

***The Role of Joint Procurement Agreement (JPA) during the COVID-19 Pandemic:  
Assessing its Usefulness and Discussing its Potential to Support a European Health Union***

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*In 2014, the European Joint Procurement Agreement (JPA) was introduced as an innovative instrument to organise the procurement of vaccines and medications in preparation for pandemics. An overriding purpose of the JPA is to secure equitable and cost-effective access to medical supplies for participating EU Member States during serious health crises. This article aims to understand the current use of the JPA in response to the Covid-19 pandemic. Post analysis of the recent use of the JPA, the article will discuss how the regional procurement mechanism can be strengthened to support the development of a European Health Union. In particular, the article will firstly question if the recent four JPA procurement actions facilitated equitable access to medical supplies and services. Secondly, it will ask if the centralised procurement actions preserved the integrity of the Internal Market. The importance and originality of this study are that it addresses an instrument, the JPA, which has been largely overlooked by legal scholars, and it explores how the provisions for the joint procurement of medical countermeasures as included in Article 5 of Decision 1082/2013/EU on serious cross-border threats to health could be extended to support the functioning of a European Health Union.*

## **I. Introduction**

The Covid-19 pandemic has caused an unprecedented demand for health goods and services, requiring Member States to ensure access to medicines, medical equipment and devices and relevant technologies in a context of disrupted demand-supply chains. At the beginning of the outbreak, a shortage of Personal Protective Equipment (PPE) and ventilators deepened the already harsh crisis of several (if not all) national health systems, making it even

more difficult to treat surges of critically ill patients.<sup>1</sup> For example, it has been reported that a lack of access to appropriate PPE resulted in high rates of infection and death amongst Italian, Spanish, Irish and UK health care workers.<sup>2</sup> It has never been so urgent for Member States to pool their purchasing power to secure timely and fair acquisitions of appropriate medical devices as well as medicines and virus-testing kits.

At the beginning of April 2020, the Commission recognised that the pandemic required “swift and smart solutions and agility in dealing with an immense increase of demand for similar goods and services while certain supply chains are disrupted”, and quickly provided guidance on how Member States can best secure urgent medical supplies.<sup>3</sup> The Guidance acknowledged the need to exploit all the flexibilities of the European Directives on Public Procurement,<sup>4</sup> with a view of allowing “public buyers to purchase goods and services directly linked to the COVID-19 crisis as quickly as possible”.<sup>5</sup> It also sought to highlight which options “are available under the EU public procurement framework for the purchase of the supplies, services, and works needed to address the crisis”.<sup>6</sup> Since the beginning, it was clear, however, that those flexibilities were not sufficient to tackle the limited purchasing power yielded by individual Member States. The Guidance, hence, not only offered clarity on the use of

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<sup>1</sup> World Health Organization, *Rational use of personal protective equipment (PPE) for coronavirus disease (COVID-19): interim guidance*, 19 March 2020 No. WHO/2019-nCoV/IPC PPE\_use/2020.2.

<sup>2</sup> Emira Kursumovic, Simon Lennane and Tim M. Cook, “Deaths in healthcare workers due to COVID-19: the need for robust data and analysis”, (2020) *Anaesthesia*. See also, Crispian Balmer and Elvira Pollina, “Italy’s Lombardy asks retired health workers to join coronavirus fight” (2020) World Economic Forum, Reuters at <<https://www.weforum.org/agenda/2020/03/italys-lombardy-etired-health-workers-coronavirus-covid19-pandemic/>> Accessed 7<sup>th</sup> July 2020.

<sup>3</sup> European Commission, ‘Guidance on using the public procurement framework in the emergency situation related to the COVID-19 crisis’ [2020] OJ C1081/1. On the Guidance see Roberto Baratta, ‘EU Soft Law Instruments as a Tool to Tackle the COVID-19 Crisis: Looking at the “Guidance” on Public Procurement through the Prism of Solidarity’ (2020) 5(1) *European Papers*, European Forum 365-373.

<sup>4</sup> Council Directive 2014/24/EU of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (Public Sector Directive) OJ 2014 No. L94/65; Council Directive 2014/25/EU of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC OJ 2014 No. L94/243.

<sup>5</sup> Commission, ‘Guidance on using the public procurement framework in the emergency situation related to the COVID-19 crisis’ (n 3) 1.

<sup>6</sup> *Ibid.* 1.

accelerated urgent national public procurement procedures,<sup>7</sup> but also encouraged Member States to participate in joint procurement actions. In a similar vein, the Communication on the Global EU response to COVID-19 also highlighted the intention to invite Western Balkans countries to join the EU's Joint Procurement Agreement to enable them to participate in EU joint procurement processes for medical equipment.<sup>8</sup>

Within the framework of a coordinated EU health response, together with the “rescEU stockpile”,<sup>9</sup> adopted under the EU Civil Protection Mechanism,<sup>10</sup> the Joint Procurement Agreement (JPA) has emerged as a core instrument to support a pan-European purchasing of PPE, ventilators and devices necessary for coronavirus testing. The JPA was introduced in 2014 in order to improve Member States' purchasing power of vaccines and medications in preparation for and during serious cross-border health crises, after the H1N1 pandemic influenza shone a spotlight on the inefficiency of Member States competing against each other for scarce medical resources, resulting in stark price increases.<sup>11</sup> In the aftermath of that H1N1 pandemic, the European Council requested the Commission to commence the preparations for conducting centralised procurement actions, focusing on the procurement of vaccines in the frame of a future pandemic. On the basis of Article 168(5) TFEU,<sup>12</sup> Decision 1082/2013/EU on serious cross border threats to health was then adopted. That Decision includes a specific provision allowing the EU institutions and the Member States to engage in joint procurement procedures “with a view to the advance purchase of medical countermeasures for serious cross-border threats to health”.<sup>13</sup> As noted by Azzopardi-Muscat *et al.*, the JPA was conceived of as

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<sup>7</sup> In cases of extreme urgency, contracting authorities may use the negotiated procedure without prior publication. However, this procedure must only be used in circumstances where the contracting authority cannot comply with the time limits specified for the standard open, restricted or competitive procedures with negotiation.

<sup>8</sup> Joint Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Communication on the Global EU response to COVID-18 [2020] JOIN/2020/11 final.

<sup>9</sup> Press Release (EC), ‘COVID-19: Commission creates first ever rescEU stockpile of medical equipment’ (19 March 2020) <[https://ec.europa.eu/commission/presscorner/detail/en/ip\\_20\\_476](https://ec.europa.eu/commission/presscorner/detail/en/ip_20_476)> accessed 18 July 2020.

<sup>10</sup> The European Civil Protection Mechanism aims strengthen cooperation between the EU Member States, and participating States, in the field of civil protection, with a view to improve prevention, preparedness and response to disasters. See European Commission, “Strengthening EU Disaster Management: rescEU Solidarity with Responsibility” COM (2017) 773 final.

<sup>11</sup> See European Commission, “Explanatory Note on the Joint Procurement Mechanism” (December 2015) [https://ec.europa.eu/health/sites/health/files/preparedness\\_response/docs/jpa\\_explanatory\\_en.pdf](https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/jpa_explanatory_en.pdf) accessed 3 July 2020. Other experiences of joint purchasing experiences were attempted before. One of those is the HAPPI (Healthy Aging Public Procurement of Innovations) project, which set out one of the first joint and cross-border contracting experiences for the purchase of innovative solutions aimed at promoting active and good aging. See the report at <<https://ec.europa.eu/docsroom/documents/22102/attachments/1/translations/en/renditions/native>> accessed 18 July 2020.

<sup>12</sup> Article 168(5) TFEU allows for the adoption of “incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health (...)”.

<sup>13</sup> Decision 1082/2013/EU OJ 2013 L 293/1.

an “instrument aimed at encouraging [Member States] to increase forms of health system cooperation on a voluntary basis to ensure better public health protection at European level”.<sup>14</sup>

After the COVID-19 pandemic, which has been consistently referred to as the most serious global health emergency since the Spanish Flu,<sup>15</sup> the time seems ripe to evaluate whether the JPA has proven to be an effective tool in response to the Covid-19 pandemic and to understand whether the use of this voluntary mechanism should be further extended to support the development of a European Health Union. In that regard, we contend that improving a centralised procurement mechanism via the JPA would carve out an important role for the EU in ensuring that all EU citizens have equitable access to high quality and affordable healthcare. The article will also tentatively suggest that the JPA should be used to procure health technologies, such as innovative health medicines and medical equipment, to prevent a future health crisis. Further to these introductory remarks, we will first recall the core legal tenets of the JPA (section II), which has been largely understudied. We will then survey and critically discuss the use of the JPA during the current pandemic (section III). We will go on to examine the extent to which the JPA might support the development of a European Health Union (section IV). Recent developments in the response to the Covid-19 pandemic have intensified the need to revise the way healthcare is delivered. As other articles in this special issue suggest, it has never been timelier to review the EU’s commitment to developing a broad and deep health care policy. In that vein, the concluding section of this article assesses if the JPA should be extended to support the functioning of a European Health Union and will consider the implications of an extended use of JPA (section V).

## **II. The EU Joint Procurement Agreement (JPA): An Overview**

As mentioned above, the JPA, provided for in Article 5 of Decision 1082/2013/EU,<sup>16</sup> is a collaborative mechanism aimed to secure high-quality public medical services and goods, while ensuring the efficient use of public finances in preparation for and during instances of

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<sup>14</sup> Natasha Azzopardi-Muscat, Peter Schroder-Bäck and Helmut Brand, “The European Union Joint Procurement Agreement for cross-border health threats: what is the potential for this new mechanism of health system collaboration?” (2017) 12(1) Health Economics, Policy and Law 43-59.

<sup>15</sup> Eoin McLaughlin and Chris Colvin, “How to measure the demographic impact of a pandemic” (RTE Brainstorm) 22 June 2020.

<sup>16</sup> Article 5 provides for participating Member States to engage in a joint procurement procedure conducted pursuant to the third subparagraph of Article 104(1) of Regulation (EU, Euratom) No 966/2012 on the financial rules applicable to the general budget of the Union and pursuant to Article 133 of Commission Delegated Regulation (EU) No 1268/2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 on the financial rules applicable to the general budget of the Union, with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.

cross-border health crises. This provision refers to medical countermeasures, defined as any medicines, medical devices, or any other related goods or services that are aimed at combating serious cross-border threats to health. The latter term is defined in Article 3 lett. g) of the Decision as “a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection”. This broad definition is commonly used in governance, public health and security studies.<sup>17</sup>

As noted in the Explanatory Note,<sup>18</sup> the JPA itself “is not an international treaty, in the meaning of the Vienna Convention on the Law of Treaties”, and is not a pure EU legal act. It is an agreement, concluded between the Commission and the participating Member States that implements “a provision of a legislative act, namely, Article 5 of Decision 1082/2013/EU”. However, interestingly, Article 5 is not the JPA’s legal basis. Rather, the JPA is “considered by the Commission as a budgetary implementing measure of Decision 1082/2013/EU”. It is worth recalling that the JPA is governed and operated by two Steering Committees: the Joint Procurement Agreement Steering Committee (JPASC), and the Specific Procurement Procedure Steering Committee (SPPSC).<sup>19</sup> The JPASC, comprised of representatives from all signatories to the JPA, is tasked with the administrative matters relating to the agreement. The SPPSC is charged with the organisation of specific procurement procedures and is comprised of participating members of planned competitions and the European Commission.<sup>20</sup> In spite of such *sui generis* nature, the JPA is fully governed by EU law and under the jurisdiction of the Court of Justice of the European Union (CJEU).

The Commission has been keen in highlighting that the JPA does not entail the exercise of “the public law powers related to health policy conferred under Article 168 TFEU”, but is an arrangement that entails executive functions. The JPA has a primarily administrative function in that it provides for the Commission to determine and manage the procedures for concluding aggregated medical supplies and medical countermeasures contracts,<sup>21</sup>

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<sup>17</sup> Stefan Elbe, Anne Roemer-Mahler and Christopher Long, “Medical countermeasures for national security: A new government role in the pharmaceuticalization of society” (2015) 131 *Social Science & Medicine* 263.

<sup>18</sup> See Commission, “Explanatory Note on the Joint Procurement Mechanism” (n 12) 1.

<sup>19</sup> Joint Procurement Agreement, Articles 5 and 6.

<sup>20</sup> Joint Procurement Agreement, Articles 5 and 6.

<sup>21</sup> Article 2 of the JPA provides that medical countermeasures are any medicines, medical devices, other goods or services that are aimed at combating serious cross-border threats to health, as referred to in Decision 1082/2013/EU.

streamlining the procedure, but also, as Sanchez-Graells contends, generating buying power.<sup>22</sup> Furthermore, from a merely legal perspective, being voluntary and complementary to national procurement procedures, the JPA still falls squarely within the scope of pure “incentivisation” measures, and could be considered somewhat exemplary of the EU supporting role in the health field. However, it is evident that the JPA, being a *sui generis* legal instrument rooted in Article 168 TFEU, demonstrates the reach of the latter legal basis. Hervey in this special issue,<sup>23</sup> as well as Purnagen et al. suggest that EU competences to support and coordinate Member States’ action and “resource activities” in the health field are significant.<sup>24</sup> In that vein, the JPA can be seen as another way to support a more collaborative pan-European health care (or to create one). It complements other financial mechanisms, such as the “EU4Health” initiative adopted to boost the EU’s preparedness for major cross border health threats. Furthermore, the JPA provides evidence that the teleological approach to cross-border health has a deep economic backlash and tallies with the exercise of (extremely wide) Internal Market powers.<sup>25</sup>

In practice, the JPA assists participating Member States in accessing high-quality in-demand medicines and medical supplies by organising procurement at a regional level. EU funds are not used to purchase the supplies on behalf of the participating Member States. Instead, the JPA is a centralised and quick procurement mechanism that facilitates the purchasing competition, including managing the call for competition notices, the acceptance and evaluation of submitted bids. Participating States can then purchase from the concluded contracts, but only if they had agreed to participate in the centralised agreement at the launch of the procurement procedure. At present total of 37 countries, which include EU Member

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<sup>22</sup> Albert Sánchez Graells, “Procurement in the time of COVID-19” (2020) 71(1) Northern Ireland Legal Quarterly 81-87.

<sup>23</sup> Tamara Hervey and Anniek de Ruijter, “The Dynamic Potential of European Union Health Law” (2020) European Journal of Risk Regulation.

<sup>24</sup> Kai P. Purnhagen, Anniek De Ruijter, Mark L. Flear, Tamara K. Hervey, Alexia Herwig, “More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak” (2020) 11(2) European Journal of Risk Regulation 297-306.

<sup>25</sup> It should be noted that the Public Sector Directive explicitly provides for contracting authorities from different Member States to collaborate in the award of public contracts. Public Sector Directive, article 39. In circumstances where the procurement is centralised through one national procurement body, the purchasing activities are governed by the national rules of the Member State where the central purchasing body is located. Certain Member States have relied on that Directive to conduct joint procurements for medicines and medical devices. One of the most notable examples of cross-border collaborative actions is the acquisitions for a BCG vaccine undertaken by Latvia, Estonia and Lithuania under the Baltic Partnership Agreement. Since 2012, other collaborative activities for innovative medicines and medical devices have been conducted, including; a BeNeLuxA Agreement between Belgium, Netherlands, Luxembourg and Austria; the Nordic Pharmaceuticals Forum between Denmark, Iceland, Norway and Sweden; Southern European initiative between Greece, Bulgaria, Spain, Cyprus, Malta, Italy and Portugal; and Central Eastern European and South Eastern European Countries Initiative between Romania, Bulgaria, Croatia, Latvia, Poland, Serbia, Slovakia, Slovenia, Republic of Moldova, and FYR Macedonia.

States, EEA countries and candidate countries, have signed the JPA to procure medical countermeasures.<sup>26</sup>

It is evident that an overriding objective of the JPA is to secure equitable access to medical supplies at a reasonable price for participating countries. It is well known that competition in the pharmaceuticals and medical technologies market is limited, due to the mergers of global companies in the 1990s.<sup>27</sup> Furthermore, EU multilateral and bilateral trade deals limited the negotiating power of individual States and paved the way for the now embedded use of set “Managed Entry Agreements” (MEAs).<sup>28</sup> Hence, individual Member States have limited purchasing power when procuring patented or innovative medicines and technologies or limited in-demand medicines, which often results in Member States procuring medical supplies at a price significantly higher than the market cost.<sup>29</sup> The JPA has been conceived as a tool to overcome those issues by strengthening buying power, relying on the sharing of best practices to improve transparency of pricing structures, and to ultimately derive benefits from risk-sharing and economies of scale.<sup>30</sup> Sánchez Graells reminds us that, while the JPA boosts participating States’ buying power, securing financial savings and access to in-demand medicines, it is “highly dependent on the supply-side structure of the relevant markets”.<sup>31</sup>

It is also worth recalling that the JPA provides for the distribution of supplies on a needs basis.<sup>32</sup> Centralised procurement actions must not result in a distortion of competition or a

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<sup>26</sup> See Commission, “Signing ceremonies for Joint Procurement Agreement” <[https://ec.europa.eu/health/preparedness\\_response/joint\\_procurement/jpa\\_signature\\_en](https://ec.europa.eu/health/preparedness_response/joint_procurement/jpa_signature_en)> accessed 1 July 2020. On the UK position see M. Flear, “EU joint procurement – UK’s delayed participation undermines the NHS and risks lives” <<https://ukandeu.ac.uk/eu-joint-procurement-uks-delayed-participation-undermines-the-nhs-and-risks-lives/>> accessed 13 July 2020.

<sup>27</sup> WHO Regional Office for Europe, “How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe?” (2016) Copenhagen, WHO Regional Office for Europe Publications <[https://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0009/331992/PB21.pdf](https://www.euro.who.int/__data/assets/pdf_file/0009/331992/PB21.pdf)> accessed 15 July 2020.

<sup>28</sup> It has been argued that the use of multilateral and bilateral trade deals which removed tariff barriers provided companies with the opportunities to develop confidential price agreements and MEAs. See Gesundheit Österreich Forschung- und Planungs GmbH, “Study on enhanced cross-country coordination in the area of pharmaceutical product pricing” (European Commission, DG Health and Food Safety, 2015), <[http://ec.europa.eu/health/systems\\_performance\\_assessment/docs/pharmaproductpricing\\_frep\\_en.pdf](http://ec.europa.eu/health/systems_performance_assessment/docs/pharmaproductpricing_frep_en.pdf)> accessed 15<sup>th</sup> July 2020. See also WHO Regional Office for Europe (n 27) 10.

<sup>29</sup> Mark Lawrence Johnson, Jean Belin, Frederic Dorandeu, and Marianne Guille, “Strengthening the cost effectiveness of medical countermeasure development against rare biological threats: The Ebola outbreak” (2017) 31(6) *Pharmaceutical Medicine* 423-426.

<sup>30</sup> Silvio Ponzio, “Joint Procurement and Innovation in the new EU Directive and in some EU-funded projects” (2014) *Ius Publicum Network Review* <[https://iris.unito.it/retrieve/handle/2318/157791/134084/Ponzio\\_IusPub\\_JointProc\\_def.pdf](https://iris.unito.it/retrieve/handle/2318/157791/134084/Ponzio_IusPub_JointProc_def.pdf)> accessed 15 July 2020.

<sup>31</sup> Sánchez Graells (n 22) 85.

<sup>32</sup> See Commission, “Explanatory Note on the Joint Procurement Mechanism” (n 11) 24.

restriction of trade, and must not create a discriminatory direct financial impact on the budget of non-participating Member States.<sup>33</sup> Concluded contracts may not be used to create a barrier to trade or hinder access to the procured medical supplies, and as such, no exclusivity agreements may be included in the terms and conditions. Indeed, participating Member States may independently procure similar supplies simultaneously to the centralised contracts.<sup>34</sup>

Critics of centralised procurement argue that large aggregation of contracts can often result in the award of extremely high-value contracts to single suppliers or to a small number of large multinational companies, who have often submitted the lowest-priced tender.<sup>35</sup> Single-supplier contracts may, thus, hinder competition in the marketplace, as competitors and small innovative companies are essentially locked out of a public market for a set period, which is generally around four years.<sup>36</sup> While these concerns should not be dismissed, and should be addressed in the centralised acquisition policies and procurement activities, there are many benefits to the use of the JPA. First, since the H1N1 outbreak demonstrated Member States' inability to access cost-effective medical supplies and vaccines,<sup>37</sup> the JPA enhances smaller States' buying power and assists with the fair distribution of in-demand medicines and medical supplies during times of health emergencies. Participating Member States also benefit from reduced administrative costs and reap financial benefits from economies of scale secured by suppliers. While an unintended outcome of the use of the JPA is its potential to curb protectionist purchasing, incentives for protectionist purchasing will be diluted, if the agreement is successfully used to achieve cost-savings through competitive cross-border tendering and price convergence.<sup>38</sup> Secondly, while suppliers of medical equipment and the pharmaceutical sector may have diverging opinions on the use of centralised contracts, the JPA may provide economic operators with an opportunity to expand their customer base. Even though the pharma sector may lose out on the financial benefits gained from the use of

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<sup>33</sup> WHO Regional Office for Europe (n 27) 15.

<sup>34</sup> For example, if a Member State is participating in a centralised contract for PPE, the State retains the autonomy to conduct a separate national competition for the provision of PPE. Smaller companies who do not have the capacity or capability to compete for the centralised contract, may find it easier to meet the decreased demands of the national contract. By engaging in more than one procurement competition, Member States may secure greater access to in-demand products from numerous suppliers.

<sup>35</sup> Gian Luigi Albano and Marco Sparro, "Flexible Strategies for Centralized Public Procurement" (2010) 1(2) *Review of Economics and Institutions*; Giancarlo Spagnolo and Chris Yukins, "Lots – the Economic and Legal challenges of centralised procurement", in Gustavo Piga and Tunde Tátrai, "Public procurement policy" (Routledge, 2015) 61.

<sup>36</sup> G. Seidman and R. Atun, "Do changes to supply chains and procurement processes yield cost savings and improve availability of pharmaceuticals, vaccines or health products? A systematic review of evidence from low-income and middle-income countries" (2017) 2 *BMJ Global Health* 2.

<sup>37</sup> Natasha Azzopardi-Muscat, Peter Schroder-Bäck and Helmut Brand (n 13) 51

<sup>38</sup> Christopher Bovis, "Research handbook on EU public procurement law" (Edward Elgar Publishing, 2016) p. xv.



individual pricing agreements, the centralised contract open or create new opportunities for interested economic operators.<sup>39</sup> In particular, small innovative start-ups might benefit from the centralised approach. However, this is only so if it is managed in a strategic manner, namely, through the division of larger contracts into smaller, more manageable, lots.<sup>40</sup> Thirdly, participating in the agreement requires a strong political trust and willingness to share expertise and skills.<sup>41</sup> Continued use of the JPA will embed mutual trust between signatories, as the mechanism is used to pool resources for the collective benefit.<sup>42</sup>

### III. Use of the JPA in response to the Covid-19 pandemic

To date, the centralised procurement actions have focussed on the procurement of vaccines, antivirals and medical countermeasures for serious cross-border threats to health.<sup>43</sup> Since February 2020, the Commission launched six procurement competitions to purchase medical supplies and equipment.<sup>44</sup> Two procurement competitions related to PPE were conducted in February and March. The first one did not lead to the award of a contract.<sup>45</sup> The second tendering attempt was, by contrast, successful, and a framework agreement was awarded in March with an estimated budget ceiling of €97 million.<sup>46</sup> A framework agreement was awarded to two companies with 20 Member States participating in the procedure.<sup>47</sup> In March, three further competitions were concluded for ventilators, goggles, face shields and masks, and laboratory equipment, including testing kits. Up to 26 Member States are

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<sup>39</sup> Baldi, Simona and Davide Vannon, “The impact of centralization, corruption and institutional quality on procurement prices: an application to pharmaceutical purchasing in Italy.” (2014) Carlo Alberto Notebooks 379 (2014).

<sup>40</sup> Anthony Flynn and Paul Davis, “The policy–practice divide and SME-friendly public procurement” (2016) 34(3) *Environment and Planning C: Government and Policy* 559. See also, Commission Implementing Decision C(2016) 63 final of 18.01.16 on the adoption of the work programme for 2016 and the financing for the implementation of the Programme for the Competitiveness of Enterprises and small and medium-sized enterprises.

<sup>41</sup> Francesco Mennini, Nicola Dimitri, Lara Gitto, Francois Lichere, and Gustavo Piga, “Joint procurement and the EU perspective”, in Gustavo Piga and Tunde Tátrai, *Law and Economics of Public Procurement Reforms* (Routledge, 2017).

<sup>42</sup> WHO Regional Office for Europe (n 30) 7.

<sup>43</sup> The first procurement competition conducted under the JPA in 2016 for the provision of Botulinum anti-toxin. In 2019 framework contracts were concluded for the production and supply of pandemic influenza vaccines. 15 signatories purchased from the concluded contract.

<sup>44</sup> Commission, “Overview of the Commission’s response” (7 July 2020) <[https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/overview-commissions-response\\_en](https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/overview-commissions-response_en)> accessed 15 July 2020.

<sup>45</sup> See Contract Award Notice 2020/S 051-119976 of 12 March 2020.

<sup>46</sup> Commission, “Covid-19 Response – Public Health” < [https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health\\_en](https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health_en). > Accessed 17 July 2020.

<sup>47</sup> Contracts were awarded to Medicom Healthcare B.V. and GYZ GmbH. See Contract Award Notice 2020/S 100-238632.

participating in these framework agreements with a budget ceiling of over €2.8 billion.<sup>48</sup> A final competition for ICU medicines was initiated in June and is ongoing.<sup>49</sup> On the whole, the Report on the EU budget, released in June 2020, stated that joint procurement for gloves and coveralls (for a maximum amount of €1.4 billion), eye and respiratory protection (for a maximum amount of €150 million), ventilators/respirators (for a maximum amount of €790 million) and laboratory equipment were concluded.<sup>50</sup>

It was already highlighted that increased voluntary collaboration between countries in the procurement of health technologies enables cross-country sharing experience and strengthens bargaining power, mitigating overly high transaction costs by pooling skills, capacities and through joint negotiations.<sup>51</sup> The Covid-19 pandemic has shown that those strengths have been appreciated by Member States and there is a growing acceptance and use of centralised cross-border procurement in the health sector. This is also evident in the participation of countries that were initially reluctant, such as Poland and Sweden. The number of signatories to the JPA has increased from 6 to 37 since its adoption in 2014.<sup>52</sup> There have been no legal challenges to the CJEU to date on the award and management of contracts organised, which would loosely indicate that the agreement is not endangering the integrity of the Internal Market, and is not perceived as a challenge to the organization of national healthcare systems nor to the public procurement structures.<sup>53</sup> While the States have the right of withdrawal at any time and to pursue national procurement strategies, the pandemic seems to show a convergence towards such a centralised mechanism. This is possibly an important step to foster cooperation in future coordinated health sector activities.

Furthermore, one of the key characteristics of the JPA is its transparent nature:<sup>54</sup> calls for competition notices are freely and openly advertised on the Official Journal (OJ); interested economic operators are provided with sufficient information in the call for competition notices

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<sup>48</sup> Commission, “Covid-19 Response – Public Health” (n 46).

<sup>49</sup> Ibid.

<sup>50</sup> Council, “EU Budget for 2020” (25 June 2020) <<https://www.consilium.europa.eu/en/policies/the-eu-budget/eu-annual-budget/2020-budget/>> Accessed 14 July 2020.

<sup>51</sup> WHO Regional Office for Europe (n 30) 7.

<sup>52</sup> See Commission, “Signing ceremonies for Joint Procurement Agreement” <[https://ec.europa.eu/health/preparedness\\_response/joint\\_procurement/jpa\\_signature\\_en](https://ec.europa.eu/health/preparedness_response/joint_procurement/jpa_signature_en)>. Accessed 1 July 2020.

<sup>53</sup> Aggrieved unsuccessful bidders, or interested economic operators or individuals can take an action against the CJEU. See Joint Procurement Agreement, article 41.

<sup>54</sup> The Public Sector Directive similarly requires contracting authorities to comply with the TFEU principles of transparency, equal treatment, non-discrimination and proportionality. See Case C-324/98 *Telaustria Verlags GmbH and Telefonadress GmbH v Telekom Austria AG* [2000] ECR I-10745, Case C-6/05 *Medipac-Kazantzidis AE v. Venizelio-Panania* [2007] ECR I-4557.

to assess if it is appropriate to tender for the contract;<sup>55</sup> selection, evaluation criteria and the award procedure are made fully available to interested companies;<sup>56</sup> and, at the end of the competitive process, a contract award notice is published on the OJ.<sup>57</sup> Furthermore, additional information on the cost and contract type is published on the Commission official website. Transparency supports trust in the centralised procurement, alongside being necessary (albeit arguably insufficient) to ensure accountability and legitimacy of the procurement decision-making.

Even though some scholars suggest that there are operational gaps which require urgent reasoning and intervention by Union institutions,<sup>58</sup> we contend that procedures set out in the JPA have facilitated a balance between promoting competition in the marketplace and securing reasonable cost and high-quality medical supplies and services.<sup>59</sup> All of the recent Covid-19 response contracts were awarded to more than one supplier, and the contract for laboratory equipment was divided into 29 separate lots. Sub-dividing large contracts into manageable sections offer smaller companies and innovative start-ups the opportunities to bid for a lot of the overall contract. Furthermore, the competitive decision-making processes and the administrative management of the procurement competitions appear to enhance price transparency. At this time, there is little evidence to demonstrate how the JPA promoted access to relevant medical supplies required to manage the Covid-19 pandemic, and, as already noted by Sdanganelli,<sup>60</sup> it will be essential to gather data on that. Nonetheless, there is anecdotal evidence that the joint procurement of masks, gloves, goggles, face-shields, surgical masks provided relief to Italy and Spain the countries first affected by the pandemic.

While, this section has focused on the administrative actions of the JPA, its overall political and economic importance within the EU should not be underestimated. Procurement plans are “at the frontline of countries’ responses to the COVID-19 crisis”.<sup>61</sup> Initial

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<sup>55</sup> Joint Procurement Agreement, article 19.

<sup>56</sup> Joint Procurement Agreement, article 18.

<sup>57</sup> Joint Procurement Agreement, article 18.

<sup>58</sup> G. Sdanganelli, “Il modello europeo degli acquisti congiunti nella gestione degli eventi rischiosi per la salute pubblica”, DPCE online, 2344 <<http://www.dpceonline.it/index.php/dpceonline/article/view/1005/979>> accessed 14 September 2020.

<sup>59</sup> The permissible competitive procedures set out in the JPA are loosely based on the procedures set out in the Public Sector Directive and are underpinned by the principles of transparency and non-discrimination, and by a general duty of sincere cooperation.

<sup>60</sup> G. Sdanganelli, “Il modello europeo degli acquisti congiunti nella gestione degli eventi rischiosi per la salute pubblica” (n 58)2344.

<sup>61</sup> OECD, “Stocktaking report on the immediate public procurement and infrastructure responses to Covid-19” (June, 2020) OECD Policy Response to Coronavirus (Covid-19) <<http://www.oecd.org/coronavirus/policy-responses/stocktaking-report-on-immediate-public-procurement-and-infrastructure-responses-to-covid-19-248d0646/>> accessed 14 September 2020.

procurement responses to the pandemic in February were less than desirable, with countries engaging in temporary nationalistic market behaviours and delayed use of the JPA. Improvements were quickly made, and nationalistic behaviours were replaced with acts of solidarity amongst Member States, which respond to the principle of sincere cooperation enshrined in Article 4 TEU.<sup>62</sup> Participating countries to the JPA pooled their purchasing power to leverage market control to secure acutely scarce PPE, diagnostics and clinical management. Early research indicate that public bodies which procured medical supplies at a local or national level were at greater risk of price gouging and not securing access to crucial medical goods.<sup>63</sup>

The JPA as example of sincere cooperation stands out given that global solidarity on the equitable distribution of scarce medical supplies has been far less evident. There have been worrying reports that the US has purchased significant volumes of the drug Remdesivir - a drug which clinical trials have shown if intravenously-administered can help shorten hospital recovery times for patients suffering with Covid-19- with that *de facto* preventing other States from accessing that medicinal product.<sup>64</sup> In particular, in June 2020, the US Department of Health and Human Services announced that it concluded a significant contract with Gilead, the company that produces the Remdesivir, securing all of the company's production of the drug for July and 90 per cent of its production in August and September.<sup>65</sup> Other nations and regions public procurement actions were stalled or delayed due to the US's efforts to "obtain political advantage".<sup>66</sup> In fact, European Member States have only been able to access new supplies of Remdesivir since August 2020.<sup>67</sup> The US's unwillingness to support global equitable access to in-demand medicines and medical equipment is further witnessed by its' non-participation in emergency Covid-19 related international measures.<sup>68</sup> Atkinson *et al.* claim that the US's

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<sup>62</sup> Commission, "Coronavirus: European Solidarity in action" (2020) <[https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response-0/coronavirus-european-solidarity-action\\_en#snapshots-of-european-solidarity](https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response-0/coronavirus-european-solidarity-action_en#snapshots-of-european-solidarity)> Accessed 14 September 2020.

<sup>63</sup> Jenny Frederic, "Economic Resilience, Globalization and Market Governance: Facing the COVID-19 Test." (2020) OECD Competition Committee. See also, Kathrin Frauscher, Hera Hussain and Sophie Brown, "5 procurement strategies for navigating the COVID-19 crisis from around the world" (2020) <<https://www.open-contracting.org/2020/04/08/5-procurement-strategies-for-navigating-the-covid-19-crisis-from-around-the-world>> accessed 15 September 2020.

<sup>64</sup> The Irish Times, "World takes stock of Covid-19 drug after US snaps up supplies" (1 July 2020) <<https://www.irishtimes.com/news/world/us/world-takes-stock-of-covid-19-drug-after-us-snaps-up-supplies-1.4293396>> accessed 15 September 2020.

<sup>65</sup> The US Department of Health and Human Services, "Trump Administration Secures New Supplies of Remdesivir for the United States" (29 June 2020) <<https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html>> accessed 15 September 2020.

<sup>66</sup> Christopher L. Atkinson, Clifford McCue, Eric Prier, and Allison M. Atkinson (n 66) 6.

<sup>67</sup> Commission, "European Commission secures EU access to Remdesivir for treatment of COVID-19" (29 July 2020) <[https://ec.europa.eu/commission/presscorner/detail/en/ip\\_20\\_1416](https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1416)> Accessed 15 September 2020.

<sup>68</sup> Most notably, the US is not participating in the Covid-19 Vaccines Global Access (Covax) Facility.

dominant purchasing adversely affected markets “in ways that caused avoidable shortages of critical goods and supplies”.<sup>69</sup>

As waves of the pandemic continue to wash over the world, recently, the WHO at the request of the UN Secretary-General and in support of the UN Crisis Management Team, established a Supply Chain Task Force which implements the COVID-19 Supply Chain System (CSCS) and oversees a coordinated approach of the procurement of supplies to ensure maximum market access.<sup>70</sup> While this is an important step at the global level, the role of the JPA within the EU and, more broadly, in the EEA, remains key. Global measures are important, but they are unlikely to remove the difficulties individual countries may face securing scarce medical supplies, and we contend that the JPA will continue to play a vital role in securing competitive access to medical goods and services as it has been in the last few months.

#### **IV. The JPA as a stepping stone towards a European Health Union?**

After a short overview of the JPA and a critical survey of its use during the pandemic, we now move on to question whether the current scope and administrative functions of the JPA are sufficient or could be extended further and whether this would be possible under the current legal basis of Article 5 of Decision 1082/2013/EU. As it stands, the JPA framework and legal basis focus on the organisation for the procurement of vaccines and medications in preparation and management of cross-border health crises. A broad interpretation of what constitutes serious cross-border threats to health could possibly support centralised procurement for the acquisitions of health technologies, aimed at managing (and possibly preventing) another pandemic (should it occur) and increase a degree of interoperability between healthcare systems. Such a broad interpretation, in light of Article 168 TFEU as a whole (but, arguably, also of Article 35 of the Charter of Fundamental Rights) would inevitably give rise to risks of challenge in front of the CJEU. It would hence be important to build on the momentum and the

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<sup>69</sup> Christopher L. Atkinson, Clifford McCue, Eric Prier, and Allison M. Atkinson, “Supply Chain Manipulation, Misrepresentation, and Magical Thinking During the COVID-19 Pandemic.” (2020) (50) *The American Review of Public Administration* 6.

<sup>70</sup> World Health Organisation, “COVID-19 Supply Chain System: Requesting and Receiving Supplies” (2020) <<https://www.who.int/publications/m/item/covid-19-supply-chain-system-requesting-and-receiving-supplies>> accessed 15 September 2020. In May 2020, the European Commission also announced a contribution of €400 million in guarantees to support the COVAX Facility. The Facility is co-led by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO, and is driven by the purpose “to accelerate the development and manufacture of COVID-19 vaccines and to guarantee fair and equitable access for every country in the world” (Commission, “Coronavirus Global Response: Commission joins the COVID-19 Vaccine Global Access Facility (COVAX)” (31 August 2020) <[https://ec.europa.eu/commission/presscorner/detail/en/ip\\_20\\_1540](https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1540)> accessed 15 September 2020).

convergence achieved on the current JPA to enact another decision (or to amend the current one) to allow for the purchase of advanced health technologies.<sup>71</sup> At the time of its approval, “the strong normative public health basis for action” was the main driver that led to a “quasi-unanimous agreement to the principle of pursuing a mechanism for joint procurement for cross-border threats”.<sup>72</sup> In the current context, where we have fragile national healthcare systems, the pandemic has heightened the need for European (and global) collaboration.<sup>73</sup> Joint purchase of those technologies would support the digital transformation of national health care systems,<sup>74</sup> would increase cross-border cooperation and complement the realisation of the objectives pursued by the Patients’ Rights Directive. Collaborative cross-border health care will also assist with reducing the costs associated with new technologies: it can be conducted in a manner that ensures the technology can be developed and updated in partnership with the participating Member States. More digitally integrated healthcare would also improve access to health care for vulnerable groups,<sup>75</sup> which have been particularly affected by Covid-19.

Even if an extended JPA remains voluntary, and hence fully dependent on the political will of the Member States, the fear of future pandemic shocks might prompt the Member States to prepare in advance and enhance their coordination. As noted above, the Covid-19 experience seems to show that participating Member States and contracted economic operators benefit financially from the potential economies of scale and that extended use of centralised procurement can limit suppliers’ discretion in price variances between States. It is clear, however, that in order for Member States to voluntarily agree to centralised procurement, there needs to be a level of trust and confidence in the process used, to ensure that the centralised procedures will provide improved costs and access to a wider variety of medical supplies.<sup>76</sup> In particular, we argue that a new centralised procurement regulation could promote the use of an

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<sup>71</sup> The latter refers to the “application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of life”. World Health Organisation Regional Office for Europe, “Access to New Medicines in Europe: Technical Review of Policy Initiatives and Opportunities for Collaboration and Research”, (2015) Copenhagen: World Health Organisation.

<sup>72</sup> Natasha Azzopardi-Muscat, Peter Schroder-Bäck and Helmut Brand (n 13) 51.

<sup>73</sup> European Parliament, “Time for a European Health Union” (5 May 2020) <<https://www.theparliamentmagazine.eu/news/article/time-for-a-european-health-union>> accessed 10 July 2020.

<sup>74</sup> Jakob Edler and Jillian Yeow, Connecting demand and supply: The role of intermediation in public procurement of innovation (2016) 45(2) Research Policy 412-416.

<sup>75</sup> Julie Doyle, Evert-Jan, Hoogerwerf, Janneke Kuiper, Emma Murphy, Caoimhe Hannigan, John Dinsmore, et al., “Designing a Proactive, Person-Centred Digital Integrated Care System” (2017) 17(5) International Journal of Integrated Care 211. See also Malcolm MacLachlan, David Banes, Diane Bell, E.J. Hoogerwerf, et al., “Assistive technology policy: a position paper from the first global research, innovation, and education on assistive technology” (2018) 13(5) Disability and Rehabilitation: Assistive Technology 454-466.

<sup>76</sup> Joint procurement is not entirely new. Member States have previously participated in the DG CLIMA framework of the “Joint Procurement Agreement of common auction platforms” dealing with the organisation of the auctioning of CO2 certificates in each Member State.

“Innovation Partnership Procedure” which would mirror the procedure set out in the Public Sector Directive.<sup>77</sup> This procedure assists procurers in purchasing innovative solutions which require significant sums of public investment.<sup>78</sup> The innovation partnership procedure is suitable for contracting authorities which require the design and development of an innovative product or service which is not commercially available on the market.<sup>79</sup> A demand-led innovation procedure is appropriate for the procurement of potential devices, equipment and health information technologies.<sup>80</sup>

The use of the JPA to enhance a technological revolution in healthcare would solve at least some of the problems associated with the acquisition of health technologies, but could be a practical stepping stone for a closer “healthcare Union”. It might be argued that this would bring EU health law even more within the Internal Market domain and would increase the level of economic considerations in such a politically sensitive policy area. However, an economic instrument like the JPA, which, as yet, has attracted very little attention in legal scholarship, might be the key to unlock a further cooperation of Member States’ healthcare system, supporting the creation of an innovative, accessible and inclusive European Health Union.

## V. Conclusion

It is quite early to fully appreciate the economic benefits of the recent acquisitions conducted through the JPA. The contracts for the provision of PPE and ventilators only came into operation in April 2020, and it will be necessary for the Commission to assess the use, availability and costs of the supplies. It is also imperative for the Commission to conduct an assessment on whether the on-going contracts do preserve competition in the Internal Market, in a disrupted demand-supply environment. However, while, the information on the actual economic effects of the aggregated contracts is limited, we contend that there are some important lessons to be drawn from the procedures used during the Covid-19 pandemic. Concluded contracts are assisting with the fair distribution of in-demand medicines and medical supplies. Furthermore, the early findings discussed in this article suggest that the use of the JPA is underpinned by a growing level of political willingness and mutual trust. It is this

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<sup>77</sup> See Council Directive 2014/24/EU, article 31.

<sup>78</sup> For low-value contracts, the mechanism could follow a Pre-commercial Procurement Procedure. See Commission, “Pre-commercial Procurement: driving innovation to ensure sustainable high-quality public services in Europe” (Communication) COM (2007) 0799 final.

<sup>79</sup> Elisabetta Iossa, Federico Biagi and Paola Valbonesi, “Pre-commercial procurement, procurement of innovative solutions and innovation partnerships in the EU: rationale and strategy” (2018) 27(8) *Economics of Innovation and New Technology* 730.

<sup>80</sup> Marta Andhov, “Innovation Partnership in the New Public Procurement Regime – A Shift of Focus from Procedural to Contractual Issues?” (2015) 2 *Public Procurement Law Review* 48-62.

willingness to pool overstretched national resources for the collective good, which suggests that the EU should now push the JPA further. A centralised procurement system, aimed at the acquisition of health technologies, would not only enhance the EU's preparedness for future pandemics, but arguably bring Member States closer to the creation of European Health Union.