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Article

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Centralizing EU Policy in Fighting Infectious Diseases: Status Quo, Citizen Preferences, and Ways Forward[1]

ABSTRACT

We confront the traditional role of the EU in the domain of health with the urgent need for collective action triggered by the coronavirus 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 toward centralizing at the EU level of policies to combat infectious diseases, which indicates considerable support.

The world is in the throes of the outbreak of COVID-19. Healthcare systems are overburdened, while the economic implications are devastating. This paper addresses the question of what the best policy options for organizing EU solidarity are with regard to medicinal countermeasures to infectious diseases. This question is analyzed against the backdrop of a legal and economic policy analysis, informed by research on public attitudes. We first discuss what "EU health solidarity" means. Second, we analyze the current options for collective EU action to address pandemics. The EU's competences in health remain limited, even after several contagious disease outbreaks in the past two decades (De Ruijter 2019). Third, we empirically report results from a survey experiment among a representative sample of Dutch citizens surveyed before the outbreak of the current crisis.

The conclusions 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 countermeasures to 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 (MS) to the cooperation that is needed ex post, once a crisis hits.

EU SOLIDARITY IN HEALTH

Solidarity is explicitly recognized in EU law and policy. In the case of disasters, such as a pandemic, the European Treaties set out a clear mandate, at least in principle. Article 222 of the Treaty on the Functioning of the EU (TFEU) stipulates that solidarity demands that in case of a disaster, MS are to provide assistance to one another and act jointly and in cooperation.

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 revolved around health exceptions to the free movement of goods.

Although health is mentioned throughout the Treaty as an exception to the free market principles and as a general EU goal, Article 168(5)(7) 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. 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 the EU level that followed after the swine flu outbreak.

EU HEALTH SOLIDARITY IN THE FACE OF DANGER

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 countermeasures more generally, we should go back

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to 2009 with the global spread of a new virus, swine flu. There was a fear that the virus would have a mortality rate comparable to that of bird flu (over 60 percent) and would spread more easily. Luckily the swine flu turned out to be no more deadly than a seasonal flu, but the current difficult choices in terms of the organization and acceptability of EU solidarity regarding the COVID-19 outbreak in Europe already came to the fore with the 2009 swine flu. 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 created the basis for the current EU role, by adding to Article 168 TFEU: "Union action, which shall complement national policies, shall be directed toward 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."

At the time of the 2009 swine flu outbreak, no secondary EU legislation had been adopted on the basis of this added paragraph in Article 168 TFEU. However, a major problem arose with respect to the availability of pandemic vaccines and antivirals. The European Commission had been trying for years to create a stockpile of antivirals. Nevertheless, this was deemed unacceptable by the MS that wanted to keep the ability to procure medication at the MS level.

Following Commission efforts in order to address some of the problems identified above, in 2013 Decision 1082/2013/EU of the European Parliament and the Council was adopted dealing with serious cross-border health threats. Again, however, MS did not agree to a binding system for public procurement. Instead, Article 5 of the Decision created the legal basis for voluntary public procurement of medical countermeasures in case of a health emergency. The Joint Procurement Agreement (JPA) that further implements Article 5 entered into force in 2014. This agreement applies to joint procurement of medicines, medical devices and "other services and goods" needed to mitigate or treat cross-border threats to health.

The procedure per procurement is agreed among the contracting parties (participating MS and the Commission). One condition is that it should not impede the functioning of the internal market. Importantly, with each tender, participating MS need to decide on the criteria governing the allocation of the available amounts of medical countermeasures among themselves. In principle, they should receive the amount that they have ordered. In urgent situations, MS may request derogation from these general allocation criteria and receive the countermeasures at a faster rate than other participating MS. Furthermore, the agreement allows MS to donate countermeasures acquired under the joint procurement procedure.

The EU can play an important role for COVID-19 in organizing health solidarity through a European public procurement process. The current system already has created a centralizing effect in a pre-purchase that was done with 15 MS in 2019, and currently more of these processes are on the way.

Another route for a more central role for the EU could be under the heading of EU solidarity proper, rather than under that of the EU health law regime. The EU Civil Protection Mechanism based on Article 222 TFEU depends on the willingness of MS to join forces. In 2019 the Mechanism was strengthened by "rescEU," in an attempt to centralize EU capacities. Article 12 of this Decision provides for the EU to use its internal funds, pre-committed national funds, and EU co-financed MS capacities at the disposal of EU efforts, to respond to a major emergency.

This mechanism also creates the possibility for joint procurement, parallel to the JPA under the health infrastructure. Here, the Commission can assume a more central role, because the Decision allows for central EU implementation of decisions toward distribution and allocation. Nevertheless, the actual capacity of rescEU still largely depends on the willingness of MS to contribute, and is likely substantially smaller than what can be nationally organized or through the JPA.

Importantly, the EU procurement of a pandemic medicine and other medical products can be severely undermined if MS, 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. Solidarity is also undermined by hoarding and limitations in the supply chain. However, even if the Commission would adopt an "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 Commission would scare MS politicians more than not having control over the stockpiles of particular goods.

WHAT WOULD CITIZENS WANT FROM EU HEALTH SOLIDARITY IN THE PROCUREMENT OF PANDEMIC MEDICINES?

In exploring the role of the EU for ensuring health solidarity when it comes to a pandemic, it is 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 given the tendency of people to express opinions about health matters in socially desirable ways rather than expressing true thinking.

To shed some light on public support for the EU's role in medical procurement, we conducted an original experiment as a pilot to a larger survey project on attitudes toward 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 2,400 policy packages judged by respondents.

The experimental part of the survey was a so-called conjoint experiment. This involved asking respondents to judge pairings of policy packages that combined 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 were: (1) Do respondents prefer a program 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. Only a narrow set of medicines; b. All medicines where pooling yields a financial advantage); (2) Do respondents prefer a program that lends access to the pooled medicines based on a country's own contribution, or instead priority access based on needs to stop epidemic spread? (Possible answers: a. Access based on a country's contribution; b. Priority access based on need); and (3) Do respondents prefer a program that is administered by national-level experts or by EU-level experts? (Possible answers: a. EU-level agency administers; b. National-level experts administer). In the conjoint experiment, 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.

This study reveals preliminary but important evidence about public support for EU medical procurement. First, there is a plurality of support for, as opposed to being against such EU pharmaceutical sharing. Figure 1 shows that the combination of somewhat and strongly support given to any given package garners almost 44 percent of the sample, while "only" 23 percent are opposed (32 percent are indifferent). These patterns are not significantly different across basic demographic sub-groups (younger versus older; more versus less educated; men versus women). This is a sign, however tentative, that EU-level procurement would command substantial support among the Dutch population.

Second, perhaps more interestingly, the respondents express preferences for a particular kind of EU procurement program with respect to the three dimensions of the procurement policy. These preferences are summarized in Figure 2, 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 that exhibits the randomly assigned policy features per dimension. The dots capture the mean prediction, while the dark lines depict the range of predicted values within 95 percent confidence.

Figure 2 shows clear patterns regarding the preferred procurement policy. The sample is indifferent as to whether EU-level or national agencies administer such programs: on "Who administers?" respondents are very weakly less likely to prefer national-level to EU-level administration (the baseline). The difference is clearly not statistically meaningful; a substantial part of the confidence interval crosses the vertical line. By contrast, Figure 2 shows that the respondents clearly tend to prefer an EU program that covers a broad swath of medicines, potentially *all medicines:* respondents are about 15 percent more likely to choose an EU procurement policy that includes such coverage over a policy

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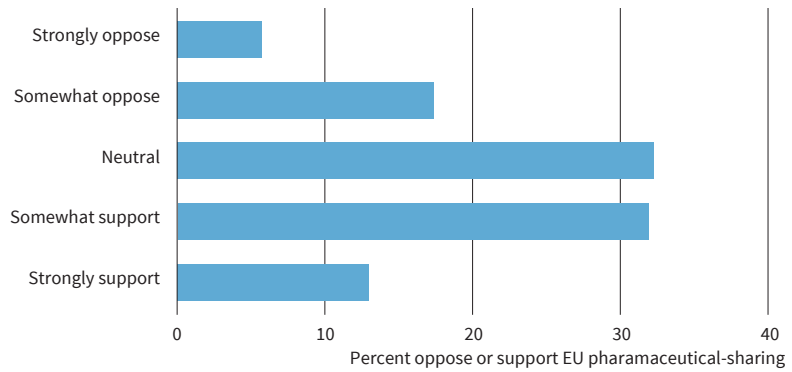
Figure 1

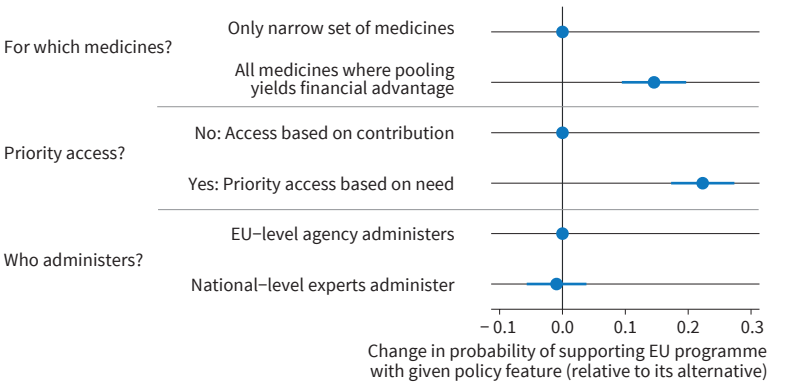
Percent of Dutch Respondents Supporting EU Medicine-procurement Sharing



Source: Authors' calculations.

Figure 2

Predicted Preference for Policy Features of EU Medicine-procurement Sharing



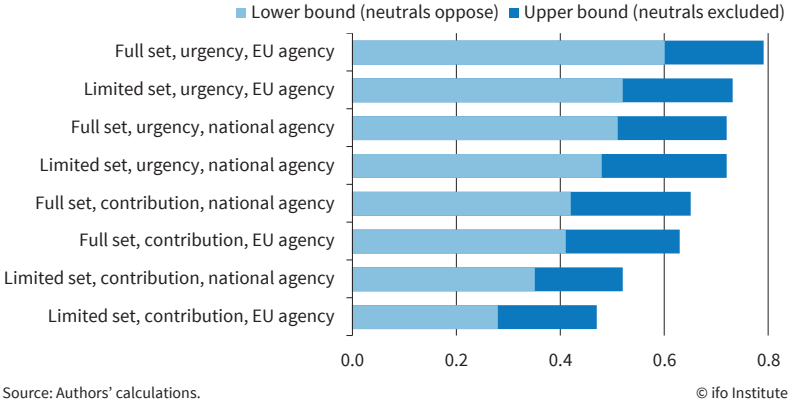
Source: Authors' calculations. © ifo Institute

that focuses only on a narrow set of medicines (the baseline). Finally, Figure 2 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 "Priority access" we see that respondents are about 23 percent more likely to choose an EU-procurement policy that gives priority access to countries where a contagion can be traced, i.e., based on need, to merely providing access based on a country's actual contributions (the baseline).

Finally, Figure 3 depicts the preference ranking over the eight possible policy packages. We show this ranking in two ways. The first, shown by the dark bars, is based on "Strongly support" plus "Somewhat support" as a fraction of all responses. The second, shown by the sum of the dark and light bars, focuses on the cases in which respondents are in favor or against, and is based on "Strongly support" plus "Somewhat support" as a fraction of all responses minus the "Neutral" responses. Both rankings are identical. Interestingly, the most preferred package is the combination in which the degree of policy centralization is at its maximum, i.e., joint procurement of all medicines, allocation based on urgency and execution at the EU level. The dimension "urgency based" versus "contribution based" seems the most important, since

Figure 3

Preference Ranking over All Policy Packages



Source: Authors' calculations. © ifo Institute

all urgency-based packages uniformly dominate all contribution-based packages. Next most important is the width of the package to be jointly procured, as "full set" always dominates "limited set," holding the other dimensions of the packages constant.

Because the survey was conducted on a limited sample from one country at one moment, one should not overinterpret the outcomes. It is also well-known that the framing of a survey may have an effect on the outcomes. Moreover, our experiment took place at a moment when the described frame was still hypothetical and before any public debate about the centralization of policies in response to infectious diseases had taken place. Finally, if the same pilot were held now, respondents' answers might be shaped by the coronavirus crisis experience so far. Overall, we interpret the results of our pilot experiment as providing qualified but significant support for the view that there is meaningful political traction for EU-level pooling of procurement capacity.

POLICY SUGGESTIONS FOR AN EFFECTIVE WAY FORWARD

Across EU countries, there are large differences in healthcare systems. Systems differ not only in terms of the quality and available budgets, but also in terms of history, culture, and organization. There are valid reasons to respect the "subsidiarity principle" in healthcare matters, as deviations from this principle carry a danger of inefficiencies or may exacerbate inequalities: a central decision that ignores differences in national health arrangements could have widely varying impacts on MS 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 EU must prove that it can also support the MS in a tangible way at the EU level. Therefore, the joint procurement initiatives both within the EU health regime (which can ensure size and volume) and the rescEU (which creates a central allocation authority for the Commission) are so important. However, "volume" and "central authority" do not coincide. It does not suffice for MS to say that the EU should merely ensure 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 to keep citizens more safe.

However, the policy legacy since the swine flu epidemic shows that national policymakers prefer a domestic-centered equilibrium, whereby the reluctance to follow internal market principles is coupled with an equal reluctance by MS politicians to pool

the procurement of medicines as it would potentially transfer redistributive power to the EU level (WHO Regional Office for Europe 2016; Espín et al. 2016). Our poll among Dutch respondents suggests that such reluctance may be misguided. The fact that even Dutch respondents are prepared to pool medicine procurement and share risks at the EU level may be seen as quite remarkable as the Dutch are among the most skeptical when it comes to European-level economic stabilization arrangements. 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 medical countermeasures, 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.

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 medical countermeasures as is outlined in rescEU, without the inefficiencies that are currently there as a result of the intergovernmental and voluntary nature of the process under the health regime and the legally embedded possibilities for behavior lacking in solidarity.[2] Central procurement is needed for protective devices, and will certainly be needed for the vaccine against the COVID-19 virus once 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 MS linked to their GDP, population, and demographics. Demographics is relevant, because countries with an elderly population make more use of medicines on average. It cannot be excluded that the proposed policy centralization has redistributive elements, which is the case when contributions are linked to per capita GDP. However, the relatively limited redistributive effects should be weighed against the benefits of centralization.

What are these benefits? First, by centralizing procurement it will be more difficult for pharmaceutical companies to play off MS against each other by threatening not to supply to an individual MS if it tries to negotiate lower prices. Secondly, with a common stockpile of medical countermeasures managed at the EU level, 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 of where to target the firepower should be made 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. Although breaking away from the cooperative solution is likely self-defeating, because it reduces the chances to quell a disease outbreak where it starts, 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.[3] Ideally, the EU sets up arrangements ex ante that are ex post credible. Obviously, Europe has missed the "ex ante" of the current crisis. However, this crisis may also provide a chance to get to solutions that are normally unthinkable. We have seen that during the European debt crisis when crisis arrangements like the ESM were set up. Our proposal for 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 must be 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 their 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 up to the experts to determine its best allocation given the availability and the objective, e.g., minimizing lost years of life or number of casualties. Ethical considerations will inevitably play an important role in determining the relevant objective. However, these are the domain of the politicians rather than the experts.

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

[2] Costa-Font (2020) argues in favor of a European "health citizenship," based on the observation that European governments adopt widely differing policy responses to the COVID-19 crisis, which is hard to motivate as an optimal solution.

[3] Here, a cooperative agreement is to be understood as an agreement among *decentralized* decisionmakers, which is to be distinguished from the case of a *single* decisionmaker at the EU level.

crisis – toward centralizing policies for medical countermeasures to infectious diseases. One such hesitation could be the democratic basis of centralized EU distributive choices with regard to medicines. However, at the MS level it is likely that such distributive choices – which require difficult scientific and ethical choices – are also a matter for the executive. 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 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.

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