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EU solidarity and policy in fighting infectious diseases: state of play, obstacles, citizen preferences and ways forward

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Abstract

In this paper we confront the role the EU traditionally plays in the domain of health with the urgent need for collective action triggered by the corona virus pandemic. In the face of such a crisis, we argue that the joint procurement, stockpiling and allocation of medical countermeasures is a key component of true European solidarity, besides maintaining the integrity of the Single Market. We present the first results of a survey experiment taken *before* the current crisis on citizens' attitudes towards centralizing at the EU level of policies to combat infectious diseases, which indicates considerable support. We conclude that a more robust policy framework with substantial centralization of procurement, stockpiling and allocation is warranted.

Keywords Covid-19, medicines, European Union, centralization.

JEL Codes: I10, I18.

Introduction

Since a few weeks the world has been in the throes of the outbreak of COVID-19. At the moment of writing, there have been over 950,000 confirmed cases and almost 50,000 deaths worldwide. Healthcare systems are completely overburdened, while the economic implications are devastating. Vaccines are the number one counter measure to stop this and future pandemic outbreaks and save human life. And yet, the development and dissemination of just such vaccines and medical countermeasures generally are where the political fights can be fiercest. The US government tried to secure rights and access to EU-based vaccine developers through its legal, political and financial power – flouting global solidarity regarding access to counter measures against the COVID-19 outbreak. Among other moves, it has reportedly sought to buy one of the companies based in Germany that has been building a vaccine dossier expected to be centrally authorized in June or July of this year. Apparently, Germany has prevented the completion of this sale and its government is now working with the EU to come up with a more general strategy and solution to address this kind of challenge, and to promote more solidarity in the pooling of resources and risk. This incident might not be the last attempt, by the US or any other country or party, to go it alone and thus disregard the need for global solidarity. In a broader sense, organizing societal solidarity is also a counter-measure against the wider implications of a serious disease outbreak, for instance in economic terms. However, this paper focuses on narrower aspect of solidarity: within the domain of healthcare, what are the best policy options for organizing EU solidarity with regard to medicinal counter-measures to infectious diseases?

This paper addresses this question on the backdrop of a legal and economic policy analysis, informed research on public attitudes. We first discuss what 'EU health solidarity' means. Solidarity is a well-known organizing principle in national health care systems, guiding the distribution and rationalization of the public goods involved in this domain. This principle is also recognized in the EU's legal constellation, although there has always been a tension between this *domestic* solidarity principle and the EU's internal market principles. Second, we outline the manner in which the EU promises to organize collective action based on true *European* solidarity to address pandemics. This promise could have come from the

Treaty changes with the Lisbon amendments and new regulation adopted after the 2009 Swine Flu outbreak; nevertheless, the EU's competences in health remain relatively limited, and even after the Swine Flu the way forward proved to be difficult, given significant hesitations in Member States. Third, we empirically report results from a survey experiment among a representative sample of 400 Dutch citizens (yielding 2400 judged policy packages) surveyed *before* the outbreak of the current crisis. The experiment explores what the EU role should be with respect to organizing solidarity regarding access to pandemic medicines.

The conclusions emerging from these three steps are clear: there are good social, economic and legal arguments, and likely also meaningful public support for procuring, stockpiling and allocating medical counter measures to COVID-19 and other infectious diseases at the EU level. This eliminates the inefficiency associated with excess demand and excess supply co-existing in various parts of the EU. More importantly, it allows massive firepower to be instantly targeted to wherever an outbreak starts. And if well-organized *ex ante*, it secures credible commitments by all Member States to the cooperation that is needed *ex post*, when a crisis hits.

1. Solidarity

1.1 Solidarity in public health and health care

Health policy and law pertains to that area of our life where we face shared risks and opportunities related to life, disease and mortality.[2] Solidarity in health is generally linked to a sense of commitment to help those in need, even if we do not know exactly whom we are helping. The donation of blood in this regard is often cited as how – in the context of shared risks and human suffering – solidarity is a driving force for

[2] Anniek de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press 2019). Anniek de Ruijter, 'The Impediment of Health Laws' Values in the Constitutional Setting of the EU' in TK Hervey, Calum Alasdair Young and Louise Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar 2017). Tamara K Hervey and Jean V McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press 2015).

societal organization.[3] Particularly when there is an emergency, people are keen to help out and solidarity is widely seen as more acceptable than self-help.[4]

Solidarity in health is multifaceted. In bioethics, solidarity has a long history;[5] it has been used particularly in the context of public health (as opposed to health care/medical care) to justify state interferences such as quarantines or mandatory medical examinations and vaccinations, i.e. the enforcement by public authorities of necessary collective action, which can be understood as a demand of solidarity.[6] When it comes to resource allocation for access to medical care and medicines, solidarity also forms a key principle and value: here, it justifies mechanisms of insurance, redistribution, planning and rationing, to ensure access to medicines and services that are needed to promote and protect human health as part of the welfare system.[7] The implementation of this notion of solidarity in the organization of public health and health care systems is key to ensure equal access to medical and preventive care, as well as 'universal access', in all EU Member States.[8]

Universal access means that each citizen is granted equal access to a specific basket of care and medicines. Solidarity in ensuring universal access to health care and medicines always entails rationing access. In most Member States this means that

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[3] 'Implicit solidarity': Catherine Waldby and Robert Mitchell, *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism* (Duke University Press 2006) 3 and 128. And see Titmuss Richard, *The Gift Relationship (Reissue): From Human Blood to Social Policy* (Policy Press 2018). A.M. Farrell, 'Is the Gift Still Good? Examining the Politics and Regulation of Blood Safety in the European Union' (2006) 14 Medical Law Review 155.

[4] Philipp Genschel and Anton Hemerijck, 'Solidarity in Europe' (2018) 01 EUI Policy Brief.

[5] Rob Houtepen and Ruud ter Meulen, 'New Types of Solidarity in the European Welfare State' (2000) 8 Health Care Analysis 329.

[6] There is some discussion as to the explanatory weight of solidarity in state level arrengements for sharing the burdens of a large scale disease outbreak, see Barbara Prainsack and Alena Buyx, *Solidarity: Reflections on an Emerging Concept in Bioethics* (Nuffield Council on Bioethics 2011); Angus Dawson and Marcel Verweij, 'Solidarity: A Moral Concept in Need of Clarification' (2012) 5 Public Health Ethics 1; Barbara Prainsack and Alena Buyx, 'Understanding Solidarity (With a Little Help from Your Friends) Response to Dawson and Verweij' (2012) 5 Public Health Ethics 206. But for its uses in interstate relations this discussion carries less weight – see Lawrence O Gostin, Lindsay F Wiley and Thomas R Frieden, *Public Health Law: Power, Duty, Restraint* (3 edition, University of California Press 2016); Howard Brody and Eric N Avery, 'Medicine's Duty to Treat Pandemic Illness: Solidarity and Vulnerability' (2009) 39 Hastings Center Report 40. And also see Prainsack and Buyx (2011), *Solidarity: Reflections on an Emerging Concept in Bioethics*.

[7] Barbara Prainsack and Alena Buyx, *Solidarity in Biomedicine and Beyond* (Cambridge University Press 2017) 7; N Daniels, *Just Health: Meeting Health Needs Fairly* (Cambridge University Press 2008); Chris James and William Savedoff, 'Risk Pooling and Redistribution in Health Care: An Emperical Analysis of Attitudes toward Solidarity' [2010] World Health Report (2010) Background paper No. 5 <https://pdfs.semanticscholar.org/96a4/6bd3f42ef4530bf6ab1e094bc9709a2e6a83.pdf>.

[8] De Ruijter (n 7).

the basket of care is limited and a matter of political choices; and for such choices democratic legitimacy is key. In public health this can entail limited access to preventive public care, such as age limits for certain prevention programmes for cancer. In health care this might mean that certain experimental treatments or alternative treatments are not part of the (social) insurance and benefits package. But it can also entail rationing care through networks, where choice and access to particular health care providers is limited. In other Member States universal access is achieved, e.g. through a 'budget model' in that health care is only provided within the constraints of limited budgets and inevitable waiting lists. Particularly also with regard to medicines, national choices on how to ensure health solidarity through rationing are a matter of intricate health insurance systems, politics, economics and bioethics.[9]

Indeed, while solidarity in the face of health risks is a shared EU value and principle, the reality of access to health care and public health protections on the ground in the Member States is very different. Out-of-pocket costs in Eastern European Countries and Greece vary from 23 to almost 50% of payments, going down to 12 to 15% in Western and Scandinavian EU Member States.[10] These health-system and public-health divergences between Member States are well-documented, and solidarity in this regard is organized largely at the Member State level. Medicines make up about 25 percent on average of national budgets for health care.[11] However, access to medicines is very different across EU Member States.[12]

1.2 EU solidarity in health

Despite these national differences, solidarity is recognized throughout the EU law and policy. Article 2 of the TFEU outlines:

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[9] WHO Europe, 'Strengthening Member State Collaboration on Improving Access to Medicines in the WHO European Region, EUR/RC67/11 67th Session Budapest, Hungary, 11 -14 September 2017'.
[10] See for a quick overview the Country Health Profiles of the European Commission: https://ec.europa.eu/health/state/country_profiles_en. Also see Eurostat, Health in the European Union – facts and figures https://ec.europa.eu/eurostat/statistics-explained/index.php/Health_in_the_European_Union_%E2%80%93_facts_and_figures.
[11] OECD, 'Pharmaceutical spending (2018)' at <https://data.oecd.org/healthres/pharmaceutical-spending.htm>.
[12] See 'Council Conclusions on Strengthening the Balance in the Pharmaceutical Systems in the EU and Its Member States (17 June 2016)'. Also, see Department of Health, The Pharmaceutical Price Regulation Scheme, Eleventh Report to Parliament, February 2012, available at <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215156/dh_132793.pdf>

> The Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities. These values are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail.

Furthermore, the Charter of Fundamental Rights of the European Union (CFREU) enshrines the values of solidarity and equality in welfare and health settings.[13]

Value	Context	Article	Application
Equality, solidarity and universal access	Non-discrimination	20-26 CFREU	Non-discrimination in access to health care services and preventive care
Equality, solidarity	Employment	32 CFREU	Occupational health employment as a social determinant
Solidarity and Equality	Social security	33 CFREU	Social security as a social determinant of public health
Equality, universal access	Right to health Right to access health care	35 CFREU	Access to health care and other (public) health services. Access to preventive care Protection of public health Reproductive Health Protection of environment as it affects public health Occupational health Regulation of services of general interests Pharmaceuticals and medical devices

Solidarity in access to health and medicines is also at the EU level explicitly recognized as a key value to be guaranteed in EU policy and law. In 2006, in the context of legislative discussions in the adoption of the Patient's Rights Directive,[14] Member States formulated in the Council Conclusions that solidarity through universal access was to be adhered to by the Union and in the Member States.[15] These common values and principles of health systems are not intended to refer to legal principles (that have the status of primary law in the EU). However, the document

[13] Charter of Fundamental Rights of the European Union [2012] OJ C326/391.
[14] Directive 2011/24/EU, 'Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the Application of Patients' Rights in Cross-Border Healthcare (O.J. L88/45, 4-4-2011)'.
[15] Council Conclusions, 'Council Conclusions on Common Values and Principles in European Union Health Systems (2006/C 146/01) (O.J. 146/1)'

does represent a European baseline for health law that is common to the Member States.

In sum, solidarity in ensuring access to health and medicines is a key organizing principle for EU health policy, economics and law. This solidarity typically is understood as playing out at the domestic, national level. However, solidarity pertains not only to redistribution and risk pooling within Member States, but also between Member States and in external relations of the EU.[16] For sure, despite the many references to 'solidarity' in official European declarations and documents, what 'solidarity' as an overarching concept exactly means for the EU as a polity remains somewhat elusive and is the subject matter of much scholarly debate.[17] Yet, in the case of disasters, such as a pandemic, the European Treaties set out a clear mandate, at least in principle, in Article 222 TFEU. This article, introduced by the Lisbon Treaty of 2007, stipulates that solidarity demands that in case of a natural or manmade disaster Member States provide assistance to one another and act jointly and in cooperation.[18] On this basis, the related Civil Protection Mechanism has been activated in the context of COVID-19. For health it works in close relation with the Health Security Mechanisms and it pools Member State resources for instance in the organization of a European Medical Corps.[19]

Simultaneously, there has always been a tension between the domestic principles of solidarity and the principles of market integration that underpin the Single Market. In the application of the internal market rules, any national health laws that created a barrier to the free movement of goods or services were suspect and needed to be justified as a valid exception to the free movement principle. In fact, some of the important 'constitutional moments' for the creation of the European internal market

[16] See Articles 21, 24(3), 31 and 32 TEU and see articles 80, 122 and 222 TFEU.{Citation}

[17] For a recent overview of the variegated understandings of 'solidarity' in the EU, see R. Coman, L. Fromont, A. Weyembergh (dir.), *Les solidarités européennes, Entre enjeux, tensions et reconfiguration*. Bruylant, 2019. For a review of different normative accounts of the role the EU should play in the realm of insurance and redistribution, as key dimensions of welfare state solidarity, see Frank Vandenbroucke, 'Solidarity through Redistribution and Insurance of Incomes: The EU as Support, Guide, Guarantor or Provider?' Amsterdam Centre for European Studies Research Paper, January 2020.

[18] 'Council Decision of 24 June 2014 on the Arrangements for the Implementation by the Union of the Solidarity Clause (2014/415/EU) OJ L 192/53'.

[19] Joana M Haussig and others, 'The European Medical Corps: First Public Health Team Mission and Future Perspectives' (2017) 22 Eurosurveillance; 'European Commission Press Release: EU Launches New European Medical Corps to Respond Faster to Emergencies (MEMO/16/276)'.

revolved around health exceptions to the free movement of goods (Arts 34 TFEU – ban on import barriers, 35 TFEU – ban on expert barriers, and 36 TFEU – exceptions). The European Court in the case *Cassis de Dijon* (1978) created an exception to Member States' barriers to free movement, as the reference to public health concerns was seen, in this case, as a disguise for economic protectionism.[20] And in the famous case of *Tobacco Advertising* (1998), the Court outlined the limitations on the EU in adopting measures outside of its legal competences.[21] Drawing and re-drawing the thin line between 'national solidarity' and 'national public health' demand, on one hand, and the principles of market integration and free movement, on the other hand, has been the subject of much of the Court of Justice of the European Union (CJEU)'s activity and case law. It is no surprise that, from the perspective of the national health care authorities, the EU's most salient role was often seen as hinging upon policies of deregulation.

At the same time, as the *Tobacco Advertising* case indicates, the removal of national health laws as barriers to the single market is not the only aspect to the role of the EU in health. The tobacco advertising regulation was a central part of the EU's cancer prevention programme that is built on regulation of advertising, the modalities of tobacco sale and research and public health programmes into cancer prevention.[22] Similarly the EU has had a central role for the regulation of health and safety of the EU products market, medical devices, pharmaceuticals, the recognition and quality of medical professionals and workplace safety. [23] And, already since the 1970s, the EU is

[20] 'Cassis' provides the principles of mutual recognition and a softening of the Dassonville case law where all Member States' regulation could be considered barriers to trade. *Case 8/74 Procureur du Roi v Dassonville [1974] ECR 837*. In 'Cassis' the Court holds that Member States must allow a good that is lawfully marketed in another Member State, unless mandatory requirements for reasons of public health would provide a legitimate 'rule of reason'. Interestingly, Article 36 TFEU already provides for a public health exception. *Case 120/78, Rewe-Zentrale AG v Bundesmonopoverwaltung fur Branntwein [1979] ECR 649*.

[21] The Court in this case determines that no regulation can be created by the European legislator that has health protection as a central and single objective. There has to be a link with internal market objectives. *Case C-376/98 Germany v Parliament and Council (Tobacco Advertising) [2000] ECR I-8419*.

[22] L Trubek, M Nance and T Hervey, 'The Construction of a Healthier Europe: Lessons from the Fight Against Cancer' (2008) 26 Wisconsin International Law Journal; 'A Programme of Action of the European Community Against Cancer (O.J. C184, 23-07-1986)'; 'Decision 88/351/EEC Europe Against Cancer Programme of the Council and Representatives of the Governments of the Member States Meeting within the Council (O.J. L160/52 1988)'.

[23] E Vos, *Institutional Frameworks of Community Health and Safety Regulation: Committees, Agencies and Private Bodies* (Hart Publishing 1999); R Hamalainen, *The Europeanisation of Occupational Health Services: A Study of the Impact of EU Policies*, vol 82 (Juvenes 2008); D

growing its capacity and role in the surveillance and early warning of public health threats, first of all with the development and use of European (disease) networks of EU-supported public health experts and epidemiologists.[24] However, all this did not carve out a strong role for the EU in organizing solidarity for health, involving redistribution or rationing.

Overall, the difficulty in separating health and the internal market is clearly apparent, but the division remains and is reiterated with each Treaty amendment. In fact, although health is mentioned throughout the Treaty as an exception to the free market principles and as a general EU goal, Article 168 TFEU, which outlines the EU's role and responsibility in health, simultaneously reinforces the premise that the EU does not have the power to create health law outside of specifically outlined situations.[25] EU scrutiny of national public health laws is highly developed in EU *case law*, particularly as it comes to the free movement of goods. This is a relevant legal backdrop for the organization of solidarity via the public procurement of vaccines at EU level that followed after the Swine Flu outbreak, which we discuss in the next section.

2. EU health solidarity in the face of danger

2.1. Limited EU competences in health, even after Swine Flu

In order to understand the current role the EU can have with respect to organizing solidarity for responding to COVID-19, particularly with regard to the public procurement of pandemic medicines and medical counter measures more generally, we should return to April 2009 with the global spread of a new virus, the Swine Flu. The virus originated in pigs from Asia that were transported to North America. The

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Gagliardi and others, 'Occupational Safety and Health in Europe: Lessons from the Past, Challenges and Opportunities for the Future' (2012) 50 Industrial Health 7.

[24] De Ruijter (n 7) 121 et seq.

[25] This restriction holds both for public health and access to health care. Art. 168 (5) stipulates that "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, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol" *exclude* "any harmonisation of the laws and regulations of the Member States.". Art. 168(7) makes clear that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them."

global health community was on high alert: in the case of the 2003 SARS (Severe Acute Respiratory Syndrome) in Asia, 774 of the 8096 people infected died.[26] This virus did not spread very easily or quickly, but it had a high mortality rate (about 10 percent). By comparison, the Spanish Flu of 1918-1919 killed millions, but had an actual mortality rate of 2.5 percent.[27]

There was a fear that the Swine Flu (influenza AH1N1) would have a mortality rate that was comparable to the Bird Flu, influenza AH5N1 (over 60 percent) and would spread more easily.[28] In June 2009 the WHO declared that there was a pandemic spread of Swine Flu and raised the threat level to phase 6 (the WHO's highest categorization of spread for pandemics).[29] Luckily the Swine Flu turned out to be no more deadly than a seasonal flu. But the difficult choices that we are now facing with regard the organization and the acceptability of EU solidarity regarding the COVID-19 outbreak in Europe already came to the fore in full force with the 2009 Swine Flu. And that experience has led to at least some of the elements in the EU policy landscape within which we now find ourselves.

In the year of the Swine Flu outbreak, new provisions in the Lisbon Treaty signed in 2007 – immediately after the earlier scares of Anthrax, SARS and Bird flu – created the basis for the current EU role, by adding to Article 168 TFEU:

> Union action, which shall ***complement*** national policies, shall be directed towards improving public health, […]. Such action shall cover the fight against major health scourges, by promoting research into their courses, their transmission and their prevention, as well as health information and education, and ***monitoring, early warning of and combating serious cross-border threats to health***. […]

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[26] See WHO Communicable Disease Surveillance and Response, *Severe Acute Respiratory Syndrome (SARS): Status of the Outbreak and Lessons for the immediate future*, 20 May 2003 at p. 3; also see WHO, *Severe Acute Respiratory Syndrome (SARS) - multi-country outbreak – Update 6 March 2003*.

[27] See, https://www.who.int/influenza/human_animal_interface/avian_influenza/h5n1_research/faqs/en/ Also see V.Wiwanitkit *Bird Flu: The New Emerging Infectious Disease* (Nova Science Publishers, New York: 2008) at p.2.

[28] J.H. Beigel *et al* 'Avian influenza A (H5N1) infection in humans' (2005) *New England Journal of Medicine* 353 (13) 1347-1385.

[29] 'World Now at the Start of 2009 Influenza Pandemic Dr Margaret Chan, Director-General of the World Health Organization, Statement to the Press by WHO Director-General Dr Margaret Chan (11 June 2009) https://Www.Who.Int/Mediacentre/News/Statements/2009/H1n1_pandemic_phase6_20090611/En/'.

With respect to EU regulation, at the time of the 2009 Swine Flu outbreak, no secondary legislation had been adopted on the basis of this added paragraph in Article 168 TFEU. However, a major problem arose with respect to the availably of pandemic vaccines and antivirals. The Commission had been trying for years to create a stockpile of antivirals. Nevertheless, this was deemed unacceptable by the Member States that wanted to keep the ability to procure medication at Member State level: Although the approval process of medicines is highly integrated at the EU level, the actual procurement of medicines is still a firm competence of the Member States. The procurement is the most costly aspect of ensuring access to pandemic medicines, given that the average cost is between 5 and 10 euros per dose per person.[30] Lack of transparency adds to these problems; often it is simply not possible to access information on development and acquisition costs, as this is part of the procurement contracts between industry and the EU Member States.[31]

After the outbreaks of Bird Flu (avian influenza) and SARS, the Member States had made pre-purchase agreements with the pharmaceutical industry. This meant in many cases that as soon as the WHO declared a public health emergency of international concern, these pre-purchase agreements were activated and Member States had to accept the volume and price that was initially agreed.[32] In some cases this meant that vaccines and antivirals did not go to the countries in the EU that needed them most, and the price was often above-and-beyond reasonable. [33] At the time the EU created in an ad-hoc fashion a voluntary public procurement system, whereby Member States that did not have access to the vaccine anymore could still

[30] This is and estimated guess based on media reporting and the costs of seasonal vaccinations.
[31] These rules also apply to EU Public procurement Article 339 of the Treaty on the obligation of professional secrecy; Article 155(3) of the Rules of Application on the secrecy of tenders.
[32] Mark Turner, 'Vaccine Procurement during an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons from 2009-H1N1' (2016) 11 Global Public Health 322.
[33] European Medicines Agency, 'European Medicines Agency, Pandemic Report and Lessons Learned Outcome of the European Medicines Agency's Activities during the 2009 (H1N1) Flu Pandemic (29 April 2011), Available at: Http://Www.Ema.Europa.Eu/Docs/En_GB/Document_library/Report/2011/04/WC500105820.Pdf (Last Accessed March 2014)'; Mark Turner, 'Vaccine Procurement during an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons from 2009-H1N1' (2016) 11 Global Public Health 322.

get access, and a stockpile was created where Member States that had too many vaccines that could be offloaded. [34]

As one EU civil servant summarized the situation in 2010:

> *We discussed the EU stockpile of antivirals until we were all exhausted and then decided that there was no agreement. And when the pandemic happened, they [MS] suddenly found themselves in the situation that some countries had far too much and some countries had none. And there was no way to deal with this in the middle of the crisis so we needed to (…) develop sufficiently good arguments in advance that convinces people to adopt the measures in good time rather than afterwards*

A Member State health representative clarified the situation in the same year (2010):

> *We [the Member States] have been trying since 2005 to come to a mechanism for joint procurement. It took the pandemic to find an agreement […]. So, in a sense it will always be crisis driven, like lot of policies are […][35]*

2.2. Public procurement: only voluntary, not mandatory

After intensive evaluations in 2010,[36] in December 2011 the Commission proposed a new decision on all serious cross-border health threats in order to address some of the problems identified above.[37] This proposal was adopted in 2013.[38] Again, however, Member States did not agree to a binding system for public procurement. Instead Article 5 of Decision No 1082/2013/EU of the European Parliament and of the Council created the legal basis for a voluntary public procurement medical countermeasure in case of a health emergency,[39] that is either declared and identified by the WHO or by the European Commission.[40] The Joint Procurement Agreement that further implements Article 5 entered into force in June 2014.[41] This agreement

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[34] Ibid. For a case study on the regulatory changes as a result of Influenza A H1N1, see de Ruijter (n 7).
[35] Both quoted in de ibid.p.138.
[36] European Commission, 'Commission staff working document on lessons learnt from the H1N1 pandemic and on health security in the European Union', Brussels SEC(2010) 1440 final, 18 November 2010, p.3.
[37] Commission proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health Brussels (COM(2011)866 final).
[38] Ibid.
[39] Art. 1 JPA; European Commission, Health and Consumers Directorate-General, 'Explanatory note: on the Joint Procurement Mechanism', Luxembourg, December 2015, available at: < https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/jpa_explanatory_en.pdf > p.9.
[40] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC [2013] OJ L 293/1.
[41] European Commission, 'Joint Procurement Agreement to Procure Medical Countermeasures'.

applies to joint procurement of medicines (antivirals, treatments or vaccines), medical devices (infusion pumps, needles) and 'other services and goods' needed to mitigate or treat cross-border threats to health, such as laboratory tests, diagnostic tools, decontamination products, masks or personal protective equipment.[42]

The procedure per procurement is agreed among the contracting parties (Member States that decide to join, the European Commission). Among other elements, it has to meet the conditions that it does not affect the internal market, does not constitute discrimination or a restriction of trade and does not cause distortion of competition; and that it does not have any direct financial impact on the budget of Member States not participating in the joint procurement.[43] The European Commission and the participating Member States should agree in particular upon the detailed practical arrangements for the evaluation of the requests for participation or of the tenders, the award of the contract, the law applicable to the contract and the competent court for hearing disputes.[44] Importantly, Member States with each tender need to decide on the criteria governing the allocation of the available amounts of medical countermeasures among the participating Member States. In principle, Member States should receive the exact amount of countermeasures that they have ordered, but the rate of delivery may be slower in accordance with the allocation criteria.[45]

In urgent situations, Member States may request derogation from these generally applicable allocation criteria.[46] This means that participating Member States in need may receive the medical countermeasures at a faster rate than other participating Member States. Furthermore, the agreement allows Member States to donate medical countermeasures acquired under the joint procurement procedure.[47] This 'urgency' or need would be decided on by the Commission and the Member States that joined in the Joint Procurement Agreement Steering Committee on the basis of

[42] European Commission, Health and Consumers Directorate-General, 'Medical countermeasures that could be procured in common under the Joint Procurement Agreement', Luxembourg, December 2014, SANCO C3, available at: < https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/jpa_note_scope_en.pdf >.
[43] Article 5(3) Decision No. 1082/2013/EU.
[44] Ibid, And see Art. 165(2) Financial Regulation.
[45] Art. 17(1) JPA.
[46] Art. 17(2) JPA.
[47] Art. 31 JPA.

the choices that are made in advance as part of the procurement procedure. Each procedure sets its own conditions and distributive regulations.[48]

In March 2019, the European Commission and 15 Member States, representing about half of the European population,[49] signed framework contracts for the joint procurement of pandemic influenza vaccines with pharmaceutical company Seqirus. Furthermore, Member States are currently preparing joint procurement procedures for diphtheria anti-toxin, Tuberculin, BCG vaccines and Personal Protective Equipment.[50]

The EU can play an important role for COVID-19 in organising health solidarity through a European Public Procurement process. In comparison to the Swine Flu outbreak, which was a low example of EU solidarity, the current system already has created a centralising effect in the pre-purchase that was done with 15 Member States in 2019,[51] and currently more of these processes are on the way.[52] In the context of the Health Security Committee, where the Member States at the level of the health ministries are in close contact during health emergencies, the Commission has indicated that new initiatives are proposed in this context, including joint procurements on eye protection and respirators, and ventilators. At the same time the EMA together with the Commission is investigating the availability of investigational therapeutics.[53]

Public procurement under 'rescEU'

[48] Art. 17 JPA

[49] Belgium, Croatia, Cyprus, Estonia, France, Germany, Greece, Ireland, Luxembourg, Malta, the Netherlands, Portugal, Slovakia, Slovenia and Spain.

[50] 'MEMO28/03/2019 Framework Contracts for Pandemic Influenza Vaccines' https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/ev_20190328_memo_en.pdf.

[51] See the press release on 29-03-2020 https://ec.europa.eu/commission/presscorner/detail/en/MEX_19_1891

[52] The Commission launched four different calls for tender for medical equipment and supplies on 28 February 2020 (gloves and surgical gowns), 17 March (personal protective equipment for eye and respiratory protection, as well as medical ventilators and respiratory equipment), and 19 March (laboratory equipment, including testing kits) - with participation of up to 25 Member States (https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health_en).

[53] 'DG Health - Health Security Committee, Summary 11th meeting on Outbreak of Coronavirusdisease (COVID-19) (13 March 2020)'.

Another route for a more central role for the EU could be under the heading of EU solidarity proper, rather than in the context of the EU health law regime. Article 222 TFEU mandates that in disasters Member States provide mutual assistance and act in cooperation. However, such cooperation is voluntary.[54] The EU Civil Protection Mechanism established on the basis of Article 222 TFEU, depends on the willingness of Member States to join forces. In 2019 the Civil Protection Mechanism was strengthened by 'rescEU', in an attempt to centralize EU capacities.[55] Article 12 of this Decision provides for the EU to use its internal funds, pre-committed national funds and EU co-financed Member States capacities at the disposal of EU efforts, to respond to a major emergency.

Importantly, this mechanism also creates the possibility for joint procurement, operating in parallel to the Joint Procurement Agreement under the health infrastructure.[56] Here the Commission can assume a more central role, because the Decision allows for central EU implementing decisions towards distribution and allocation. Nevertheless, the actual capacity of "rescEU" still largely depends on Member States' willingness to contribute, and it is doubtful that for medical countermeasures EU internal funding will be comparable to what can be organized at the national level or through the JPA in the EU health context.

All these are steps forward, but, simultaneously, one needs to be mindful of the very diverse realities of medicinal purchasing powers in the Member States, the absence of a EU budget in this regard and the highly intergovernmental nature of the process, which is inevitably very bureaucratic, difficult to manage and not generating the speed that an urgent procurement process would need. Furthermore, in a context such as the COVID-19 pandemic, difficult and delicate decisions will have to be taken along the process: think about the order of priority in which Member States receive their part of the common stockpile of medical countermeasures, if the industry (e.g. the pharmaceutical industry in case of a new vaccine) cannot immediately answer a large-scale demand. The challenge of a process where the Member States have to decide on this among themselves would mandate a larger role for the European

[54] Council Decision of 24 June 2014 on the Arrangements for the Implementation by the Union of the Solidarity Clause (2014/415/EU) OJ L 192/53.
[55] Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77I , 20.3.2019, p. 1–15).
[56] Par 20. ibid.

Commission, rather than the current structure where all contracting parties have to instantly agree on the deployment of medical counter measures in accordance to urgency and need, and rules that are sufficiently clear *ex ante*, with strong measures against any free-riding.

2.3. EU role for health solidarity: export limitation of medicines and other crucial goods

When it comes to medicines as one of the counter measures of central importance in combating COVID-19, in the Commission Communication that was published recently,[57] the free movement of goods is mentioned as one of the instruments for coordinating Member States' actions. Particularly, the Communication addresses the situation in which certain medical equipment and goods are scarce and need to be 'channeled to those who need them most'.[58] Thus, free movement and the integrity of the Single Market are now seen as necessary vehicles for true European solidarity. As a rule within internal market law, whenever a Member State creates a barrier to the free movements, this needs to be communicated, so all other Member States can be informed.[59] In the case of goods that are deemed essential for fighting COVID-19 the Commission has established a task force to ensure that these comments are mediated. One of the limitations to the use of the public health exception is already that these national restrictions cannot exist in rules that prevent national firms from responding to public procurement that is tendered at EU level.[60]

As some Member States have started hoarding certain products or limiting their suppliers' access to the European market, these measures can also interfere with the public health goal at the EU level of getting these supplies to those who need them most. This means that the Commission sees stockpiling or interrupting supply chains of vital importance to the whole of the EU as potentially prohibited export limitations. The EU in this regard in the Communication reiterates Article 35 TFEU. This article addresses national restrictions on exports. Legally, all the public health

[57] Communication from the Commission to the European Parliament, the European Council, the Council, the European Central Bank (March 13, 2020), the European Investment Bank and the Eurogroup, *Coordinated economic response to the COVID-19 Outbreak*, COM(2020) 112 final, Brussels.
[58] page 3.
[59] Decision No.1082/2013/EU, 'Decision No 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 (O.J. L 293/1 5-11-2013)'.
[60] See supra note 57.

exceptions in the case law and in Article 36 TFEU simply apply. This means that if Member States for a solid public health reason want to restrict export, they have the authority to do so as long as it is done in a proportionate and non-discriminatory fashion. The principle of proportionality however that is outlined by the Commission is of a different nature:

> [The measures need to be] appropriate, necessary and proportionate to achieve such [health] objective, by ensuring an adequate supply to the persons who need the most while preventing any occurrence or aggravation of shortages of goods, considered as essential – such as individual protective equipment, medical devices or medicinal products – **throughout the EU.**

Particularly this last iteration is a novel addition that is not based on case law or any other legal instrument. It assumes a concept of EU public health and EU solidarity, rather than the usual interpretation where public health is a policy area in which – even in the face of the strong economic and integrative forces of the internal market of the EU – domestic solidarity within Member States (and Member States' sovereignty in this domain) is the principle that has to be traded-off against market integration.

According to the European Commission, this means an outright export ban will not be deemed proportionate; the measure needs to be aimed and ensuring that the products reach the persons who need them most, and it needs to suit the objective of the health of people who need them most. Clearly this is not the usual interpretation of Article 35 TFEU juncto Article 36 TFEU, which was never intended to only serve public health at EU level. Rather, it was there for the creation of the internal market, *despite* national health laws. However, other measures that may create barriers to free movements, such as price regulation in Member States, as long as these are not discriminatory, are allowed according to the Commission. So too are other national measures to regulate the market of medical supplies.

Importantly, the EU procurement of a pandemic medicine and other medical products can be severely undermined if Member States, in the face of COVID-19, disrupt supply chains. The process within the JPA is intergovernmental, and runs the risk of playing out in the context of actual export bans. Beyond the case of an EU-wide procurement arrangement, solidarity is also undermined by hoarding and

limitations in the supply chain, let alone by the economic impact of such measures. However, even if the Commission would adopt a 'EU health solidarity - based' interpretation for scrutinizing whether national export bans fall under the public health exception to the free movement of goods, the question is whether at the current moment, the possibility of an infringement procedure from the European Commission would scare Member State politicians more than not having control over the stockpiles of particular goods.

One manner in which the Commission's proposal in the Communication is creating more political pressure in this regard is through the taskforce that involves the Member States for looking into national export limitations. Member States' markets are highly integrated, hence in this intergovernmental taskforce the Commission might be able to leverage political power more than a mere infringement procedure might be able to do. At the same time, this situation also clearly calls for a pandemic budget and power at the EU level to ensure the distribution of medicines and urgently needed medicines for the whole of the Union.

3. What would citizens want from EU health solidarity in the procurement of pandemic medicines?

In exploring the role the EU could have for ensuring health solidarity when it comes to a pandemic emergency and the availability of countermeasures, it is also important to consider citizens' preferences. This is difficult, however, given the paucity of well-formulated survey questions and research designs – not least given the unfamiliarity among citizens with medical risk-pooling, and also the given the tendency of people to express opinions about health matters in socially desirable ways rather than expressing true thinking.

To shed at least some light on public support for the EU's role in medical procurement, we conducted an original experiment as pilot to a larger survey project on attitudes towards EU fiscal and medical policies. The pilot was administered in November 2019, just *prior* to the COVID-19 outbreak, and involved a broadly representative sample of 400 Dutch respondents, yielding a sample of 2400 policy packages judged by respondents. Our survey explored support for risk pooling in the

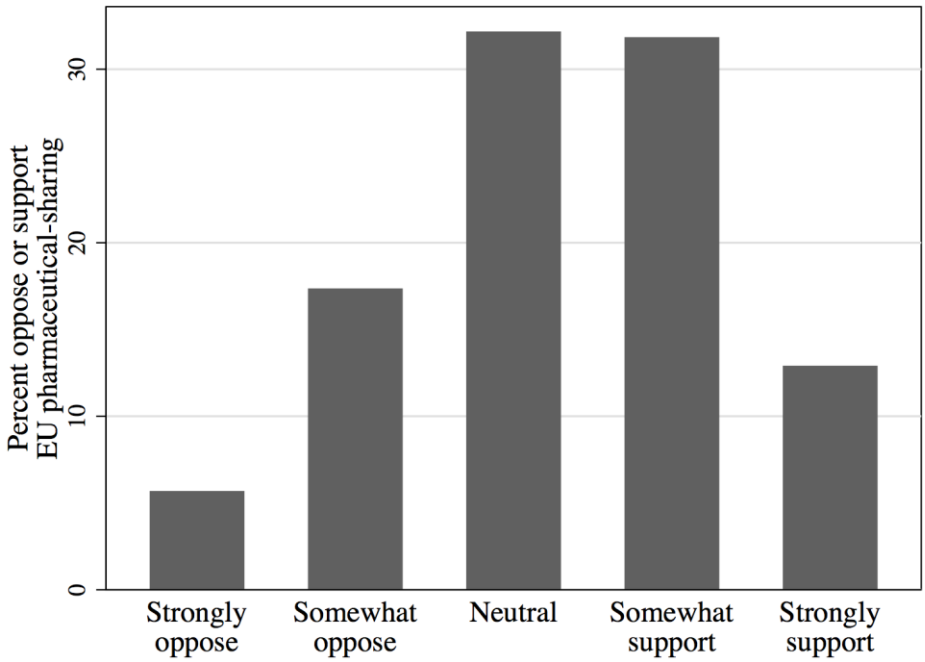
purchases and accessibility of pharmaceutical medicines relevant to major outbreaks.

The experimental portion of the survey was a so-called conjoint experiment. This involved asking respondents to judge pairings of policy packages that combined policy features on three dimensions of a hypothetical EU pooling of risk and purchases of pharmaceuticals. The three dimensions and possible answers for any given policy package being judged were: (1) Do respondents prefer a programme for a limited range of medicines crucial to large-scale disease outbreaks or for all medicines where collective purchases can be financially beneficial? (Possible answers: a. limited and essential medicines; b. potentially all medicines); (2) Do respondents prefer a programme that lends access to the pooled medicines based on a country's own contribution, or instead priority access based on needs to stanch epidemic spread? (Possible answers: a. access based on a country's contribution; b. access based on prioritizing countries to prevent spread); and (3) Do respondents prefer a programme that is administered by EU-level experts or instead national-level experts? (Possible answers: a. national-level experts; b. EU-level experts). In the conjoint experiment, respondents do not issue a judgment about the individual dimensions. Instead they are asked to judge entire packages exhibiting a given combination of policy features of those dimensions. In particular, respondents choose among and rate randomly assigned alternative packages that combine a random combination of policy features (from each of the three policy dimensions one answer from the set of possible answers to that dimension). This experimental approach evokes more honest answers from respondents even with respect to socially undesirable answers.

What this experimental study has revealed is preliminary evidence, being based on a limited sample in a given country and a particular period of time just prior to the corona virus outbreak. But what it reveals about public support for EU medical procurement is important. We shall focus on two basic patterns in the answers that Dutch respondents gave. First, there is a plurality of support for as opposed to opposition to such EU pharmaceutical sharing. This is clear in Figure 1 below, where the combination of somewhat and strongly support given to any given package garners almost 44 per cent of the Dutch sample, while 'only' 23 percent is opposed

(32 percent is indifferent). These patterns are not significantly different across basic demographic sub-groups (younger versus older respondents; more or less educated respondents; men versus women). This is a sign, however tentative, that EU-level procurement would command substantial support among the Dutch population.

Figure 1:
Percent of Dutch Respondents Supporting EU medicine-procurement sharing



Second, and perhaps more interestingly, the Dutch respondents express preferences for a particular kind of EU procurement programme with respect to the three dimensions of procurement policy that we showed respondents. These preferences are summarized in the Figure 2 below, showing the predicted preference of respondents for a given value on a given dimension – based on an experimental inference of choice for a given package exhibiting the randomly assigned policy

features per dimension. The dots capture the mean prediction, while the dark lines on either side of those means depict the range or interval of predicted values within 95% confidence. Where both the mean and the confidence interval are in their entirety to the right of the vertical line, we have 95% confidence that respondents are more likely (and when to the left of the vertical line that respondents are less likely) to choose an EU-procurement policy package that has this particular feature.

Figure 2:
Predicted Preference for Policy Features of EU medicine-procurement sharing

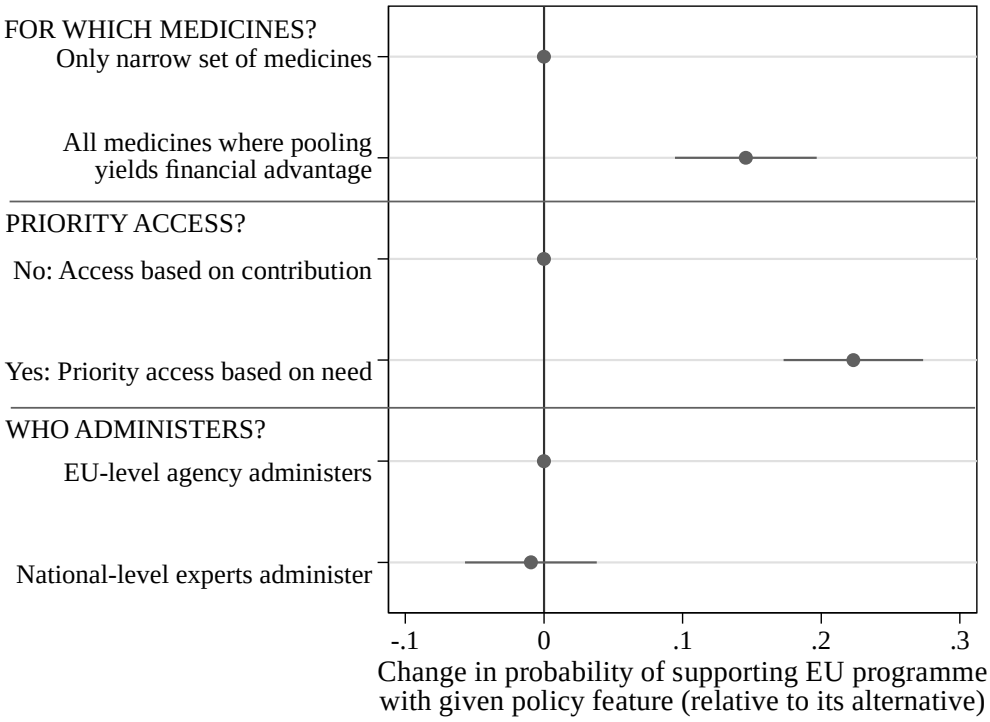


Figure 2 shows clear patterns in what kind of procurement policy Dutch respondents preferred. The Dutch sample population is indifferent as to whether EU-level or national experts and agencies administer such programmes: Focusing on the third

dimension on 'WHO ADMINISTERS?', respondents are very weakly less likely to prefer national-level administration than EU-level administration (the baseline), but this is clearly not a statistically meaningful difference (note that a substantial part of the confidence interval crosses the vertical line). On the other hand, Figure 2 shows that the Dutch respondents clearly do tend to prefer an EU programme that covers a broader swath of medicines, potentially *all medicines*: focusing on the first dimension 'FOR WHICH MEDICINES?' we see that respondents are about 15% more likely to choose an EU procurement policy that includes such coverage over a policy that focuses only on a narrow set of medicines (the baseline). Finally, Figure 2 also shows that the respondents are even more likely to prefer an EU procurement policy that gives priority access to particular countries to prevent contagion: focusing on the second dimension 'PRIORITY ACCESS', we see that respondents are about 23% more likely to choose EU-procurement policy that gives priority access to countries where a contagion can be traced, to simply providing access to medicines based on a country's actual contributions, without looking at such a priority in need (the baseline).

Obviously, because the survey was only conducted among a limited number of respondents from one country at one specific moment, one should not overinterpret the outcomes. It is also well-known that the framing of a survey experiment can have a substantial effect on the outcomes. Moreover, the current experiment took place at a moment when the described frame was still hypothetical and before any public debate about centralization of policies in response to infectious diseases has taken place. In the midst of the current corona virus crisis respondents' answers would likely be shaped by the crisis experience so far. Given that the shortcomings of the current decentralized policies have become so obvious, it is not at all clear that support for more centralized policies will have fallen. Hence, we interpret our pilot experiment's results as providing qualified but significant support for the view that there is meaningful political traction for EU-level pooling of procurement capacity in the Dutch sample.

4. Policy suggestions for an effective way forward

For a long time, the organization of solidarity or health concerns were seen as potential arguments to set limits on the Single Market principles that guide European integration, and even to organize a degree of 'protectionism' – against the thrust of

EU integration. Drawing and re-drawing the thin line between 'national solidarity' and 'national health' demands, on one hand, and the principles of market integration and free movement, on the other hand, has been the subject of much CJEU activity and case law. We have now entered into a debate that is, in a sense, *opposite*: now, the European Commission considers restrictions to the free movement of goods as in breach of *European* solidarity and *European* public health. In yet other words, we are witnessing a clash between claims of 'national prerogatives' in the domain of solidarity and public health, and a true 'pan-European approach'.

Across EU countries, there are large differences in health care systems. Systems differ not only in terms of the quality of the care and the available budgets, but also in terms of history, culture and organization. There are valid reasons to respect the 'subsidiarity principle' in health care matters, as deviations from this principle carry a danger of major inefficiencies or exacerbate inequalities: a central decision that ignores differences in national health arrangements could have widely varying impacts on Member States' healthcare systems. The issue is different, however, when it comes to decisions related to infectious diseases, because such decisions may have large cross-border spillovers. In this case, 'national prerogatives' may create a problem of collective action that yields, in the end, bad outcomes for everyone.

If the line of argument is accepted that claims based on 'national prerogatives' now have to give way to true European solidarity, then the European Union must prove that it can also support the Member States in a tangible way at the EU level. Therefore, the Joint Procurement initiative both within the EU health regime (which can ensure size and volume) and the "rescEU" (which creates a central allocation authority for the European Commission) are so important. However, the two elements, volume and central authority, do not coincide. It does not suffice for Member States to say that the EU can only have the role of steering them to respect the integrity of the Single Market and allow for unfettered free movement. The EU will then also need to be empowered to set up real cooperation so that, in the end, it can keep citizens more safe. In yet other words: EU action today cannot only be 'negative' ('Don't block your borders!'), it must also be 'positive' (together, we organize a cooperative effort).

However, the policy legacy since the Swine Flu epidemic shows that national policy-makers prefer a domestic-centered equilibrium, whereby the reluctance to follow internal market principles is coupled with an equal reluctance on the part of the Member States' politicians to pool the procurement of medicines as it would potentially transfer redistributive power to the EU level.[61] Our research into EU solidarity strongly suggests that such reluctance may be misguided. Not only a possible better equilibrium exists, whereby the internal market is protected by EU-level solidarity provisions; but also considerable political support for it can be found in the public opinion. A poll among Dutch respondents suggests that a majority of the Dutch are prepared to pool medicine procurement and share risks at the EU level. This may be seen as quite remarkable as the Dutch are among the most skeptical when it comes to European-level economic stabilization arrangements.[62] Hence, it is highly plausible that EU *citizens* are more willing than their leaders to accept solidarity arrangements when these are only there for emergencies.

Europe is now paying the price for a lack of a centralized policy in the face of pan-European health threats. Countries are competing with each other to acquire these products, for example by imposing export bans. The result is a decentralized outcome that is suboptimal in the sense of these products not always being allocated where they are most needed. However, in the current circumstances legal threats from infringements of the internal market rules likely have little effect. In short, the current corona virus crisis shows the catastrophic costs of a lack of central policy for infectious diseases. With export bans and other measures, each country tries to secure as many resources as possible for itself. And this is hastening a tragedy of the European health care commons.

So what needs to be done? The EU urgently needs to develop and use a well-embedded and efficient central capacity for a truly centralized EU procurement of

[61] See WHO Regional Office for Europe, "Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region (2010)"; see further documents on risk pooling and solidarity in health https://www.who.int/health_financing/documents/pooling/en/ and see in a similar vein Jaime Espin and others, 'WHO-Europe Policy Brief, How Can Voluntary Cross-Border Collaboration in Public Procurement Improve Access to Health Technologies in Europe?'

[62] For a sceptical view, though expressed in a personal capacity, by Dutch (senior) civil servants, see Heijdra, M., Aarden, T., Hanson, J. and T. van Dijk (2018, November 30), A more stable EMU does not require a central fiscal capacity, VoxEU.

medical counter-measures as is outlined in "rescEU", without the inefficiencies that are currently there as a result of the current intergovernmental and voluntary nature of the process under the health regime and the legally embedded possibilities for unsolidary behavior.[63] Central procurement is needed for protective devices, and will certainly be needed for the vaccine against the COVID-19 virus as soon as it becomes available. It will also be needed for *future* infectious diseases. Funding of the capacity can come from the EU budget or by levying a separate contribution from the Member States, say in proportion to their GDP, their population and their demography. The demography is relevant, because countries with an elderly population will on average need to make more use of medicines. It cannot be excluded that the proposed centralization of policies has elements of redistribution, for example when contributions are linked to GDP. However, there relative limited redistributive effects should be weighed against the benefits of the centralization.

What are these benefits? First, an advantage of centralizing procurement is that it will be more difficult for pharmaceutical companies to play off Member States against each other by threatening not to supply to an individual Member State if it tries to negotiate lower prices.
Secondly, the advantage of having a common stockpile of medical counter-measures managed at the EU level is that excess demand in some countries and excess supply in other countries, an obvious economic inefficiency, can no longer co-exist. Thirdly, and most importantly, because the stockpile is common and, hence, larger than any potential national stockpile, there is much greater firepower to target outbreaks of infectious diseases wherever and as soon they emerge. In other words, risk sharing against the consequences of pandemics becomes much more effective than when each country is responsible for its own stock of medicines and equipment.

Finally, the decision where to target the firepower should be taken at the central level. This avoids that each country tries to deviate from the cooperative solution by securing as much of the medicine supply as possible at the cost of other countries.

[63] Costa-Font, J. (2020), Europe's failure to address Covid-19 shows the need for a European 'health citizenship', argues in favour of a European 'health citizenship', https://www.socialeurope.eu/europes-failure-to-address-covid-19-shows-the-need-for-a-european-health-citizenship . His arguments are mainly based on the fact that European governments adopt widely differing policy responses to the Covid-19 crisis, which is hard to motivate as an optimal solution.

Breaking away from the cooperative solution would likely be self-defeating, because it reduces the chances to quell a disease outbreak where it starts. However, political decision makers may not be able to see this or may be under political pressure to secure the safety of their own population first.

In other words, once a disease outbreak has started, cooperative agreements are not credible.[64] Ideally, the EU sets up arrangements *ex ante* that are *ex post* credible. Obviously, Europe has missed the '*ex ante*' of this crisis. However, a crisis may also be a moment to get to solutions that are unthinkable in normal times '*Crises which hit the consumer are excellent ways of speeding up policies.'*[65]. We have seen that during the European debt crisis when crisis arrangements like the ESM were set up. Our proposal of the centralization of procurement, stockpiling and deployment decisions of medical countermeasures to infectious diseases is ex-post credible, provided the design is right. This requires centrally-controlled guidance on the use of medicines based on the pooled expertise and instructions of the European Medicines Agency and the European Centre for Disease Prevention and Control. Such guidance will be easier when it is laid down in advance, before an infectious disease emerges. New diseases will obviously have unknown features. However, the optimal response to an infectious disease in its very first stages is likely to always be very similar, namely the concentration of substantial resources targeted at the first victims and containment within direct environment. The optimal response to a crisis that is already in full swing, like the current one, is more difficult to define. In particular, once a vaccine for Covid-19 becomes available, it would be to the experts to determine the best allocation of the vaccines given the availability and the objective, for example the minimization of lost years of life or number of casualties. Ethical considerations will inevitably play an important role for in determining the relevant objective. However, these are the domain of the politicians rather than the experts.

Risk-sharing arrangements dealing with disease outbreaks can even be taken a step further. It is obvious that the cost of drastic measures like a lockdown of a local economy are mostly borne at the level of that economy, while the benefits in terms of containing a disease are enjoyed by the entire EU. The uneven cost-benefit trade-off

[64] A cooperative agreement in this context is to be understood as an agreement among *decentralized* decision makers, which is to be distinguished from the case of a *single* decision maker at the EU level.
[65] Ruijter (n 7) 114.

at the local or national level may make the authorities at those levels reluctant to take drastic measures. Having a central capacity that can compensate for the financial consequences of such measures will help to equalize the return" to such measures to their broader EU return.

No doubt there will be hesitations and obstacles in place – despite the lessons learned from the Swine Flu epidemic and the tragic lessons from the Covid-19 crisis – towards centralizing policies for medical countermeasures to infectious diseases. One such hesitation could be the democratic basis of centralized EU decision making in making distributive choices with regard to medicines. However, at Member State level it is likely that such distributive choices – which require difficult scientific and ethical choices – are also a matter for the executive. The national parliament has the possibility to hold the executive to account after the choice has already be made, given the speed of decision making that the pandemic might require. When it comes to centralizing policies in response to infectious diseases, there is accountability to the national parliaments for the delegation decision and to the European Parliament and the national parliaments for the specific design of the policy. When it comes to the actual execution of the policy in the face of an urgency, accountability to the European Parliament can only be exerted ex post. The situation may be seen as analogous to Eurozone monetary policy, in which decisions are made by "technocratic experts", while the President of the ECB appears regularly for hearings in the European Parliament.