (such as fake medicines and food as well as dietary)[22].

European Commission, *Press Release, Digital Services Act: Commission designates Shein as Very Large Online Platforms and Search Engines,* Brussel, 26 April 2024.

[19] European Commission, *2022 report on online counterfeiting*, December 2022, p. 42 ff.

[20] European Commission, *Press Release Commission sends request for information to AliExpress under the Digital Services Act*, Brussels, 6 November 2023.

[21] See deeply *infra*, paragraph 2.2.

[22] The other infringements contested are: the lack of effective measures to prevent dissemination of illegal content; the lack of effective measures to prevent intentional manipulation on the online platform through so-called 'hidden links'; the lack of effective measures to prevent risks deriving from features, such as influencers promoting illegal or harmful products through the "Affiliate Programme" of AliExpress; the compliance with the DSA obligation to allow all users, including those who are not registered, to notify illegal content and to receive confirmation of the receipt of the notice; the compliance with the DSA obligation to provide an effective internal complaint-handling system; the compliance with the DSA obligation to gather and assess the reliability and completeness of the information requested from traders using AliExpress including in relation to traders within the "AliExpress Affiliate Program", in line with the traceability of traders' provision; the compliance with the DSA obligation to provide transparency on the main parameters used in AliExpress' recommender systems and to provide at least one option of recommender system not based on profiling; the compliance with the DSA obligation to provide a searchable and reliable repository for advertisements presented on AliExpress; the compliance with the DSA obligation to give researchers access to AliExpress' publicly accessible data as mandated by Article 40 DSA. If proven, these failures would constitute infringements of Articles 16, 20, 26, 27, 30, 34, 35, 38, 39 and 40 DSA.

The opening of formal proceedings empowers European Commission to take further enforcement steps, such as interim measures (Article 70 DSA), and to accept commitments made by AliExpress to remedy the matters subject to the proceeding (Article 71 DSA). According to Article 73 and 74 European Commission could adopt a non-compliance decision and impose sanctions.

AliExpress case puts in evidence the importance attributed by European Commission to the risks connected to the online selling of fake medicines, that becomes increasingly heavy within the so called deep/dark web, that is the part of the web escaping from the big search engines[23]. EU agencies' and United Nations (UN) studies underlined that most part of the illegal medicine online selling transits on these websites[24]. This part of the web inevitably gets out of the DSA monitoring and supervision system. Nevertheless, AI and blockchain, due their ability to monitor and detect transitions and payments as well as to build predictive scenarios, could help public authorities involved in medicine counterfeiting contrast to speedly identify illegal transitions.

As digital environment appears the "place" where fake medicine selling is more frequent, new technologies seems the most effective tools to contrast this phenomenon able to put significantly at risk the well-functioning of EHU.

2.2. Data Access to researchers as a tool of European Health Data Space effectiveness

Data access to researchers in the European health data context, regulated by the (DSA) and other relevant legislation, is a key pillar to improve the effectiveness and efficiency of data management in the health sector. This regulatory obligation not only plays a crucial role in promoting evidence-based approaches for a better understanding of health and disease patterns, but also represents a fundamental pillar for prevention through lifestyle analysis[25]. The need to grant data access to researchers, enshrined in the DSA, plays a key role in the context of healthcare, as it enables evidence-based approaches and a better

[23] Although being often confused, the dark web is only a little part of the deep web. More specifically, the deep web refers to all web pages that are unidentifiable by search engines. Deep web sites may be concealed behind passwords or other security walls, while others simply tell search engines to not "crawl" them. Without visible links, these pages are more hidden for various reasons, as protection of privacy, property, intellectual and industrial property rights (for example, databases or intranet, financial accounts like banking and retirement, email and social messaging accounts, private enterprise databases, HIPPA sensitive information like medical documentation, legal files). The dark web refers to sites that are not indexed and only accessible via specialized web browsers (for example, no webpage indexing by surface web search engines, "Virtual traffic tunnels" via a randomized network infrastructure, inaccessible by traditional browsers due to its unique registry operator). Tor ("The Onion Routing" project) network browser provides users access to visit websites with the ". onion" registry operator and allows users to connect to the deep web without fear of their actions being tracked or their browser history being exposed.

[24] European Monitoring Agency for Drugs and Drug Addiction (EMCDDA), *The Internet and drug markets Summary of results from an EMCDDA Trendspotter study*, 2014; United Nations Interregional Crime and justice Research Institute (UNICRI), *Counterfeit Medicines sold through the Internet*, 2022.

[25] E. Laroche, S. L'Espérance, E. Mosconi, *Use of social media platforms for promoting healthy employee lifestyles and occupational health and safety prevention: A systematic review,* in *Safety Science*, 2020, p. 1 ff.

understanding of health and disease patterns. However, this provision comes with a number of ethical and legal challenges and considerations that need to be addressed to ensure responsible access that respects individual privacy[26]. One of the main issues to consider is access to data for research on lifestyles and related risk factors. Data from social media and other online platforms can provide valuable information to understand health-related lifestyles and behaviours, enabling the development of targeted policies and interventions to improve public health[27]. However, the use of these data raises privacy and data protection concerns, requiring strict measures to be taken to ensure the security and confidentiality of information. Access to data for research on online disinformation and violence is crucial for understanding and addressing threats to democracy[28]. The spread of online disinformation can significantly influence public opinion and undermine trust in democratic processes. In addition to classic disinformation about political and social issues, disinformation related to health issues that can mislead people into accessing appropriate care is becoming increasingly popular. Just think of the recent well-known misinformation concerning the use of vaccines during the emergency period caused by Covid-19. Researchers' access to data is therefore essential for analysing the patterns of spread of misinformation and developing effective strategies to counter it[29]. However, it is important to ensure that this access takes place while respecting individual rights and privacy regulations[30]. In developing secure access models, it should never be forgotten that the use of these data raises privacy and data protection issues, requiring strict measures to be taken to ensure the security and confidentiality of information[31].

In the intricate landscape of health data research, ethical and legal considerations surrounding the use of personal data take on paramount importance. The utilization of such data, while potentially transformative for public health, must navigate the moral imperatives of respecting individual autonomy and privacy. Ethical scrutiny must ensure that data usage adheres to principles of beneficence, doing good by enabling advancements in

[26] A. Ghahramani, M. de Courten, M. Prokofieva, *The potential of social media in health promotion beyond creating awareness: an integrative review*, in *BMC Public Health*. 2022, 1 p. 2402 ff.; C. Colomina, H. Sánchez Margalef, R. Youngs, *The impact of disinformation on democratic processes and human rights in the world*, European Parliament Coordinator: Policy Department for External Policies of the Union. PE 653.635 – April 2021.; S. McKay, C. Tenove C., *Disinformation as a Threat to Deliberative Democracy*, in *Political Research Quarterly*, 2021, 3, pp. 703 ff.

[27] J. Chen, Y. Wang, *Social Media Use for Health Purposes: Systematic Review*, in *Journal of Medical Internet Research,* 2021, 5, pp. 2402 ff.; C. Westberry, XL. Palmer, L. Potter., *Social Media and Health Misinformation: A Literature Review*, in Arai K. (edit.), *Proceedings of the Future Technologies Conference (FTC)* 2023, Cham, Springer, 2023.

[28] E. Aïmeur, S. Amri, G. Brassard, *Fake news, disinformation and misinformation in social media: a review,* in *Social Network Analysis and Mining*, 2023, 1, p. 30 ff.

[29] T.S. Muhammed, S.K. Mathew, *The disaster of misinformation: a review of research in social media*, in *International Journal of Data Science and Analytics*, 2022, 4, pp. 271 ff.

[30] European Parliament, Policy Department for Citizens Rights and Constitutional Affairs. Directorate-General for Internal Policies. *IPR and the use of open data and data sharing initiatives by public and private actors*, May 2022.

[31] C. Thapa, S. Camtepe, *Precision health data: Requirements, challenges and existing techniques for data security and privacy*, in *Computers in Biology and Medicines*, 2021, pp. 129 ff.

healthcare, while avoiding maleficence, the harm that might arise from privacy breaches or misuse of sensitive information[32]. Legally, researchers are bound by the GDPR to uphold the rights of data subjects, ensuring informed consent, data minimization, and purpose limitation. The handling of health data calls for a nuanced approach where the potential public good is weighed against the imperative to protect individuals' sensitive information. This ethical-legal nexus mandates a governance framework that can foster trust, promote transparency, and ensure accountability in health data research, ultimately fostering an environment where innovation thrives alongside the steadfast protection of individual rights. The implementation of "sandboxes" or controlled environments is a promising solution to address the challenges associated with data access to researchers. These environments allow researchers to work with data in a safe and secure manner while ensuring confidentiality and security of information[33]. Furthermore, the adoption of appropriate regulations, such as the delegated regulation envisaged by the Article 40 DSA, is crucial to ensure responsible and secure use of researchers' data in the European health data environment. Access to social media data is also of crucial importance for academic and civil society research. The implementation of the DSA has led to significant changes in the way social media data is made available to researchers, raising important questions regarding transparency and equity in data access. Furthermore, the promotion of public interest research through the sharing of public data is an urgent need, considering the importance of addressing systemic risks in the European Union[34]. The General Data Protection Regulation (GDPR) in the European Union plays a key role in protecting privacy and individual rights in the digital environment. This regulation establishes fundamental principles for the processing of personal data, ensuring that individuals have control over their data and that the highest standards of security and privacy are met[35]. In the EU regulatory landscape, the Data Act fits in as an integral part of initiatives to promote the data economy, sometimes overlapping with other regulations such as the GDPR, which takes precedence over personal data, while the Data Act takes a leading role in the Internet of Things (IoT) and cloud sectors by providing clear and binding guidelines for access to and use of non-personal data[36]. The Data Act introduces five key principles aimed at ensuring fair and transparent

[32] L. Kisselburgh, J. Beever, *The Ethics of Privacy in Research and Design: Principles, Practices, and Potential,* in B.P. Knijnenburg, X. Page, P. Wisniewski, H.R. Lipford, N. Proferes, J. Romano (eds), *Modern Socio-Technical Perspectives on Privacy*, Springer, Cham, 2022.

[33] K. Prifti, E. Fosch-Villaronga, *Towards Experimental Standardization for AI governance in the EU*, in *Computer Law and Security Review*, 2024.

[34] S.M Williamson, V. Prybutok, *Balancing Privacy and Progress: A Review of Privacy Challenges, Systemic Oversight, and Patient Perceptions in AI-Driven Healthcare*, in *Applied Sciences,* 2024, pp. 675 ff.

[35] Regulation (Eu) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), *OJ* L 119, 4.5.2016, p. 1 ff.

[36] Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act), *OJ*

access to data, protecting the rights of European small and medium-sized enterprises and providing a clear regulatory framework for the sharing and use of data among stakeholders[3737]. The ultimate goal of the Data Act is to foster the participation of SMEs in the data economy, enabling them to access and make fair use of data generated by IoT products[38]. In the context of health data research, it is crucial to address the ethical and legal issues surrounding data collection and utilization, particularly when dealing with sensitive health-related information. The ethical and legal implications of researchers' access to data in healthcare and research have been examined, underscoring the need to ensure fair and responsible data access while upholding individual rights and user privacy[39]. The DSA came into force with the aim of making the Internet safer, fairer and more transparent for all online intermediaries in the EU. However, there were many questions and hopes about its proper implementation and its actual impact on the health sector and research. Data access to researchers in the healthcare context is a complex issue that requires a careful balance between research interests[40], privacy protection, and respect for individual rights, crucial to ensure safe and responsible use of data[41].

3.1. New technologies a means of medical supply chain effectiveness: AI using in the joint procurement procedures

As is well-known, since the beginning of the pandemic, the Commission resorted to joint procurement procedures. Employed in the health sector after the 2009 A/H1N1 pandemic (swine flu)[4242], these procedures where formalized in the Decision 1082/2013/EU on

L, 22.12.2023.

[37] D. Eke, B. Stahl, *Ethics in the Governance of Data and Digital Technology: An Analysis of European Data Regulations and Policies*, *Digital Society*, 2024, 11.

[38] European Commission, Press Release, *European Data Act enters into force, putting in place new rules for a fair and innovative data economy*, 11 January 2024.

[39] B. Riso, A. Tupasela, D.F. Vears, H. Felzmann, J. Cockbain, M. Loi, N.CH. Kongsholm, S. Zullo, V. Rakic, *Ethical sharing of health data in online platforms - which values should be considered?*, in *Life Science, Society and Policy*, 2017 1, pp. 12 ff.

[40] COM (2022) 197, 3.05.2022, *Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space*.

[41] M. A. Brown, J. Lukito, K.-C. Yang, *What Does Crowdtangle's Demise Signal For Data Access Under The Dsa?*, *Tech Policy Press*, Mar 27, 2024

[42] Council meeting General Affairs Brussels, Conclusions, 13 September 2010, doc. 12655/2010, 28.07.2010, *Lessons to be learned from the A/H1N1 pandemic*. See also 3053rd Employment, Social Policy Health and Consumer Affairs Council Meeting, Council conclusions *Innovative approaches for chronic diseases in public health and healthcare systems*, 7 December 2010. See also European Parliament resolution of 8 March 2011 on reducing health inequalities in the EU (2010/2089(INI)). From this perspective, Regulation No 966/2012 on the financial rules applicable to the general budget of the Union, *OJ* L 298, 26.10.2012, p. 1 ff., Article 104, established that "where a public contract or framework contract is necessary for the implementation of a joint action between an institution and one or more contracting authorities from Member States, the procurement procedure may be carried out jointly by the institution and the contracting authorities, in certain situations, which are to be specified in the delegated acts adopted pursuant to [the] Regulation. Joint procurement may be conducted with European Free Trade Area (EFTA) States, and Union candidate countries, if this possibility has been specifically provided for in a bilateral or multilateral treaty".

serious cross-border threats to health, article 5[43][43]. To apply this provision, in 2014, the Commission adopted the "Decision on approval of the Joint Procurement Agreement to procure medical countermeasures"[44] (JPA). Today the JPA is specifically disciplined by Regulation 2018/1046 on the financial rules applicable to the general budget of the Union and repealing Regulation No 966/2012[45], article 165, §2[46]. European Commission is charged with the conduct of the joint procurement procedures, including the contract award, and the management of the framework contracts establishing general supply conditions, including the signature of any amendment of a non-substantial nature, as well as with the adoption of the award decision, after approval by the SPPSC. After the award decision is adopted, the participating Contracting Parties sign a specific contract, previously approved by the SPPSC, establishing the details. During the Covid-19 emergency, on the JPA basis, European Commission published tenders and stipulated framework contracts for all the goods useful for the contagion prevention, the Covid-19 care within the hospitals, and positivity testing[47]. In April 2020, the European Economic Area (EEA) States[48] and six can-

[43] Decision 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, *OJ* L 293/2013, p. 1 ff. According to paragraph 2, "The joint procurement procedure referred to in paragraph 1 shall comply with the following conditions: (a) participation in the joint procurement procedure is open to all Member States until the launch of the procedure; (b) the rights and obligations of Member States not participating in the joint procurement are respected, in particular those relating to the protection and improvement of human health; (c) the joint procurement does not affect the internal market, does not constitute discrimination or a restriction of trade or does not cause distortion of competition; (d) the joint procurement does not have any direct financial impact on the budget of Member States not participating in the joint procurement".

[44] Commission Decision C (2014) 2258 final of 10.4.2014, based on the Article 5 of Decision 2013/1082. For a JPA detailed analysis, see S. Pugliese, *Appalti di aggiudicazione congiunta nell'emergenza Covid-19 e sistema OMC: un esperimento regionale per una risposta globale*, in *Quaderni di SIDI BLOG*, 7/2020, 2021, p. 251 ss. S. Pugliese, *Verso un sistema di regolazione commerciale multilivello per contrastare il sovranismo: gli appalti congiunti nell'emergenza COVID-19 come laboratorio di sperimentazione*, in M. L. Tufano e Al. (a cura di), *Sovranazionalità e sovranismo in tempo di COVID-19*, Bari, 2021, p. 371 ss.; M. D'Arienzo, S. Pugliese, *Health services after COVID-19 emergency: toward a multilevel system?*, in *Amministrativamente*, 2021, p. 228 ff., p. 243 ff.;

[45] Regulation 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, *OJ* L 193/2018, p. 1 ff.

[46] JPA management is attributed to the Joint Procurement Agreement Steering Committee (JPASC), composed of one representative of the Commission and one representative of each Contracting Party. Management of single procedures and the elaboration of technical specifications and general allocation criteria are attributed to the Specific Procurement Procedure Steering Committees (SPPSC o Steering Committees), composed of one representative of Member States participating in the procedure. The inter-governmental feature of these bodies is well-evident. On the JPA intergovernmental feature, M. Nabbe, H. Brand, *The European Health Union: European Union's Concern about Health for All. Concepts, Definition, and Scenarios*, in *Healthcare*, 2021, p. 1 ff., 5 ff.

[47] Tenders were open for gloves and coveralls; eye and respiratory protections; ventilators; laboratory equipment; medicines used in intensive care units, the medicine "remdesivir", medical equipment for vaccination, rapid antigen tests; monoclonal antibodies. For all these goods framework contracts were signed, excepting the medicines and monoclonal antibodies, that followed the procedures of authorization managed by the European Medicine Agency (EMA) according to the 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, *OJ* L 136/2004, p. 1 ff.

[48] The countries of the European Free Trade Area (EFTA) that signed the EEA agreement with EC in 1994 are Island, Norway, Liechtenstein.

didate countries[49] and potential candidate countries[50] signed the JPA, bringing the total number of the signatories to 37.
Based on the "EU vaccine strategy"[51], the Commission also stipulated the Advanced Purchase Agreements (APA) with individual vaccine manufacturers on behalf of Member States. These agreements are partially different from those signed within the JPA because, in return for the right to buy a specified number of vaccine doses in a given timeframe and at a given price, the Commission financed, through the Emergency Support Instrument[5252], a part of the upfront costs faced by vaccines manufacturers. This funding was considered as a down-payment on the vaccines that have been purchased by the MS. This approach decreased risks for companies while speeding up and increasing manufacturing. While the JPA attributes to the Commission a role of mere coordination, within the APA framework the Commission invests EU funds in the procedure, even if these funds are used not to purchase vaccine doses but to support and accelerate their invention and experimentation. It is a so-called pull strategy in financing vaccine, different from the push strategy funding research where it is not started yet. The pull strategy main advantage consists in speedily leading manufacturers to the development of a final product and to allow the funder to serve for itself (or in the EU case, for its MS) the vaccine quantity necessary to face its need[53]. On 18 June 2020, Commission adopted the Decision approving the agreement with the MS on procuring Covid-19 vaccines on behalf of the MS and related procedures[54]. By signing the Agreement, the Participating MS confirm their participation in the procedure and agree not to launch their own procedures for advance purchase of that vaccine with the same manufacturers (exclusivity clause)[55].

[49] Albania, Montenegro, North Macedonia, Serbia.

[50] Bosnia and Herzegovina, Kosovo.

[51] COM (2020) 245 final, 17.06.2020, *EU Strategy for COVID-19 vaccines*.

[52] See Council Regulation 2016/369 of 15 March 2016 on the provision of emergency support within the Union, *OJ* L 70/2016, p. 1 ff., Article 4 ff., and Council Regulation 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, *OJ* L 117/2020, p. 3.

[53] C.M. Snyder et al., *Designing Pull Funding for A COVID-19 Vaccine*, in *Health Affairs*, 2020, p. 1633 ff.; A.P. Antunes, *Vaccines against COVID-19: Issues to Consider*, *SSRN Research Paper*, 2020, p. 12 ss.; S. Pugliese, *Appalti di aggiudicazione congiunta nell'emergenza Covid-19 e sistema OMC*, cit., p. 264 f.

[54] C (2020) 4192 final, 18.6.2020, based on the Article 4, §5, point b) of the Council Regulation (EU) 2016/369 on the emergency support instrument, as modified by the Council Regulation (EU) 2020/521.

[55] Art. 7. The vaccines authorized against Covid-19 for use in the EU are BioNTech-Pfizer (21 December 2020), Moderna (6 January 2021), Astrazeneca (29 January 2021), Johnson&Johnson (11 March 2021), Novavax (20 December 2021); Valneva (27 June 2022); Bimervax/previously COVID-19 Vaccine HIPRA (30 March 2023). The vaccination campaign started at the end of December 2020 and it is in progress. Contracts stipulated by EU and vaccine manufacturers have a common structure. For a detailed analysis, see M. D'arienzo, S. Pugliese, *Health services after COVID-19 emergency,* cit., p. 249 ss.; S. Pugliese, *Appalti di aggiudicazione congiunta nell'emergenza Covid-19 e sistema OMC,* cit., p. 263 ss. Vaccines were authorized with a conditioned authorization released, through a rolling review procedure, when clinical trials are still ongoing. For a deep analysis, V. Salvatore, *L'approvvigionamento dei vaccini per far fronte alla pandemia: un esempio di collaborazione virtuosa tra l'agenzia europea per i medicinali, la Commissione europea e gli Stati membri*, M.L. Tufano et al. (a cura di), *Sovranazionalità e sovranismo in tempo di COVID-19,* Bari, 2021, p. 395 ff.

Through instruments such as joint procurements and APAs, the Commission offers MS its expertise and competences to assure transparency, procedural speediness, and effectiveness as well as to avoid competition in supplying between Central Authorities and their local entities[56]. During the pandemic, JPA And APAs principal advantage consisted in strengthening the contractual power of MS against the medical device and medicine manufacturers and sellers. At the same time, they assured the just distribution between the MS, taking into account their needs on the basis of the contagion situation and the characteristics of their sanitary system, regardless their dimension and economic condition. These instruments were able to realize a reform of the EU governance system in a logic of solidarity and good governance[57].

These two experinces put in evidence that centralizing procurement procerdures during the health emergencies could improve effectiveness in making the procedures speeder, assuring product quality, reinforcing the public entities' contractual power against the big pharma, controlling prices as well as warranting a proper and equal distribution of medical countermeasure between MS according to their real needs, avoiding the creation of unuseful storages. On this basis, on September 2021 the European Commission established the Health Emergency Preparedness and Response Authority (HERA), a Commission service charged with the function of "strengthening health security coordination within the Union during preparedness and crisis response times, and bringing together Member States, the industry and the relevant stakeholders in a common effort; addressing vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures; contributing to reinforcing the global health emergency preparedness and response architecture"[58].

Differently from the JPA bodies, connoted by a clear inter-governmental structure, the HERA organigram is characterized by the central role of the Commission both in the appointment

[56] N. Azzopardi-Muscat e al., *The European Union Joint Procurement Agreement for cross-border health threats: what is the potential for this new mechanism of health system collaboration?*, in *Health Economics, Policy and Law*, 2017, p. 43 ff.; G. Sdanganelli, *Il modello europeo degli acquisti congiunti nella gestione degli eventi rischiosi per la salute pubblica*, in *Dir. pubb. comp. eur. on line*, 2020, p. 2323 ff., 2341; E. McEvoy, D. Ferri, *The Role of Joint Procurement (JPA) during the COVID-19 Pandemic: Assessing its Usefulness and Discussing its Potential to Support a European Health Union*, in *European Journal of Risk Regulation*, 2020 p. 1 ff., 5 ff.

[57] P. Vila Maior e I. Camisão, *The European Union, Covid-19 and Crisis Management*, Oxon, NY, 2022, p. 34 ff., put in evidence the importance of JPA and APA as an instrument to change the narrative of the EU reaction to Covid-19 from an idea of profound disunion to one based on solidarity and coordinate strategy. On the EU contribution in terms of solidarity and leadership, see *Ibidem*, p. 106 ff.

[58] Commission Decision n. 6712 of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, *OJ* C 393I, 29.9.2021, p. 3. More specifically, HERA is responsible for the following tasks to be exercised in cooperation with MS: (a) assessment of health threats and intelligence gathering relevant to medical countermeasures; (b) promoting advanced research and development of medical countermeasures and related technologies; (c) addressing market challenges and boosting the Union's open strategic autonomy in medical countermeasures production; (d) swift procurement and distribution of medical countermeasures; (e) increasing stockpiling capacity of medical countermeasures; (f) strengthening knowledge and skills in preparedness and response related to medical countermeasures.

of the management[59] and in the decision making[60]. Furthermore, its inter-governmental nature is reduced by the apport of expertise[61] and by the possibility that a representative of the Parliament participates as observer in the meetings. At the same time, the Advisory Forum ('Forum'), a mechanism for an exchange of information and the pooling of knowledge aimed at ensuring close cooperation between HERA and the competent bodies in the Member States[62], could be considered as a new form of co-administration[63].

HERA as a Commission service put the basis for the effective establishment of the EHU conceived as a platform of coordination between EU and national level in the field of

[59] European Commission is competent to appoint the head of HERA, ranked as Director-General, and the Deputy Head, and ranked as Director. The Head of HERA is competent with: (a) preparing a multiannual strategic plan for HERA and an annual draft work programme for HERA's various fields of activity, taking into account the programming cycle calendar of contributing Union programmes; (b) negotiating and concluding procurement and other contracts related to medical countermeasures with third parties; (c) being responsible for the implementation of HERA's activities and for the financial administration; (d) determining the internal organisation of HERA, within the constraints of the budget allocated to it by the budgetary authority; (e) reporting to the Member of the Commission in charge of Health. See S. Villa e al., *HERA: a new era for health emergency preparedness in Europe?*, in *The Lancet*, 2021, p. 2145 ff.; M. Fraundorfer, N. Winn, *The emergence of post-Westphalian health governance during the Covid-19 pandemic: the European Health Union*, in *Disasters*, 2021, p. 5 ff., 17 ff.

[60] Indeed, the political steering on the planning and implementation of HERA's tasks are attributed to the Coordination Committee, composed by Commission members, while the HERA Board, composed of one high-level representative from each Member State, appointed by the Commission on the basis of nominations by the relevant national authorities, has a mere advisory function. The Coordination Committee is composed of: (a) the Vice-President of the Commission in charge of Health; (b) the Member of the Commission in charge of Health; and (c) the Members of the Commission in charge of the Internal Market, Innovation and Research and Crisis Management. The Coordination Committee shall be co-chaired by the Vice-President and the Member of the Commission in charge of Health. The Head of HERA and the Director General in charge of Health and Food Safety shall attend meetings *ex officio*. The HERA Board shall assist and advise the Commission in the formulation of strategic decisions concerning HERA in the following fields: (a) the functions of HERA within the Union's crisis preparedness and response management, research, and innovation as well as industrial strategy in the area of medical countermeasures; (b) the scientific/technical management of HERA; (c) the performance of the tasks entrusted to HERA.

[61] A representative of the European Centre for Disease Prevention and Control (ECDC) and a representative of the European Medicines Agency (EMA) may participate as observers in the meetings of the HERA Board. Representatives of the Emergency Response Coordination Centre, other Union decentralized and relevant executive agencies and other bodies relevant to public health emergencies may participate as observers in the meetings of the HERA Board upon invitation by the Commission. The Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the HERA Board on an *ad-hoc* basis.

[62] The Forum shall be composed of members from technically competent bodies designated by each Member State. Members of the Forum shall not be members of the HERA Board. The Forum shall support the HERA Board in providing scientific and technical advice. The HERA Board may set up sub-groups of the Forum for the purpose of examining specific questions in the fields of science, research, or industrial matters. In particular, a subgroup named 'Joint Industrial Cooperation Forum' composed of the representatives of the industry and Member States shall be set up. The Head of HERA may invite experts or representatives of professional or scientific bodies, or non-governmental organizations with recognized experience in disciplines related to the work of HERA to cooperate in specific tasks and to take part in the relevant activities of the Forum. As far as possible, the Health Crisis Board shall deliberate by consensus. If consensus cannot be reached, the Health Crisis Board shall deliberate by a majority of two thirds of the Member State representatives. Each Member State shall have one vote.

[63] "Co-administration" is a term often associated to comitology. See R. Dehousse, *Misfits: EU law and the transformation of European governance*, in C. Joerges, R. Dehousse (eds), *Good governance in Europe's integrated market*, 2002, Oxford, p. 207 ff.; M.L. Tufano, *La comitologia e le misure di esecuzione degli atti e delle politiche comunitarie*, in *Il Diritto dell'Unione europea*, 2008, p. 149 ff., p. 170, nota 101.

preparedness and response of health crises[64]. The composition of HERA bodies, aimed at assuring legitimacy to the Commission service measure by giving a strong weight to the expertise and involving the national sectorial authorities, seems be devoted to overcoming the JPA intergovernmentalism towards a more complex organizational pattern able to assure the full coordination between EU level, charged with coordination, and national level, responsible for management.

In the same direction, Regulation (EU) 2022/2371 on serious cross-border threats to health and repealing Decision n. 1082/2013/EU aims to facilitate adequate Union-wide preparedness for and response to all cross-border threats to health by creating "a more robust mandate for coordination at Union level"[65]. As it concerns prevention, European Commission, in cooperation with MS and the relevant Union agencies and bodies, shall establish "the Union prevention, preparedness and response plan" to promote an effective and coordinated response to cross-border threats to health at Union level. The plan has a complementary function of the national plans.

To this extent, Decision n. 1082/2013/EU has been repealed by a broader legal framework imposing MS additional reporting requirements and analyses regarding health systems indicators, and strengthening cooperation between MS, Union agencies and bodies, and international organizations, in particular the WHO. In this new framework, the joint procurement mechanism is strengthened and extended to become more suitable to face serious cross-border threat to health. According to Regulation 2022/2371, Article 12, European Commission and any of the MS may engage, as contracting parties, in a joint procurement procedure conducted pursuant to Article 165, §2 of Regulation 2018/1046 "with a view to the advance purchase of medical countermeasures for serious cross-border threats to health within a reasonable time frame". While being used as a reaction measure during the pandemic, the joint procurement has definitely become a preparedness measure[66].

[64] HERA Director General, Pierre Delsaux, in *Preparing Europe for future health threats and crises – the European Health Emergency and Preparedness Authority; improving EU preparedness and response in the area of medical countermeasures*, in *Euro Surveillance*, 24 November 2022, p. 1 ff., underlines that the two HERA operational modes (the preparedness mode to anticipate and respond to threats before they turn into crises, and the crisis mode empowering HERA to coordinate and take action against health emergencies) are conceived in full respect of the subsidiarity principle. For a HERA analysis in an organizational perspective, where HERA is conceived as a "partial organization… that lacks a full suite of organizational elements at its disposal—such as monitoring or sanctions—for effecting decisions", L. Välikangas, M. Luistro-Jonsson, S. L. Jarvenpaa, *Health crisis and the EU's HERA: amplifying partial organizing with resourcing for stability, agility, and evolvability*, in *Journal of Organization Design*, 2022, p. 169 ff. Nevertheless, it has to be underlined that the final choice to establish it as a Commission service and not as an autonomous authority allows it to resort to monitoring and sanction instruments available to the Commission, strengthening its legitimacy and accountability.

[65] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision n. 1082/2013/EU, *OJ* L 314, 6.12.2022, p. 26, Recital 5. See S. Gallina, *Preparing Europe for future health threats and crises: the European Health Union*, in *Euro Surveill.* 2 February 2023, p. 1 ff.

[66] To strengthen joint procurement transparency, accountability, and effectiveness, Regulation 2022/2371 introduces the joint procurement assessment where the Commission shall indicate the general envisaged conditions of the joint procurement procedure, including as regards possible restrictions to parallel procurement and negotiation activities by the participating countries. It is the so-called exclusivity clause, already experimented within the Agreement for vaccines,

As it concerns reaction, an early warning and response system has been established enabling the Commission, the ECDC, and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alert notifications. These authorities are charged with assessing public health risks and determining the measures that may be required to protect public health.
Regarding the serious cross-border threats to health, European Commission is charged with the role of formally recognizing a public health emergency at Union level, assisted by an independent advisory committee[67]. The recognition has the relevant legal effect to enable the introduction of measures related to medicinal products and medical devices and mechanisms to monitor shortages of, and to develop, procure, manage, and deploy medical countermeasures. In this scenario, designing a well-defined method of health crisis prevention and management, procurement procedures acquire a central role in assuring promptness, security, and equality in the medical countermeasure supply during health emergencies.
On this ground, Regulation 2022/2371 shall be read in connection with Council Regulation 2022/2372 establishing an emergency framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level[68]. In the event of recognition of a public health emergency, the Council, upon

according to which participating countries commit to not procuring the medical countermeasure in question through other channels and to not running parallel negotiation processes for that countermeasure. This clause is useful to avoid that, by adhering to the joint procurement initiatives and at the same time negotiating directly with manufactures, most powerful countries could accumulate useless stockpiles determining medical countermeasure shortage and price increasing to the detriment of the smaller and weaker participants. In sum, the exclusivity clause is a parameter of fairness and solidarity It should be preceded by a Joint Procurement Agreement between the parties determining the practical arrangements governing the procedure and the decision-making process with regard to the choice of the procedure, the joint procurement assessment, the assessment of the tenders and the award of the contract. To strengthen the joint procurement solidarity and responsibility in a macro-regional dimension, participation in the joint procurement procedure is open to all Member States, European Free Trade Association (EFTA) States and Union candidate countries, as well as the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State. To detect the availability of relevant countermeasures, European Commission has started working on the development of an intelligence gathering and threat assessment tool, the Medical Countermeasures Intelligence Platform (HERA MCMI platform). COM (2022) 669, 30 November 2022, *State of Health Preparedness Report*, p. 9. More specifically, the clause seems to have the objective to "balance" the structural imbalances between MS, that appear sharpened and worsened by the emergencies, and to assure greater support to the most damaged and fragile MS. On the potential "re-balancing" role of solidarity in EU, G. Morgese, *La solidarietà tra gli Stati membri dell'Unione in materia di immigrazione e asilo*, Bari, 2018, p. 86; Idem, *Solidarietà di fatto … e di diritto? L'Unione europea allo specchio della crisi pandemica*, in Aa.Vv., *L'emergenza sanitaria Covid-19 e il diritto dell'Unione europea. La crisi, la cura, le prospettive*, Milano, p. 77, p. 92.

[67] The advisory committee will provide expertise on whether a threat constitutes a public health emergency at Union level and advise on public health response measures and on the termination of such emergency recognition. The advisory committee should consist of independent experts, including representatives of healthcare and social care workers and civil society representatives, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring. Representatives of the Member States, of the ECDC, of EMA, and of other Union agencies or bodies or of the WHO, should be able to participate as observers.

[68] Council Regulation (EU) 2022/2372 of 24 October 2022 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, *OJ* L 314, 6.12.2022, p. 64 ff.

the proposal of the Commission, may adopt a regulation activating, for a minimum of six months, the emergency framework, taking into account the need to ensure a high level of protection of human health. In this case, a Health Crisis Board (HCB) shall be established and shall ensure coordination of action by the Council, European Commission, the relevant Union bodies, offices and agencies and MS to ensure the supply of and access to crisis-relevant medical countermeasures[69].

Regulation 2022/2372 established a mechanism to monitor crisis-relevant medical countermeasures where the Commission has the role to draw up and regularly update a list of crisis-relevant medical countermeasures and raw materials, while the HCB shall advise the Commission on the appropriate mechanism to purchase crisis-relevant medical countermeasures and raw materials. Three purchasing methods are established:

1. activation of existing contracts or the negotiation of new contracts, using available instruments, such as Article 4 of Regulation (EU) 2016/369[70], the joint procurement procedure referred to in the above-mentioned Article 12 of Regulation (EU) 2022/2371, or European Innovation Partnerships, established by Regulation (EU) 2021/695 of the European Parliament and of the Council[7171];
2. a purchasing mode whereby the Commission acts as a central purchasing body on behalf of Member States, either in conjunction with other available instruments or as an autonomous procurement mode;
3. carrying out the procurement procedures and conclude the resulting agreements with economic operators on behalf of the participating Member States, in accordance with Regulation 2018/1046.

In reality, these three methods are not new. They were already established by the Regulation 2020/521 modifying the Emergency Support Instrument (ESI) discipline[72]. Neverthe-

[69] [69] The HCB is composed of the Commission and one representative from each MS and shall be co-chaired by the Commission and the MS holding the rotating presidency of the Council. Each Member State shall nominate its representative and alternate representative. As in the JPA and differently from the HERA Board, the inter-governmental nature of this body is well-evident. It is explained by the specificity of legal basis, that is art. 122, §1 TFEU. See F. Sciaudone, *Articolo 100*, in A. Tizzano (a cura di), *Trattati dell'Unione europea e della Comunità europea*, Milano, 2004, p. 669 ff.; Idem, *Articolo 122*, in A. Tizzano (a cura di), *Trattati dell'Unione europea*, Milano, 2014, p. 1311 ff. . Goffin, D. Mas, *Article 100*, in V. Constantinesco, Y. Gautier, D. Simon (sous la direction de), *Traités d'Amsterdam et de Nice. Commentaire article par article*, Paris, p. 425 ff.

[70] Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union, *OJ* L 70, 16.3.2016, p. 1 ff. Based on the Article 122, §1, the Regulation establishes the Emergency Support Instrument (ESI), through which, as stated above, during pandemic the APA for anti-Covid vaccines were funded.

[71] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, *OJ* L 170, 12.5.2021, p. 1 ff.

[72] 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, *OJ* L 117/2020, p. 3, Article 4, §5 "Emergency support under this Regulation may be granted in any of the following forms: (a) joint procurement with Member States as referred to in Article 165(2) of Regulation 2018/1046 whereby Member States may acquire, rent or lease fully the capacities jointly procured; (b) procurement by the Commission on behalf of Member States based on an agreement between the Commission and Member States; (c) procurement by the Commission, as wholesaler, by buying, stocking

less, during the pandemic the sole joint procurement was resorted to, probably because the MS involvement in the JPA bodies allow them to maintain a control in the procurement procedure decision-making. In sum, the JPA has been preferred as being more inter-governmental than the other two procedures. In this perspective, in an effort to incentivize the other two purchasing methods, Regulation 2022/2372 strengthens the Commission accountability towards MS, by reinforcing its duties of informing and involving the MS[73], and established simplified procedure justified by the extreme urgency of the health crisis[74]. Centralization of strategic decision-making in medical countermeasure supply is not limited in enhancing the procurement procedures. Indeed, Regulation 2022/2372 also establishes other provisions specifically aimed at allowing the Commission to gain a pivotal role in managing the medical countermeasure shortage in situations of health emergency. Indeed, according to the Article 8, §7, when the Commission acts as a central purchasing body, it may have the ability and responsibility, on behalf of participating MS and according to their needs, to enter into purchase agreements with economic operators, including individual producers of crisis-relevant medical countermeasures. On the APA experience, those agreements can include a prepayment mechanism for the production or development of such countermeasures in exchange for the right to the result[75]. The choice to invest the ESI to address the public health emergency overcomes a gap characterizing the 2014 JPA, where no direct EU funds were envisaged, and confirms the clear EU In-

and reselling or donating supplies and services, including rentals, to Member States or partner organisations selected by the Commission. In the event of a procurement procedure as referred to in point (b) of paragraph 5, the ensuing contracts shall be concluded by either of the following: (a) the Commission, whereby the services or goods are to be rendered or delivered to Member States or to partner organisations selected by the Commission; (b) the participant Member States whereby they are to directly acquire, rent or lease the capacities procured for them by the Commission".

[73] The Commission shall inform the HCB, on a regular basis, of the progress made in the procurement process and on the substance of negotiations. The Commission shall take the utmost account of the advice of the HCB and of the MS real needs. In particular, the Commission shall only consider launching negotiations where a sufficient number of MS have expressed their support. All participating MS shall be associated to the procurement process. To that effect, the Commission shall invite participating MS to nominate representatives to take part in the preparation of the procurement procedures as well as the negotiation of the purchasing agreements. Representatives of participating MS shall have the status of experts associated to the procurement process, in accordance with Regulation 2018/1046. Where the Commission intends to conclude a contract containing an obligation to acquire crisis-relevant medical countermeasures, it shall inform the participating MS of such intention and the detailed terms. The participating MS shall have the opportunity to express their comments on the draft contracts, that the Commission shall take into consideration. If the opt-out mechanism is applied, participating MS shall have the right of at least five days to opt out.

[74] More specifically, derogations are: (a) possibility to provide, after the signature of the contract, proof or evidence on exclusion and selection criteria, provided that a declaration on honour has been submitted in that regard before the award; (b) possibility offered to the Commission of modifying the contract as necessary to adapt it to the evolution of the public health emergency; (c) possibility to add, after the signature of the contract, contracting authorities that are not identified in procurement documents; (d) entitlement of the contracting authorities to request the delivery of goods or services from the date on which the draft contracts resulting from the procurement carried out for the purposes of this Regulation are sent, which shall be no later than 24 hours as from the award.

[75] In order to enter, on behalf of all participating Member States, into purchase agreements with economic operators, representatives of the Commission, or experts, the Commission may carry out on-site visits in cooperation with relevant national authorities at the locations of production facilities of crisis-relevant medical countermeasures.

stitutions' intention to acquire a strategic role in the crisis preparedness both in decision making and in funding.

As a further reaction instrument, European Commission shall have the ability and responsibility to activate the Network of Ever-warm Production Capacities for Vaccines and Therapeutics manufacturing (EU-FAB) facilities[76], a network of medical product manufacturers created in 2021 to make available reserved surge manufacturing capacities to ensure the delivery of crisis-relevant medical countermeasures and raw materials. In the ambit of the network, contracts are signed where quantities and timing are agreed, object of specific procurement procedures. To assure European Commission against the risk of wasting funds, where it provides financing for the production and/or development of crisis-relevant medical countermeasures, if an economic operator abandons its development effort or is unable to respect the terms of the agreement concluded[77], European Commission could acquire the licensing and know-how. The centralization of decision-making concerns not only the prevention phase but also the management. Indeed, although the deployment and use of the crisis-relevant medical countermeasures remaining a participating MS competence, the Commission shall ensure the equality of treatment when carrying out the procurement procedures and when implementing the resulting agreements.

These rules, that are clearly inspired by the APA experience, represents a vehicle for European Commission to enter the medical countermeasure production chain, acting as an "entrepreneur" able, in emergency situations, to assure the supply security through a direct management and funding intervention[7878]. This intention is clearly expressed in the Article 12, establishing measures to assure the availability and supply of crisis-relevant medical countermeasure aimed at ensuring the efficient reorganization of supply chains and production lines and the use of existing stocks to increase the availability and supply of crisis-relevant medical countermeasures[79]. In this perspective, it would be important to

[76] See COM (2021) 576, 16.9.2021, *Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union*, p. 7 ff.

[77] Covid-19 experience demonstrated that, in procedures to assure medical countermeasure supply, risk of disputes between EU and manufactures is frequent. See the dispute between EU Commission and Astrazeneca about an alleged breach of contract concerning the delivery of its coronavirus vaccine, resolved through a negotiated settlement. See European Commission, *Press Release. Coronavirus: The EU and AstraZeneca agree on COVID-19 vaccine supply and on ending litigation*, Brussels, 3 September 2021.

[78] The following provisions, concerning emergency research and innovation aspects of the preparedness and response plans, the use of clinical trial networks and data-sharing platforms, and inventory of crisis-relevant raw materials, consumables, medical devices, equipment, and infrastructure, confirms the aim of control the production chains.

[79] More specifically, the measures may include: (a) facilitating the expansion or repurposing of existing, or the establishment of new, production capacities for crisis-relevant medical countermeasures; (b) facilitating the expansion of existing, or the establishment of new, capacities related to activities and the introduction of measures ensuring regulatory flexibility, in order to support the production and placing on the market of crisis-relevant medical countermeasures, while respecting the responsibilities of EMA and national medicines authorities with regard to the evaluation and supervision of medicinal products; (c) implementing procurement initiatives, reserving stockpiles and production capacities to coordinate approaches, and providing critical supply, services and resources for the production of crisis-relevant medical countermeasures; (d) facilitating the collaboration of relevant companies in a joint industry effort to ensure

take into account some initiatives, as the European Commission's proposals for a Single Market Emergency Instrument[80] and the Critical Raw Material proposal[81], that, although being external to the EHU, could contribute to strengthening the health supply security.
Centralized procurement procedures as a means of supply chain management are a relevant issue also within the EU strategy to combat antimicrobial resistance in a One Health approach, where, on the basis of fruitful experienced APA pull strategy, a well-structured set of pull mechanisms of different financial size for ensuring access to antimicrobials is envisaged[82].
Furthermore, they seem to affirm itself as effective procedure beyond the health sector, as new financial rules applicable to the general budget of the Union proposed by the European Commission on May 2022 explicitly acknowledges the joint procurement as a useful tool during the "situation of extreme urgency resulting from a crisis"[83].

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the availability and supply of crisis-relevant medical countermeasures; and (e) facilitating the licensing of intellectual property and know-how pertaining to the crisis-relevant medical countermeasures.

[80] COM (2022) 459, 19 September 2022, Proposal for a Regulation of the European Parliament and of the Council establishing a Single Market emergency instrument and repealing Council Regulation No (EC) 2679/98, based on Articles 114, 21 and 45 TFEU; COM (2022) 461, 19 September 2022, Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency, based on the Article 114 TFEU; COM (2022) 462, Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU as regard emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency, based on Article 91 and 114 TFEU.

[81] COM (2023) 160 final, 16 March 2023, Proposal for a Regulation of the European Parliament and of the Council establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) 168/2013, (EU) 2018/858, 2018/1724 and (EU) 2019/1020, based on Article 114 TFEU.

[82] Council recommendation of 13 June 2023 on stepping up EU actions to combat antimicrobial resistance (AMR) in a One Health approach, *OJ* C 220, 22.6.2023, p. 1 ff., Recital 27 and point 30. A Commission study on bringing AMR medical countermeasures to the market assessed four major types of procurement mechanisms that may help increase the expected revenue for developers: revenue guarantee, market entry rewards combined with revenue guarantee, lump-sum market entry rewards and milestone payments. With the annual revenue guarantee mechanism, the public authorities 'top up' revenue for developers to reach the 'guaranteed' amount. If sales reach the threshold amount, no further 'top up' is awarded. Market-entry rewards consist of a series of financial payments to an antibiotic developer for successfully achieving regulatory approval for an antibiotic that meets specific pre-defined criteria. Milestone-Based Reward is an early-stage financial reward upon achieving certain R&D objectives prior market approval (e.g. successful completion of phase I). While these mechanisms would serve primarily to provide access to existing antimicrobials, they could also support new antimicrobials in the development phase. The initial pre-feasibility assessment determined that all options may be implemented as procurement transactions – notwithstanding some notable restrictions and considerations that require further in-depth investigation. Both EU and Member State contributions will probably be required. Cfr. COM (2023) 190, 26 April 2023, *Reform of the pharmaceutical legislation and measures addressing antimicrobial resistance*. The push to move toward a One Health logic emerged also by the Conference of the Future of Europe (COFE) proposals. See *COFE Final Report*, p. 51, proposal n. 9.

[83] See COM (2022) 223 final, 16 May 2022, *Proposal for a Regulation of the European Parliament and of the Council the financial rules applicable to the general budget of the Union (Recast)*, Article 169. According to the Recital 22, «"crisis" means: (a) a situation of immediate or imminent danger threatening to escalate into an armed conflict or to destabilise a country or its neighbourhood; (b) a situation caused by natural disasters, man-made crisis such as wars and other conflicts or extraordinary circumstances having comparable effects related, inter alia, to climate change, public and animal health, food safety emergencies and global health threats such as pandemics, environmental degradation, privation of

Centralized procurement procedures and verticalized production networks, appearing as an "accidental lifeboat" during the Covid-19 pandemic, became a milestone of the process of supply chain management verticalization, representing the crucial point of the EU health crisis preparedness and management strategy. Initially conceived as residual procedures, they are definitely evolved toward instruments to stimulate a domestic medical countermeasure production and free the EU from the third country dependency. In this perspective, they become a tool to realize the "open strategic autonomy" the EU is pursuing in several sectors (defence, trade, investment, energy, critical materials, technology and cybersecurity)[84].

In these procedures, AI application allows the assumption of automated decisions by an algorithm according to specific predetermined criteria. More specifically, predictive algorithms that exploit AI systems, in particular machine learning (ML) technologies, could assist operators in planning tenders and evaluating offers, as they are able to detect patterns in historical supply chain data, i.e., the critical points and crucial factors for determining the correct quantity of supplies, such as unpredictable risks, logistics, and optimization of procedures. Furthermore, due its ability to learn from the data it relies upon and conducts analyses without a defined structure or specific instructions, a machine could be very efficient in planning quantities or auction bases for supply tenders. As it concerns medical countermeasures, AI could pinpoint the quantities of drugs/medical devices to be purchased and the relevant auction base[85]. There are software allowing to manage the whole life cycle of products and other ones are specialized in supply risk management and supply chain visibility as well as in the detection of procurement frauds[86].

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access to energy and natural resources or extreme poverty». In such situations new contracting authorities may be added after the launch of the procurement procedure and before contract signature. In this way, the EU bodies and MS could decide to adhere to the procurement procedure in progress. Furthermore, the availability to launch joint procurement procedure is extended to the executive agencies and the possibility of adhering to the JPA is open not only to the EFTA Members and EU candidate countries, but also to third countries if such possibility is specifically provided for in the applicable basic act. In analogy with Council Regulation 2020/521, near to the joint procurements, the "procurement on behalf of Member States" is established, where a Union institution, body, or agency "may procure on behalf of or in the name of one or several Member States on the basis of a mandate, or act as a wholesaler, by buying, stocking and reselling or donating supplies and services, including rentals, to Member States or partner organisations"

[84] See COM (2022) 60, 15 February 2022, *Commission contribution to European defence*, p. 15.

[85] See, for example, the STEINBOCC Project (TENDER NEEDS: IMPACT variaBles and prediCtive data analytiCs), conducted by researchers at the Healthcare Datascience LAB at LIUC-Università Cattaneo, in collaboration with EGUALIA (generic, biosimilar, and value-added medicines industries). This research developed a forecasting algorithm, accessible via a web interface, that can be adapted for different active ingredients and used free of charge by regional contracting authorities and pharmaceutical companies to identify future needs or size purchases for future tenders. See also the "piece price estimator," designed to identify the optimal price for the auction base—the threshold below which the probability of unsuccessful tenders increases. After conducting research on the piece price estimator, the University of Oviedo proposed a machine learning mechanism for the identification of the auction base for tenders for the supply of medicines. See E. Stefanini, C. Todisco, *Digitization In The New Public Procurement Code: New Technological Frontiers And Artificial Intelligence*, in *Public Procurement Corner*, November 3, 2023.

[86] M. Guida and Others, *The role of artificial intelligence in the procurement process: State of the art and research agenda*, in *Journal of Purchasing and Supply Management*, 2023, p. 1 ss.

For their ability of improving procurement procedure efficiency, transparency, and speediness, the AI instruments could be specifically useful in centralized purchase procedures, facilitating negotiation and supplier selection, higher accuracy in the planning process, and real-time adaptation to external requests. For their ability to analyze and prevent risks, they could also support the activities of the FAB LABs, allowing the proper assessment of necessary production and stockpile amounts. Surely, AI use in procurement procedure could generate some doubts as it concerns the risk of reducing administrative discretion and incentivizing too deterministic decision-making. In this perspective this risk could be avoided through a conscious algorithmic building, considering all the administrative and technical criteria and burdens necessary to safeguard the Public Authority autonomy[87]. Expertise and expensiveness necessary to properly build the algorithms confirm the European Commission as "optimum procurement level" in emergency situation.
Furthermore, it has to take into account that, according to the European Commission's traditional approach in risk regulation[88], while the technical issues about the procurement procedure could be delegated to machines, strategical decisions about crisis management remain "eminently political". As a consequence, only a proper cooperation between European and national decision-makers could assure effectiveness and accountability to the choices concerning how to prevent, manage, and mitigate emergency.

3.2. AI using in prevention and mangement of medical countermeasure shortage

In the EHU framework, EU health agencies acquire an important role in the shortage preparedness and management of medical countermeasures. More specifically, European Medicine Agency (EMA), decentralized agency responsible for the scientific evaluation, supervision, and safety monitoring of medicines in the EU[89], and European Centre for Disease Prevention and Control (ECDC), aimed at strengthening Europe's defenses against infectious diseases[90], are charged with new functions to contrast to the medicinal product shortage. As it concerns EMA, according to Regulation 2022/123[91] it will have the role of preparing for, preventing, coordinating, and managing the impact of public health emergencies on medicinal products and on medical devices and monitoring, preventing, and

[87] See, *amplius*, V. Visone, *Contributo allo studio della dimensione algoritmica della funzione amministrativa*, Napoli, 2023, p. 175 ss.

[88] See COM (2000) 1, *Communication from The Commission on the precautionary principle*, p. 15.

[89] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, *OJ* L 136, 30 April 2004, p. 1 ff.

[90] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 april 2004 establishing a European Centre for disease prevention and control, *OJ* L 142, 30 April 2004, p. 1 ff.

[91] 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, *OJ* L 20, 31 January 2022, p. 1 ff.

reporting on shortages of medicinal products and devices[92]. To this extent, EMA should set up an interoperable information technology platform at Union level and provide advice on medicinal products that have the potential to address public health emergencies. More specifically, the Agency has the task of monitoring events, in cooperation with the national competent authorities for medicinal products, and, when it considers that an actual or imminent major event needs to be addressed, it shall raise the issue[93].

The intention of consolidating the standardization function at EU level is confirmed not only by the task given to EMA of elaborating a clear and transparent working methods and provision of information on medicinal products[94], but also to the task given to the European Commission to take all necessary action with a view to mitigate actual or potential shortages of medicinal product, facilitate the coordination between marketing authorization holders and other relevant entities to address demand surges, and "consider the need for guidelines and recommendations to be addressed to Member States, marketing authorization holders, and other entities, including relevant entities from the supply chain for medicinal products"[95]. Even if these words express caution in imposing MS Commission standardization role, the EMA reform appears devoted to consolidating its expertise-based legitimacy[96].

As it concerns ECDC, its mission and tasks have been changed through Regulation 2022/2370 to enhance the capacity of the Union and the Member States to protect human

[92] According to Article 2 "'public health emergency' means a situation of public health emergency recognized by the Commission in accordance with Article 12(1) of Decision No 1082/2013/EU; (b) 'major event' means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State, which concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin, or a serious incident that can affect the supply of or demand for medicinal products, or quality, safety or efficacy of medicinal products, which may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection".

[93] In this perspective, an Executive Steering Group on Shortages and Safety of Medicinal Products (the 'Medicine Shortages Steering Group – MSSG') and an Executive Steering Group on Shortages of Medical Devices (the 'Medical Device Shortages Steering Group – MDSSG') (Article 21 ff) are established within the Agency having charged with a role of technical advice. They have the competence of establishing lists with the main therapeutic groups of medicinal products and medical devices that are necessary for emergency care in to inform the preparation of the critical medicines lists to be used to respond to a public health emergency or major even.

[94] According to Article 9, the Agency shall specify the procedures and criteria for establishing and reviewing the critical medicines lists; specify the methods of and criteria for the monitoring, data collection and reporting with a basic minimum data set; develop streamlined IT monitoring and reporting systems, in coordination with the relevant national competent authorities, also creating a European shortages monitoring platform ('ESMP'), and elaborate shortage prevention and mitigation plans that include, at a minimum, information on production and supply capacity and approved production sites of the finished medicinal product and of active substances, potential alternative production sites and minimum stock levels of the medicinal product.

[95] Article 12.

[96] To the same aim, the Emergency Task Force ('ETF') is established within the Agency, entirely composed by experts, with the tasks of providing scientific advice and reviewing the available scientific data on medicinal products that have the potential to address the public health emergency, providing advice on the main aspects of clinical trial protocols and scientific recommendations with regard to the use of any medicinal product which have the potential to address public health emergencies. Its standardization function is particularly critical during a public health emergency, when it shall provide advice on clinical trial protocols as part of an accelerated scientific advice process.

health through the prevention and control of communicable diseases in humans and related special health issues, identifying and assessing current and emerging threats to human health from communicable diseases and related special health issues, to report thereon and, where appropriate, to ensure that information thereon is presented in an easily accessible way[97]. As EMA, also ECDC acquires specific standardization functions in the crisis preparedness and response[98], but it is charged also with a significant networking role[99].
As it concerns method, the ECDC operates in the following phases:
1. prevention, preparedness, and response planning, where the Centre shall provide MS and the Commission for science-based recommendations and scientific and technical expertise.
2. Operation of the Early Warning and Response System (EWRS), where the Centre shall support and assist the Commission and ensure, together with the MS, the capacity of responding to health threats in a coordinated and timely manner.
3. serious cross-border threat to health, where the Centre has to realize public health risk assessment and response coordination.
As it concerns HERA, both Regulation 2022/2371 and Regulation 2022/2372 envisages a coordination and cooperation with the other relevant Union agencies and bodies in appointing the mechanism of preparedness and response to the crises[100].
Finally, in the revision of pharmaceutical legislation, the proposal for a Regulation laying down Union procedures for the authorization and supervision of medicinal products also strengthens the EMA role in crisis preparedness and management. In fact, complementing the other EHU regulations[101], proposal sets out a framework for the activities to be deployed in synergy between private operators (marketing authorization holders, wholesale distributors, importers, and other suppliers) and public authorities (the MS, the EMA) to improve the EU's capacity to react efficiently and in a coordinated manner to support shortage management and security of supply of critical medicinal products.

[97] Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control, *OJ* L 314, 6 December 2022, p. 1 ff., Article 3, §1.

[98] Article 4.

[99] Article 5.

[100] See Recital 5. Article 33, concerning Regulation 2022/2371 evaluation, gives the Commission the task of reviewing the implementation by the HERA, as well as an assessment of the need to establish HERA as a distinct entity, considering relevant agencies or authorities active in the field of health preparedness and response.

[101] COM (2023) 193 final, 26 April 2023, Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorization and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency. V. Salvatore, *Oltre la pandemia: nuove norme nell'Unione europea per affrontare le emergenze sanitarie*, in *Ordine internazionale e diritti umani, Numero Speciale "The Day After: le Organizzazioni internazionali di fronte alle minacce globali alla salute" Supplemento al n. 1/2024* - Aprile 2024, p. 65 ff.

New organigram created by EHU acts, where HERA, EMA, and ECDC, and their internal bodies and committees[102], aims to overcome approach prevailed during the Covid-19, where lack of EU competences induced to resort to joint procurement intergovernmental structure, by reinforcing EU expertise-based legitimacy and consolidating, pending Treaty reform[103], its role in preparedness and resilience against further health emergencies. The agency main function in crisis preparedness and management appears to support MS towards standardization of methods and principles able to strengthen the EU and national health resilience. In reality, during Covid-19 pandemic standardization in medical sector showed all its limits, as authorization procedures for medical product placing on the market were considered too complicated and slow to assure the proper quantity of medical devices necessary to face the emergency. As a consequence, procedures were temporary lightened to speed up medical product supply without renouncing to a safety rapid control[104]. These decisions put in doubt the effectiveness of standardization as the better regulation method in emergency situations[105]. Centralizing in the EU agencies the standardization function both as it concerns not only security and safety requirements but also procedures to assure them could give it back its effectiveness in assuring the right balance between security and safety needs not only in ordinary times but also during crises. This choice could also assure the EU a leading role in the ongoing negotiations for the establishment of a WHO convention on pandemic prevention, preparedness, and response (so called "WHO CA+" or "Pandemic Treaty")[106]

Due the new role gained by the EU agencies, AI could become an important tool of medical product supply management, crisis preparedness, and standardization, as underlined by the European Commission in the Communication "Addressing medicine shortages in

[102] E. Cooke, in *Preparing Europe for future health threats and crises – the European Medicines Agency; ensuring safe and effective medicines and medical devices*, *Euro Surveillance*, 20 October 2022, p. 1 ff., 3; M. Kokki, A. Ammon, *Preparing Europe for future health threats and crises – key elements of the European Centre for Disease Prevention and Control's reinforced mandate*, *Euro Surveill.* 2023, p. 1 ff., 3.

[103] See *COFE Final Report*, Recommendation n. 49, p. 162.

[104] See Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat, *OJ* L 79I, 16 March 2020, p. 1 ff., establishing the possibility to use standards different from harmonized standards (as the WHO recommendations on the appropriate selection of PPE) for conformity assessment and to make PPE or medical devices available for the healthcare workers for the duration of the health crisis. Regulation 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation 2017/745 on medical devices, as regards the dates of application of certain of its provisions, *OJ* L 130, 24 April 2020, p. 18 ff., that postponed since 26 May 2020 to 26 May 2021 the application of Regulation, although allowing an anticipated application of emergency authorization procedures established in the Article 59. In sum, exceptions entered into force before the general rule. See S. Pugliese, *L'impatto dell'emergenza COVID-19 sul mercato europeo dei prodotti sanitari tra sicurezza degli approvvigionamenti, prevenzione del rischio e protezione degli investimenti*, in *Il Diritto dell'Unione europea. Osservatorio europeo*, 4 giugno 2020, p. 1 ff.

[105] For relevance of strandardization as a regulation method in uncertain situations, S. Pugliese, *Il rischio nel diritto dell'Unione europea tra principi di precauzione, proporzionalità e standardizzazione*, Bari, 2017, p.

[106] See the Zero Draft, adopted on 1 February 2023.

the EU" adopted on 24 October 2023[107]. It stressed that the COVID-19 pandemic and the Russian military aggression against Ukraine exposed Europe's supply chains dependencies and the risk that economic dependency could be weaponized. This has also heightened awareness of the risk of medicine shortfalls, experienced across all Member States and involving both original and generic medicines[108]. In this perspective, the European Commission proposed a broad set of short-term and longer-term actions to address shortages of medicines and enhance their security of supply in the EU to prevent or mitigate critical shortages at EU level and to assure a particular focus on the most critical medicines for which security of supply needs to be assured in the EU at all times, in normal times, and in times of crisis. In this strategy, a pivotal role is played by the new IT tools, that should help to harness the data behind the monitoring of demand and supply of medicines. Near to the establishment of a new European Shortages Monitoring Platform for reporting information regarding available stocks and shortages of medicines, expected to become operational in 2025, the use of AI will also be used to provide information about trends in demand and supply from existing data is envisaged, improving the European Health Data Space potentialities and the cybersecurity measures[109]. To identify the medicines more exposed to the shortage risk, while elaborating a "Critical Medicine Act", the European Commission adopted, on 12 December 2023, a first version of the Union list of critical medicines agreed to help avoid potential shortages in the EU. On 16 January, it launched a call for expression of interest to join the Critical Medicine Alliance aimed at identifying priority areas for action and propose solutions to support the supply of critical medicines in the EU including incentives for relevant projects[110].

At the same time, Commission Decision n. 8828 of 21.12.2023 on the annual work plan for 2024 of the Health Emergency Preparedness and Response Authority gives HERA the task of developing a comprehensive intelligence system for early threat identification and effective response coordination: ATHINA ('Advanced Technology for Health Intelligence and Action'), an IT system that will ensure complementarity and interoperability with existing platforms such as those of the EMA, the ECDC, and the Directorate-General for Civil Protection and Humanitarian Aid Operations (DG ECHO). Designed to be interoperable with other platforms, ATHINA is envisaged to have four different functions making it possible to (i) collect information on health threats and medical countermeasures, (ii) assess and prioritize threats in relation to medical countermeasures, (iii) map and simulate potential

[107] COM(2023) 672 final.

[108] More specifically, during the winter of 2022-2023 shortages of key medicines, such as antibiotics, triggered particular public and political concern. In June 2023, also the European Council called for urgent measures to ensure sufficient production and availability of the most critical medicines and components European Council, *Conclusions*, June 2023, p. 16 ss.

[109] For cyberattacks in heath sector, see *Enisa Threat Landscape 2023. July 2022 – June 2023*, October 2023, p.

[110] See Critical Medical Alliance Declaration. The closing of the first stage of the open call for expression of interest to join the Alliance is established on 16 February 2024.

scenarios and (iv) allow for an adequate medical countermeasures-related response in the event of an emergency. ATHINA would also include several horizontal features such as administration, collaboration, searching and visualization and reporting[111].
Furthermore, building on the ongoing process to set up a global consortium for wastewater surveillance and the EU sentinel system, HERA is creating a Global Wastewater Sentinel System – an interconnected network of sentinel systems, to facilitate the sharing of information and resources, ultimately enhancing the global capacities to identify and respond to emerging health threats. HERA will build on its collaborations with national, European, and international partners, including the WHO and the United Nations Environment Programme (UNEP), to enhance international surveillance and response capabilities to various health threats and ensure synergies, complementarities, and alignment of priorities at global level.
Nevertheless, it is not to undervalue the risk that the AI Act, adopted by European Parliament on 13 March 2024, could generate shortage of medical devises due to the difficulties of productors to comply with the heavy requirements of risk assessment and prevention[112]. This is another example of the difficult relationship between new technologies and medical supply sector and the necessity to establish an effective governance and regulation aimed at making these technologies effective instruments and decreasing their risks.

4. AI in the European Health Data Space

On 13 March 2024, the final version of the AI Act text was approved by the European Parliament. The integration of AI into the European Health Data Space (EHDS) is a topic of great interest and with potential spin-offs in the context of public health and health data management in Europe. As reported in section 2.2, the EHDS is a European Union initiative aimed at facilitating the secure exchange and access to health data between member

[111] The first modules and features of ATHINA are expected to be available by the end of 2024, thus supporting decision-making in relation to medical countermeasures. To allow for a phased development in the coming years, analysis of the requirements for outstanding modules are also planned take place in 2024, including for the 'simulation and analytics module' that would use cutting-edge technology to provide real-time insights into the complex networks of suppliers, distributors, and manufacturers. Without mandating data collection from Member States, it would assess their demand for critical medical countermeasures, taking into account of data already available from other sources, including the EMA, particularly during public health emergencies. The scope will include active pharmaceutical ingredients and intermediate ingredients/components. HERA intends to propose a structured approach for identifying issues with access, identifying possible gaps, and supporting the management of the supply networks of critical medical countermeasures, thereby facilitating the availability and accessibility of critical medical countermeasures, active pharmaceutical ingredients, intermediate ingredients/components, and raw materials. Until the ATHINA module on analytics is ready, HERA will rely on analytics as managed services that are expected to be available in early 2024. Additionally, the Epidemic Intelligence from Open Sources (EIOS) initiative is planned to be developed further in collaboration with the JRC, the ECDC and the WHO Hub for Pandemic and Epidemic Intelligence.

[112] A. Olbrechts, *How the AI Act could unintentionally impact access to healthcare*, in *Euractive*, 1° March 2023

countries and stakeholders in order to promote research, innovation and the delivery of better care.

When it comes to the integration of AI in EHDS, the need for certification according to the Medical Device Regulation (MDR) of the European Union is a crucial aspect. The Medical Device Regulation (MDR) sets strict standards to ensure the safety, performance and quality of medical devices, including those incorporating advanced technologies such as artificial intelligence (AI)[113]. The AI Act classifies AI systems according to the risk they may pose to health, safety and fundamental rights, establishing progressively more stringent safety requirements depending on the class of risk. However, the application of the regulation in the health sector presents challenges, as it is difficult for manufacturers to determine which general AI can be used for medical purposes and which could pose a high risk. This requires constant monitoring and updating of rules and regulations, taking into account the evolution of AI technologies and the needs of patients and healthcare professionals[114].

The application of AI in the EHDS, in accordance with the MDR, requires AI systems to undergo a thorough compliance assessment before being authorized for clinical use[115]. This certification process ensures that AI devices and applications meet the required quality, safety, and performance standards. The MDR's regulatory approach is of paramount importance and can help build user confidence in the effectiveness and reliability of AI systems used in healthcare. Indeed, use in this area raises several crucial legal and ethical considerations[116].

From a legal point of view, in the context of integrating artificial intelligence into the healthcare sector, the role of regulators and standard bodies is critical in ensuring that the use of AI technologies is safe and compliant with privacy and data protection regulations[117]. These bodies are tasked with outlining guidelines that include detailed instructions on how to effectively implement data protection techniques, such as pseudonymization and anonymization, that reduce the risk of identifying subjects from their data[118]. Such

[113] Regulation (Eu) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, *OJ* L 117, 5.5.2017, p. 1 ff.

[114] T. Petročnik, S. Palmieri, J.Marot, *The AI Act and European Health Data Space Proposal: Seeing 'AI to AI' With Each Other?*, Blogpost 26/2023. 30 May 2023. https://europeanlawblog.eu/2023/05/30/the-ai-act-and-european-health-data-space-proposal-seeing-ai-to-ai-with-each-other/

[115] AG Fraser, E. Biasin e al., *Artificial intelligence in medical device software and high-risk medical devices - a review of definitions, expert recommendations and regulatory initiatives*, Expert Review of Medical Devices, 2023 6, ppp. 467 ff.

[116] M. N. Alam, M. Kaur, M. S. Kabir, *Explainable AI in Healthcare: Enhancing Transparency and Trust upon Legal and Ethical Consideration*, in International Research Journal of Engineering and Technology 6, 2023, p. 828 ff.

[117] P.G.R.de Almeida, C.D dos Santos, J.S. Farias, Artificial Intelligence Regulation: a framework for governance, Ethics Inf Technol, 2021, p. 505 ff.

[118] Z. He, *From Privacy-Enhancing to Health Data Utilisation: The Traces of Anonymisation and Pseudonymisation in EU Data Protection Law*, DISO, 2023, p. 17 ff.

guidelines should specify criteria for assessing whether AI solutions comply with existing laws, such as GDPR. As we know, it imposes strict requirements for the processing of personal data, including the need for data minimization, user consent, transparency, and data security[119]. Developers of AI in healthcare, as referenced in Article 22 of the GDPR prohibiting decision based solely on automated processing if they have a significant legal impact on the individual, must incorporate safeguards into their systems that allow for appropriate human intervention, thus ensuring that clinical decisions remain under control of healthcare professionals and are not left entirely to machines[120].

On the other hand, from an ethical point of view, it is necessary to ensure transparency and accountability, respecting patient autonomy and increasingly promoting an approach to care where patients are at the center. One of the main ethical and legal dilemmas concerns the balance between the potential benefits of AI and the risk of privacy breaches. AI algorithms requires access to large volumes of data to be effective, which can put privacy of personal data at risk if not adequately protected. Patients must be adequately informed about how their data will be used, including the implications of AI use, in order to give truly informed consent. This requires transparency on the part of health authorities and AI providers about what data processing entails, how it is protected and what are the potential risks[121]. Therefore, it is essential that there be interdisciplinary collaboration among technologists, lawyers, ethicists, and healthcare professional to develop a regulatory and operational framework that balances the technological potential of AI with the needs of data protection and medical ethics[122]. This cooperative approach should aim to formulate standards that not only comply with existing laws but also anticipate emerging challenges related to the use of AI in the healthcare settings.

The tools and measures used to balance the accessibility of health data, its analysis by AI tools and the protection of personal data are essential to harness the benefits of AI in public health without compromising the privacy of individuals. This balance is particularly critical given that the effectiveness of AI depends on access to large volumes of, often sensitive, data. A key measure is the implementation of robust cybersecurity systems to protect data from unauthorized access or breach. This includes the use of advanced encryption techniques during data transmission and storage, as well as authentication and

[119] G. Sartor, F. Lagiola, *The impact of the General Data Protection Regulation (GDPR) on artificial intelligence*, 2020.

[120] R. Binns, M. Veale, *Is that your final decision? Multi-stage profiling, selective effects, and Article 22 of the GDPR*, *International Data Privacy Law*, Volume 11, Issue 4, November 2021, pp. 319 ff.

[121] K. Patel, *Ethical reflections on data-centric AI: balancing benefits and risks*, in *International Journal of Artificial Intelligence Research and Development (IJAIRD)*, Volume 2, Issue 1, January-June 2024, pp. 1-17.

[122] N. Díaz-Rodríguez, J. Del Ser, M. Coeckelbergh, M. L. De Prado, E. Herrera-Viedma, F. Herrera, *Connecting the dots in trustworthy Artificial Intelligence: From AI principles, ethics, and key requirements to responsible AI systems and regulation*, *Information Fusion*, Volume 99, 2023.

authorization systems to control access to data[123]. Federated learning can be a very useful tool for improving data access and analysis using AI, while maintaining a high level of personal data protection. Federated learning is an approach to AI and machine learning that allows multiple participants or device to collaborate in building a common model, without the data leaving its original location[124]. Another important tool is the application of principles of "privacy by design" and "privacy by default". These principles requires that personal data protection be built into technologies from their design and that default settings ensure the highest level of privacy. This means that only data necessary for a specific purpose are collected and access to data is limited to the maximum extent possible[125]. Data protection impact assessments (DPIAs) are a proactive tool that can be used to identify and mitigate privacy-related risks before AI systems are implemented. These assessments are particularly useful in high-risk areas, such as the processing of sensitive health data[126]. The establishments of independent review bodies and oversight mechanisms is essential to monitor the use of AI tools and ensure that they are used ethically and in compliance with data protection regulations. These bodies can conduct regular audits, evaluate data management practices and intervene in cases of noncompliance with privacy regulations. AI plays a fundamental role in population health management, with a focus on predictive analysis, risk assessment and therapy optimization[127]. Artificial intelligence algorithms can be used to analyze health data and identify risk factors early, enabling timely preventive interventions. This is facilitated by predictive analytics that uses modelling, data mining, AI and ML to analyze historical and current data in order to 'predict the future'. However, the success of predictive analysis depends on the quality of the data and the technological infrastructure where human supervision is required to ensure appropriate and effective interventions.

This is where EHDS and AI intersect, because the former provides a rich and vast pool of health data that are then essential for training AI algorithms. A vast database of reliable, high-quality data from a variety of sources, including national health registries, clinical data, medical images, and patient information, is essential to ensure that AI algorithms are accurate, generalizable, and representative of the diversity of clinical cases. Integrating AI

[123] A. Mughaid, I. Obeidat, L. Abualigah et al., *Intelligent cybersecurity approach for data protection in cloud computing based Internet of Things*. Int. J. Inf. Secur. 2024.

[124] N. Truong, K. Sun, S. Wang, F. Guitton, Y. Guo, *Privacy preservation in federated learning: An insightful survey from the GDPR perspective*, *Computers & Security*, Volume 110, 2021.

[125] S. Shehzadi, *Privacy by Design: Integrating Information Theoretical Privacy in AI Development*. In *Integrated Journal of Science and Technology*, 2024.

[126] A. Kelly-Lyth, A. Thomas, *Algorithmic management: Assessing the impacts of AI*, in *European Labour Law Journal*, 14(2), 2023, p. 230 ff.

[127] Sa. Alowais, Ss. Alghamdi, *Revolutionizing healthcare: the role of artificial intelligence in clinical practice*, in *BMC Medical Education* 2023 1, pp. 689 ff.; G. M. Dogheim, A. Hussain, *Patient Care through AI-driven Remote Monitoring: Analyzing the Role of Predictive Models and Intelligent Alerts in Preventive Medicine*, in *Journal of Contemporary Healthcare Analytics*, 1, pp. 94 ff.

into the EHDS facilitates data sharing across European and non-domestic markets, while complying with the GDPR, which facilitates the secure and transparent sharing of health data between Member States promoting greater interoperability and standardization of the system[128].
Certification according to the MDR, the use of AI in EHDS for research, prevention and treatment, together with the importance of reliable EHDS data for AI training, are crucial elements to optimize the integration of artificial intelligence in healthcare in Europe. Promoting easier data sharing across European and non-national markets and standardizing the system will help to improve effectiveness, efficiency, and equity in healthcare.

5. Conclusion

The proposed analysis put in evidence the importance of a proper regulation to maximize the opportunities offered by the digitalization of European Health Union while contrasting the risks. The DSA, with its mechanism of illegal content individuation and removal, is a really useful instruments to individuate and remove from the online environment the fake medicines and the health misinformation, while the AIA could become an important instrument to increase the effectiveness of procurement procedures, stockpile assessment and management, data management. It is important to underline that both the regulations are oriented to affirm in the digital service operators a culture of risk assessment, prevention, and management. Furthermore, the DSA imposes to the VLOPs to adopt or participating to the drawing up of crisis response mechanisms and crisis protocols when "where extraordinary circumstances lead to a serious threat to public security or public health in the Union or in significant parts of it"[129]. In this perspective, digital service regulation and European Health Union shares an approach aimed at assuring a more secure environment, where, both off and online, safe medical products, transparent and protect data management mechanism, and stable and affordable purchase and supply procedures are applied. It is important that also the delegated and implementing regulation, as well as the soft law (guidelines, recommendations) and voluntary instruments, aimed at involving the operators in the standard-setting (as, for example, the code of conducts and the crisis protocols) will be oriented to the risk and crisis prevention and management logic, in order to assure the realization of an effective "European Health Union" able to exploit all the potential of digital environment to assure heath security and resilience. Role played by the European Commission and Agencies in standardizing crisis preparedness and management, designed within the EHU acts, could be significantly reinforced by resorting to new technologies not

[128] P. Terzis, E. Santamaria Echeverria, *Interoperability and governance in the European Health Data Space regulation*, in *Medical Law International*, 4, pp. 368 ff.

[129] Articles 36 and 48 DSA

only to manage data, but also to reinforce their abilities to forecast crises, prevent them, and strengthen the EHU preparedness and resilience.