Securing circulation pharmaceutically: Antiviral stockpiling and pandemic preparedness in the European Union

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Introduction

Looking back over the first decade of the 21st century, we could be forgiven for thinking that Europe was besieged by an epidemic of epidemics. It was the decade in which the United Nations Security Council first discussed a health issue (HIV/AIDS) as a threat to international peace and security. It was also the decade in which European governments had to contend with the rapid international spread of a new coronavirus causing Severe Acute Respiratory Syndrome (SARS). No sooner had the threat of SARS dissipated than governments were confronted by a cascade of pandemic flu scares – from 'bird flu' (H5N1) and 'swine flu' (H1N1) through to the more recent human infections with H7N9 in China. The battery of virus alerts quickly elevated pandemic preparedness to a top-level political priority in Europe and beyond. Reflecting this increased threat perception, security agendas evolved to explicitly incorporate 'health security' as a crucial addition to the portfolio of European security policy – frequently ranked on a par with the threat of terrorism.

Yet all the while there was also another, and rather less obvious, 'epidemic' sweeping across the European continent: an epidemic of pharmaceutical stockpiling. Spurned by intense fears of an imminent H5N1 'bird flu' pandemic in 2005, governments across Europe anxiously lined up at the gates of pharmaceutical companies in order to place vast orders for scarce antiviral medications such as oseltamivir (brand name *Tamiflu*). Between them, the national governments of Europe would expend billions of euros over the next few years amassing new antiviral stockpiles. Yet the human pandemic of H5N1 did not materialize, and many public health planners were caught off-guard when the next pandemic was eventually caused not by H5N1, but by H1N1. As it became clear that the course of that new H1N1 pandemic would not nearly match the dire predictions that had formed the basis for so many pandemic preparedness plans, an intense public backlash against the costly pharmaceutical stockpiles ensued. Do they represent reasonable value for money, given the considerable resources expended in their creation and maintenance? Was there undue commercial influence in the decision-making processes to create those stockpiles? How persuasive and transparent is the scientific evidence that they would actually work as intended in a pandemic? All of these questions, in turn, have prompted yet a third epidemic – an epidemic of detailed reviews, exhaustive audits and lengthy hearings into the evolution of pandemic preparedness planning, carried out at institutional, national and international levels. The dissection of pandemic preparedness planning is now in full swing.

Scholars of security studies have made vital contributions to that dissection, using pandemic preparedness policy to illustrate the rapid expansion of security agendas to incorporate health-based threats (Cooper, 2008; Elbe, 2003, 2009, 2010b; Enemark, 2009; Lakoff and Collier, 2008; McInness and Lee, 2006; Rushton and Youde, 2014). The new notion of global health security has also formed the basis for detailed studies into the social dynamics and political implications of securitizing international health issues (Davies, 2008; Elbe, 2006, 2010a; McInnes and Rushton, 2013). Further scholarship has attended to the play and proliferation of anticipatory logics in pandemic preparedness planning (Diprose et al., 2008; Lakoff, 2008; Whitehall, 2010), and has even explored pandemic flu as the manifestation of a new 'preparedness' paradigm in security policy (Anderson, 2010; Lakoff, 2008; Lakoff and Collier, 2008; Samimian-Darash, 2011, 2013; Stephenson and Jamieson, 2009).

One critical area of pandemic preparedness planning, however, has so far attracted comparatively little attention in security studies. Very few scholars have looked in detail at the material technologies that lie at the heart of the pandemic preparedness apparatus: pharmaceuticals. Novel pharmaceutical products – such as the antiviral medication *Tamiflu* – were widely identified by governments in Europe and around the world as the 'first line of defence' against pandemic threats, and as the cornerstone of 21st-century pandemic preparedness planning. The two frequently went

agreement on strengthening EU health security reached at the end of 2013 extended the existing European coordination mechanism for communicable diseases to cover *all* health threats of biological, chemical, environmental and unknown origin. It also provided an institutional foundation for the EU Health Security Committee, which had been newly established as an informal committee after the 2001 anthrax letters in the United States. The draft decision even created a new legal basis for the (voluntary) joint procurement of pandemic vaccines – which is intended to help member-states achieve lower prices and allow greater flexibility, and to create more equitable access given limited production capacities at the global level (EU, 2013).

That last element was not only a particularly complex area of diplomatic negotiation, but – more crucially – exemplifies just how central the procurement of pharmaceuticals has become for European security policy in the space of just a couple of years. It was only a few years ago – in 2005, to be exact – that many governments across Europe first rushed to amass such vast pharmaceutical stockpiles for the purposes of strengthening health security. The arrival of dead birds infected with highly pathogenic avian influenza (H5N1) at the eastern borders of the EU triggered that stockpiling frenzy, especially of antiviral medications such as *Tamiflu* (manufactured by Roche). As William Burns, head of Roche's pharmaceuticals division, put it in October 2005: 'Following four ducks (that died) in Romania last weekend, Europe went mad. I don't think you'll find a single pack (of *Tamiflu*) in Paris. And this is not because we've had an influenza outbreak' (cited in Turner, 2005). The epidemic of pharmaceutical stockpiling that would rapidly sweep

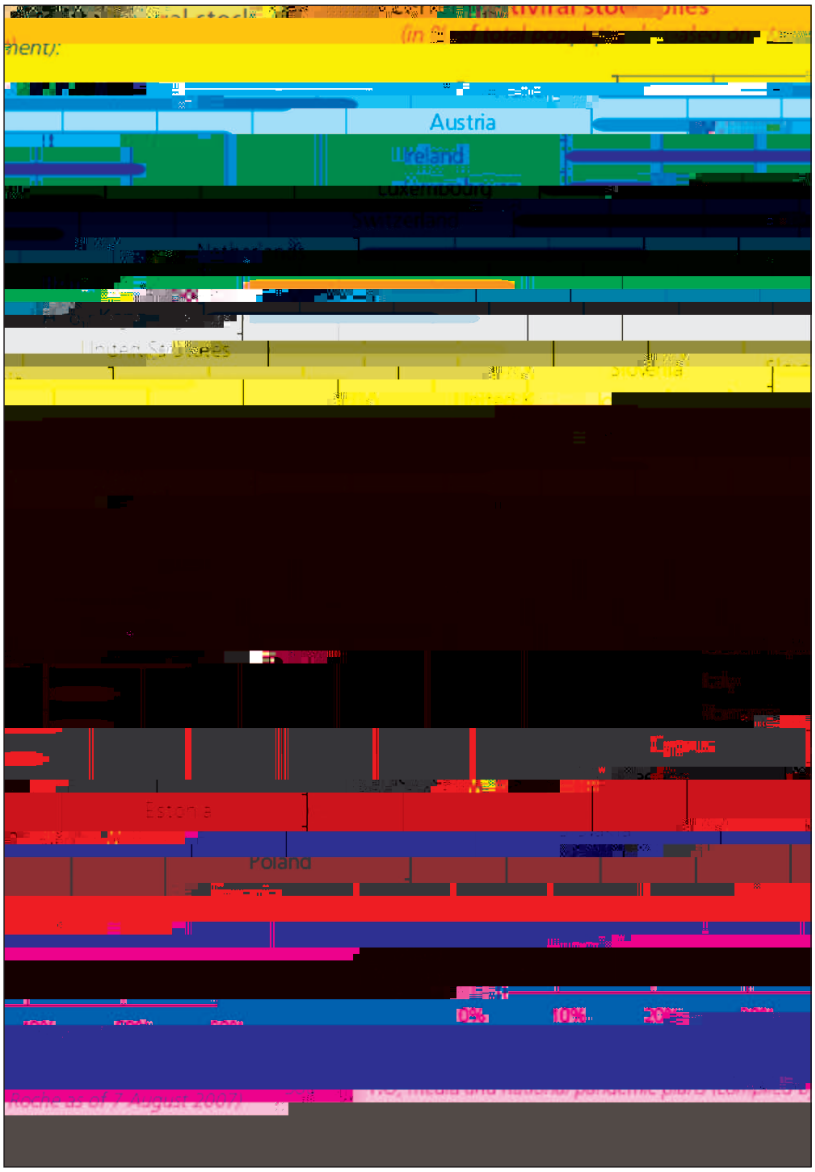

Figure 1. [illegible] 2007, [illegible]
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more than any other, it is surely this rapid surge to create vast new pharmaceutical stockpiles of antiviral medications. Indeed, the entire pandemic preparedness apparatus that has been erected over the past decade is unthinkable without the central role played by pharmaceuticals at the very heart of that structure.

The widespread move towards large-scale stockpiling of antivirals marks a novel development in European security policy in three respects. First, and as we will explore in further detail later, these antiviral medications represent an entirely new class of medicines called neuraminidase inhibitors. Although older types of antivirals were used for treating influenza infection in prior decades, the

development of this new class of neuraminidase inhibitors was dependent on quite significant scientific and technological advances in virology, biochemistry and pharmacology. Neuraminidase inhibitors such as *Tamiflu* were only developed commercially as recently as the mid- to late 1990s, and did not receive regulatory approval in Europe until 2002. First and foremost, neuraminidase inhibitors such as *Tamiflu* therefore constitute a new and previously unavailable pharmaceutical intervention that governments could have at their disposal for pandemic preparedness planning. They would no longer have to rely solely on the much older vaccine technology.

Second, those antiviral stockpiles also represent a new – or at least augmented – societal deployment of pharmaceuticals. While pharmaceuticals have been routinely used in medical care for decades, the significance and function of antiviral stockpiles stretch beyond the confines of routine healthcare, trespassing deeply into the domain of national security policy. In fact, antivirals such as *Tamiflu* have become part of a whole new discursive category of medicines labelled 'medical countermeasures' – a term reserved for precisely those pharmaceuticals such as *Tamiflu* that exist at the intersection of health and security policy, and that can be made available to the civilian population during an emergency. The augmented security significance of those medications also goes some way towards explaining why – physically – antiviral stockpiles are often kept separate from other medicines destined for use in routine healthcare. In many European countries, the creation of these antiviral stockpiles led to the identification of novel spaces for storing them, while in some countries (including the United States) the packaging of the capsules for pandemic use was also changed to indicate their special pandemic preparedness role. In most instances, such antivirals are now stored in large, separate warehouses capable of maintaining the required environmental conditions. Those warehouses have special security arrangements in place to protect their contents in the event of a pandemic, which is also why the precise location of these warehouses remains secret in most countries. The fact that these antivirals are now deliberately acquired for broader security purposes, and with security considerations expressly in mind, marks a second novel aspect of those pharmaceutical stockpiles.

Finally, antiviral stockpiles also represent a significant development within the much longer history of strategic stockpiling. Historians trace the broader practice of stockpiling back at least 4000 years, usually on the basis of a reference in the Old Testament to Egypt building a stockpile of food equal to two years of normal consumption (National Research Council (NRC), 2008: 133). There is nothing new about stockpiling, per se. There is, to be sure, also a considerable history of stockpiling strategic resources crucial to maintaining a war effort during the Cold War (Snyder, 1966). Yet those 20th-century precedents of national stockpiling were predominantly focused on minerals and other strategic goods required for sustaining combat operations, or on keeping the economy afloat – as in the case of the creation of oil reserves in 1973 following the energy crisis of that year.

The recently established antiviral stockpiles stand out against the backdrop of this longer historical experience of stockpiling because they are devoted specifically, and even exclusively, to medicines and pharmaceuticals. They are part of a wider *biological* turn in security policy where, as Melinda Cooper (2008: 75) argues, 'the frontier between warfare and public health, microbial life and bioterrorism [has] become strategically indifferent'. With the rise of the twin biological threats of pandemics and bioterrorism, the kinds of materials now deemed crucial to national security are not confined to those narrowly related to military efforts, or even to the broader maintenance of the economy – but also include the overall health of the population. Security policy needs 'to arm itself against the generic microbiological threat, from wherever it might emerge' (Cooper, 2008: 75). Pharmaceuticals are emerging as the weapon of choice.

Yet no sooner had governments begun to create those towering pharmaceutical stockpiles than the whole practice quickly became embroiled in a number of intense public controversies. Many of those controversies were triggered by the unexpectedly mild experience of the 2009 H1N1 outbreak. The 2009 H1N1 pandemic was 'unexpectedly' mild in the sense that the morbidity and mortality

rates of the virus did not nearly mirror the ways in which a future flu pandemic had been widely predicted by a number of elaborate socio-economic models, as well as the dramatic large-scale simulation exercises in which many public officials had participated. Nor, of course, did the experience of H1N1 in 2009 and 2010 match the way in which the catastrophic experience of pandemics had been more publicly premediated in a series of popular fiction novels and blockbuster films – from *Outbreak* and *28 Days Later*, all the way through to *Contagion* (Aradau and Van Munster, 2011; De Goede, 2008). A public backlash against these antiviral stockpiles soon ensued.

Today, probing questions are being openly raised as to whether the initial expenditure on these antiviral stockpiles was ever justified in the first place (National Audit Office (NAO), 2013). Investigative journalists have expressed disquiet about whether the commercial interests of large pharmaceutical companies may have unduly influenced the political decisionmaking leading up to the creation of these stockpiles – especially in the United States government and at the WHO (Cohen and Carter, 2010; Stanton, 2005). All the while, *Tamiflu* has also found itself at the eye of a much larger political storm about insufficient public access to detailed clinical trial data that is used to demonstrate the efficacy and safety of new drugs in general. This latter dimension has been the subject of intensive scrutiny by groups – such as the Cochrane Collaboration – who conduct systematic reviews of the evidence base for the efficacy of drugs (Jefferson et al., 2010). In many ways, antiviral stockpiling has now become as controversial as it has been pervasive in Europe.

Security, circulation and governmentality

Given the enduring public controversy surrounding *Tamiflu*, how did governments first come to view pharmaceutical stockpiling as such an indispensable element of pandemic preparedness planning? What are the underlying political rationalities that rendered pharmaceutical stockpiling such an attractive policy response for governments across Europe? Taking a broadly genealogical perspective, at least three crucial transformations in the rationalization of government had to occur for this recent 'epidemic' of pharmaceutical stockpiling to unfold across Europe. Those transformations are described in Michel Foucault's (2007) influential and well-known lecture series on the emergence of a new form of political rationality he called 'governmentality'.

First, and again viewed in a much longer historical perspective, security policy would have to become broadly concerned with improving the welfare of populations – rather than just with the more narrow task of securing the rulers and their power. This, Foucault famously argued, is one of the key features of the new 'governmental' economy of power that began to emerge in Europe from the 18th century, and that rationalizes political rule precisely around a new political object of the 'population'. The 'population will appear above all else as the final end of government', and it now 'appears as the end and instrument of government rather than as the sovereign's strength' (Foucault, 2007: 105). From that point onwards, political rule is increasingly articulated with a view to 'improv[ing] the condition of the population, to increas[ing] its wealth, its longevity, and its health' (Foucault, 2007: 105). Pharmaceutical stockpiling is integral to this political rationality because it is intended – and legitimated publicly – as a way of protecting the welfare of populations. Indeed, the very reason those stockpiles are built on such a large scale is to make it possible to extend antiviral protections to the population as a whole.

Second, security policy would also have to directly encompass care for the underlying *biological* dynamics shaping population welfare. Security could not be confined to protecting and defending the territory of the state, or even organizing the material enrichment of society; it would also have

a population can perish or, on the contrary, grow' (Foucault, [1981] 2007: 161). Designed to protect the health of populations from the biological threat of infectious disease, pharmaceutical stockpiles are integral to a political rationality that also encompasses the active management of biological dynamics underlying the population (Foucault, 1976: 142–143).

That said, there are plainly very many different diseases affecting the health of populations – most of which are dealt with through private or national systems of healthcare. Only very few, if any, of those other diseases have prompted the same large-scale creation of pharmaceutical stockpiles in the way that the threat of pandemic influenza has recently witnessed. What is it about the threat of pandemic flu in particular that necessitates such an extraordinary policy response? The l rationatix088 Tw a politicalulear thabeencehas levaren the).

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Yet a careful reading of Foucault's lecture series *Security, Territory, Population* indicates that this observation really only begins to scratch the surface of the complicated relationship between circulation and security. In fact, that relationship runs much deeper than merely sorting the 'good' circulation from the 'bad' circulation (defined broadly in terms of how it impacts the welfare of the population). The transition towards a governmental economy of power will also give rise to a whole new category – or class – of security threats. For there will be specific circulatory systems that have a natural tendency to spiral out of control in a way that directly undermines population welfare. Foucault argued that such an inherently unstable system of circulation, which could not simply be left to circulate freely, begins to constitute a new kind of 'crisis'. Indeed, a *crisis* would now come to consist precisely of any 'phenomenon of sudden, circular bolting that can only be checked either by a higher, natural mechanism, or by an artificial intervention' (Foucault, 2007: 61). Those new 'crises' of circulation are the correlative of a particular way of rationalizing political rule according to the principles of liberalism and *laisser faire*. They effectively represent the 'dark side' of a rationalization of political rule bent on allowing the free play of social dynamics and constantly seeking to stimulate circulation (Elbe, 2007, 2012).

With the rise of the era of governmentality, then, security policy becomes about more than just the traditional geopolitical games of territorial influence. It also becomes about managing circulation and sorting the 'good' from the 'bad' circulation. More still, it becomes concerned with identifying precisely those social phenomena that cannot be left to circulate freely lest they spiral out

systems of circulation, leading to stasis. A pandemic is the quintessential 'crisis of circulation' because it is a circulatory threat to the very notion of circulation itself.

Beyond vaccines: Securing circulation pharmaceutically

What can governments do to protect populations against pandemic threats? Is there, to remain with Foucault's (2007: 61) terminology just a little bit longer, any 'higher, natural mechanism' or 'artificial intervention' that governments could adopt in order to secure their populations against the emergence of such a crisis of (viral) circulation? The traditional mechanism that Foucault himself referred to in his lecture series *Security, Territory, Population* was vaccination. Reflecting on the threat posed by smallpox in the 18th century, Foucault argued that the discovery of a vaccine meant that the problem of smallpox could now be contained through a 'higher, natural mechanism' – in this case, the human immune system. By exposing people in advance to small doses of the disease, the natural human immune system could develop new antibodies, allowing people to quickly fight off future infections – and before the infectious disease could take hold in the population as a whole. Of course, the introduction of vaccination during this historical period still predated the modern germ theory of disease, as well as our contemporary understanding of the workings of the human immune system. At the time, vaccination in fact stood completely apart from, and very much outside, accepted medical knowledge. It was not even known how or why the practice of vaccination worked. It was simply a matter of trial and error and empirical record that it did (Foucault, 2007: 58).

The fact that it evidently worked meant that one could now raise additional statistical questions about what chances an individual had to succumb to smallpox, or to acquire smallpox when vaccinated, and indeed how the vaccine would affect the distribution of the disease in the population, and so forth. The availability of vaccines thus gave rise to a new logic of managing infectious diseases that was not based on the sovereign principle of exclusion, as was historically the case with leprosy, where those infected were simply excluded physically from society. Nor was it the disciplinary logic of quarantine, as had been the case with plague in the Middle Ages. Instead, it was the question of efficiently managing smallpox and keeping it within socially and economically acceptable limits by stimulating a 'higher, natural mechanism' through vaccines to contain its circulation (Foucault, 2007: 10).

Foucault's discussion implicitly recognizes just how desirable vaccines are to governments as a technology for managing the problem of infectious diseases. They are preventative, can have a high rate of success, and can be extended to the entire population without major material or economic difficulties (Foucault, 2007: 58). In addition – returning to the threat of pandemic flu today – we can see that vaccines also continue to remain the most desirable intervention against pandemic flu for many governments. According to the WHO (2009), 'vaccines are among the most important medical interventions for reducing illness and deaths' available today. In an 'ideal' world, many governments would thus like to acquire the capacity to routinely vaccinate their populations against the threat of pandemic influenza, and would then no longer have to worry about the destabilizing threat it poses. All kinds of flows and systems of circulation could continue to unfold unfettered.

Unfortunately, there is a major catch when it comes to vaccines for influenza. Precisely because vaccines work through the advance stimulation of the human immune system (provoking it to create new antibodies), they have to be virus-specific in order to be effective. In the case of pandemic flu this is a major problem, because influenza viruses are constantly changing and evolving. The incessant circulation of influenza viruses also fans their continuing mutation and evolution. Even vaccinating citizens for seasonal flu requires constant monitoring of the evolution of influenza

viruses circulating around the world, as well as a considerable amount of educated guesswork to predict which strands of the virus are likely to be circulating in the next flu season so as to mass produce the correct type of vaccine.

This problem is exacerbated in the case of *pandemic* flu because – by definition – it is not possible to know in advance exactly what form a new virus might take. A pandemic is usually caused not by a virus that evolves gradually from season to season (genetic 'drift'), but by one that entails a more substantial recombination of viral material (genetic 'shift') to which humans may have much less or even no prior immunity. This makes it extremely difficult to develop a preventative vaccine *prior* to any flu pandemic. Nor can governments simply wait for a new virus to emerge and then quickly mass produce a new vaccine. In the current model of vaccine production, it would take at least six to nine months to mass produce any new vaccine. Even countries that have their own domestic vaccine-production capabilities (and most countries in the world do not) would have to endure the effects of a pandemic for many months without the widespread availability of a vaccine for the population. Even then, there would not be enough international supply to meet global demand.

The unsavoury and thorny dilemma that pandemic flu therefore poses for governments is as

demand, as countries around the world would all seek to acquire large amounts of the medicine simultaneously.

Nor, Roche warned further, could governments simply wait for commercial production to be rapidly scaled up following the onset of a pandemic. Roche representatives briefed governments about how complex the *Tamiflu* production process is, that it is dangerous in parts, and that it involves a series of complicated steps. What is more, it is a pharmacological property of neuraminidase inhibitors that they must be administered within 48 hours of the onset of symptoms in order to have a significant effect. In terms of making these antivirals available to the population at large, governments and authorities would thus require not just large-scale access to the medication, but also *rapid* access to the medicine in order to make it available before it is too late. Some kind of artificial mechanism would be needed to align the correct levels of viral and antiviral circulation in the immediate aftermath of a pandemic.

In a context of limited international production capability and the extraneous demands that a pandemic would pose, the only way to guarantee such rapid access to large quantities of antiviral

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