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Invoking Security to Bypass Procedure: The European Union's Critical Medicines Act

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Abstract

The European Union's recently proposed Critical Medicines Act (CMA) was published without recourse to standard democratic policy-making procedures. Framed by the European Commission as an urgent response to a pressing security threat, the CMA was not subject to an impact assessment, and the stakeholder consultation designed to inform its development was both short and last-minute. In this commentary, we examine the implications of the CMA case for the democratic legitimacy of EU policy-making. We argue that, since medicine shortages have been on the EU agenda for nearly a decade and the CMA extends beyond emergency provisions to address long-term industrial policy, it does not constitute an urgent or exceptional policy issue in the usual sense. Situating the CMA within wider patterns of EU health securitisation, we highlight the risks posed by circumventing procedural safeguards, concluding that this shift may exacerbate perceptions of a democratic deficit within EU governance.

Keywords: Critical Medicines Act; democratic legitimacy; European Union; impact assessment; securitisation

Introduction

The democratic legitimacy of EU policy-making has long been subject to contestation (Follesdal and Hix, 2006). Responding to this challenge, the European Commission has developed a set of procedures – ex ante impact assessment, ex post evaluation, stakeholder consultation and others – designed to enhance legitimacy by fostering transparency, inclusivity and accountability (Alemanno, 2015; Borrás and Ejrnæs, 2011). Under the banner of Better Regulation, it has established a system that institutionalises broad consultation and detailed policy analysis, with the goal of fostering evidence-based policy-making. However, in response to destabilising events unfolding over recent years, the Commission increasingly operates in 'crisis mode', bypassing these procedures as part of a widespread securitisation of EU governance (Kaunert and Léonard, 2021). Using a salient case study from the field of health – a policy area not traditionally linked to security – this commentary traces how the recent proposal for a Critical Medicines Act (CMA) referred to security to justify bypassing Better Regulation procedures. We first introduce the CMA and its emergence on the EU agenda, highlighting how the urgency of the proposal was crafted by the Commission. We then offer some initial challenges to the urgency framing, noting the history of EU action on medicines shortages, which was not undertaken as a matter of urgency or security, and the scope of the proposed CMA, which reaches beyond emergency provisions. We consider the case of the CMA within the wider context of the securitisation of medicines and health policy in the EU and conclude that

this trend is likely to continue under the new, fragmented health mandate. Finally, we reflect on the broader implications that the securitisation of EU governance may have on its (perceived) democratic legitimacy.

I. What Is the CMA and Where Did It Come From?

The proposal for a CMA was published on 11 March 2025. It aims to address shortages of pharmaceutical products in the EU, specifically those labelled critical medicines, by addressing supply chain vulnerabilities and reducing dependency on other countries for raw materials (European Commission, 2025b). The issue of critical medicine shortages was highlighted during the COVID-19 pandemic – most notably via difficulties in manufacturing vaccines and maintaining the supply of medical countermeasures (MCMs) – and has been exacerbated by the disruption resulting from the Russian invasion of Ukraine. However, it is not a new problem, and it was not traditionally considered an issue of security. The Commission's proposal acknowledges that '[s]hortages of medicines have been on the EU's political agenda for almost a decade', and earlier initiatives make no mention of security or defence as considerations relevant to shortages (European Parliament, 2017). Yet, the proposal published in March was expedited and adopted without the procedural elements required of most EU legislation, on account of an urgency that became explicit only in late 2024 and is justified with reference to security. Moreover, its scope reaches beyond critical medicines to address 'medicines of common concern', and many of its provisions serve wider industrial policy and competitiveness priorities, raising questions about the proportionality of the urgency invoked and the potential consequences of securitising medicines policy.

Though discussed previously, concrete commitment to a CMA was made in July 2024, when then candidate for President of the Commission, Ursula von der Leyen, set out her political guidelines for the forthcoming mandate (European Commission, 2024a). Following her confirmation and the appointment of the new Commission, von der Leyen outlined a more detailed health policy agenda in her mission letter to the new health commissioner, Olivér Várhelyi (European Commission, 2024b).[1] The CMA was one of several initiatives listed, without a specific timeline, indicating that it would be adopted in this term (2024–2029) but not as a matter of urgency. However, at his November 2024 hearing in the European Parliament, Commissioner Várhelyi committed to introducing the CMA 'within the first 100 days as a priority action' (European Parliament, 2024). This timeframe was subsequently confirmed in the Commission's work programme (European Commission, 2025a), and the proposal was published on 11 March 2025.

II. Crafting Urgency to Expedite the Policy Process

Commissioner Várhelyi's decision to pledge the CMA's publication within the first 100 days of the new Commission made the initiative urgent. As such, an expedited policy process was put in place, curtailing stakeholder consultation and opportunity for participation and exempting the initiative from the requirement for impact assessment. The proposal justifies this by stating:

[1]The mission letters, a practice started by Commission President Barroso and now sent at the start of each new mandate, communicate the specific tasks and responsibilities of each commissioner.

> Given that security of supply and addressing medicine shortages were a central focus during the evidence-gathering activities for [other, previous EU] initiatives, along with the pressing need for urgent action, no dedicated impact assessment or online public consultation could be conducted ex-ante for this proposed Regulation. (European Commission, 2025b, p. 9)

In practice, an open public consultation (OPC) was conducted, but it was severely curtailed. OPCs are usually required to run for a minimum of 12 weeks and feed into the impact assessment; in the case of the CMA, the OPC was online for just 4 weeks and closed 10 days before the publication of the proposal, limiting (if not precluding) the possibility for its findings to be taken into account. Of particular note, in its justification, the Commission described the 'rich evidence base and extensive stakeholder input' that had been gathered via related initiatives in recent years (European Commission, 2025b, p. 9). These included the revision of the pharmaceutical legislation, the structured dialogue on the security of medicines and the Critical Medicines Alliance. Whilst relevant to pharmaceutical policy and medicines supply, none of these initiatives was designed to support the development of the CMA specifically.

The claim to urgency also exempted the CMA from the requirement to conduct an impact assessment for all new legal acts, which are 'likely to lead to significant economic, environmental or social impacts', or entail significant spending (European Commission, 2023a, p. 42). In its place, the Commission will publish within 3 months of the proposal a staff working document, supported by an external study, summarising the evidence base, consultation findings and the underpinning analysis. Again, the Commission asserted that, though no impact assessment was available, the CMA's provisions 'are based on existing analyses, stakeholder consultations, and lessons learned from past initiatives to ensure a proportionate and evidence-based approach' (European Commission, 2025b, p. 12).

III. Challenging the Urgency Framing

There are valid arguments to be made about the urgency of the medicines shortages facing European healthcare systems and the need to reform the pharmaceutical supply chains that contribute to them. European pharmaceutical manufacturers are heavily reliant on a small number of countries (predominantly China, in the case of antibiotics) for access to key raw ingredients (Glencross, 2024), and the worsening geopolitical situation has exacerbated these weaknesses (Connelly, 2023). But the root causes of shortages are multiple and long-standing (European Commission, 2023b), and there are grounds to question the basis on which the Commission has invoked exception and bypassed standard policy procedure in its adoption of the CMA. We present two such arguments below.

The Steady Proliferation of EU Action on Medicine Shortages

Against the COVID-19 backdrop, the supply chain resilience of MCMs has been high on the EU's health agenda and was made a core element of the new European Health Union. The mandate of the Health Emergency preparedness and Response Authority (HERA), established to boost the EU's pandemic response capacity, focuses predominantly on securing MCMs. The European Medicines Agency's (EMA) mandate has, since March

2022, included the administration of a European Shortages Monitoring Platform and an Executive Steering Group on Shortages and Safety of Medicinal Products. The focus on shortages of critical medicines also features in the revisions of the EU pharmaceutical legislation. In 2021, a structured dialogue on the industrial dimension of supply security produced a staff working document on vulnerabilities of the global supply chains of medicines, published in 2022. In October 2023, the Commission adopted a Communication on addressing medicine shortages in the EU. This was followed in December by the publication of a list of critical medicines developed jointly by the Commission, EMA and national experts. January 2024 saw the launch of a Critical Medicines Alliance, hosted by HERA and tasked with identifying challenges resulting from vulnerabilities and the actions and instruments to address these. A number of additional channels, networks and platforms[2] have been set up to enhance close collaboration with the pharmaceutical industry with the aim to address pharmaceutical supply chain bottlenecks and shortages.

Though these initiatives cite the experience of COVID-19 within their rationale, they were not, for the most part, established in conditions of urgency. Rather, they seem to represent a 'traditional' build-up of EU health capacity, formalising the EMA's ad hoc extension of responsibilities during the pandemic and creating new instruments within ongoing processes, such as the pharmaceutical legislation reform. The existence of a steadily expanding and already operational regulatory scaffolding aimed at securing MCM supply chains raises the question, not of the importance of a CMA, but of the urgency of this specific piece of legislation.

Addressing Competitiveness and Industrial Strategy for Non-Critical Products

Perhaps more fundamentally, the CMA does not sit comfortably alongside other health-related legislation that has been adopted without an impact assessment. The majority of this was adopted in response to the pandemic and includes laws to create a common digital COVID certificate, revise the rules governing cross-border threats to health and extend the mandates of the EMA and the European Centre for Disease prevention and Control (ECDC). These laws respond to threats to the integrity of the EU's free movement principles, a declared public health emergency of international concern and the need for legal certainty following the ad hoc operation of health agencies during the pandemic, respectively. By contrast, the CMA proposal addresses the long-term economic needs of a single sector, in relation to both the critical and the non-critical goods that it produces.

It opens with a discussion of the 'landscape for pharmaceutical manufacturing' and the competitiveness of the industry. Many of the proposal's provisions are related to amending the standard marketing authorisation process rather than introducing emergency measures and it is carefully aligned with the Commission's regulatory fitness and simplification objectives. To this end, it will seek to 'facilitate the creation or expansion of manufacturing capacities of critical medicines, their active substances and key inputs in the EU' (2025b, p. 13), as well as to facilitate the streamlining of environmental

[2]These include 'EU FAB', a network of EU-based vaccine manufacturers, also contracted by HERA, which reserve capacity for vaccines to be fully produced in the EU, and ready to be activated at any time in the case of a crisis. Other examples include the Joint Industrial Cooperation Forum, which allows industry actors representing supply chains related to MCMs (including animal health) to collaborate with the EC and members states representatives to identify and address potential bottlenecks across the supply chain (European Commission, 2022, 2023c).

assessment and permit-granting processes. Finally, the CMA is aligned with the EU's longer term industrial policy goals of reshoring manufacture and favouring EU-made products to strengthen strategic autonomy. Art 18 proposes that '[w]ith regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed […] the contracting authorities shall, where justified, apply procurement requirements that *favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union*' (emphasis added) (pp. 35–36).

In addition to its rationale, the scope of the CMA proposal also reaches beyond what we might expect of an 'urgent' initiative. Critical medicines are defined as those 'for which no appropriate alternative is available and for which insufficient supply would result in serious harm or risk of harm to patients' (European Commission, 2025b, p. 1), but these are not the only focus of the CMA. It also addresses 'medicines of common interest', defined as 'a medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients' (European Commission, 2025b, p. 27). The policy issues engaged here are about market size, demand and availability, rather than security of supply, and are thus quite different from those addressed in the expedited legislation adopted during the pandemic, for instance. In sum, when compared to previous health-related legislation implemented without impact assessment, the aims and purpose of the CMA are much more long term, concern changes to the market structure and regulatory landscape for pharmaceuticals, and address both critical and non-critical products.

IV. The Wider Context: Securitisation of Health in the EU

The political space to craft a sense of urgency in the CMA was created by the broader trend for securitising EU medicines and health policy. Securitisation can occur when an issue is presented as an existential threat to a referent object, to the point that the scale of the perceived threat legitimises resorting to extraordinary measures (Buzan et al., 1998). In this way, successful securitisation 'frames the issue either as a special kind of politics or as above politics' (Buzan et al., 1998, p. 23). Securitisation theory has frequently been used to explain how crises open the political space for health to become securitised (Akhavein et al., 2025). Urgency, severity, uncertainty and unexpectedness are features associated with crises which legitimate treating health in a securitised manner. Whilst crises and exceptional external circumstances are associated with trends of securitisation, the reverse is also true: a securitised governance architecture perpetuates its own logic (Bengtsson et al., 2019).

In the EU, whilst the governance of health started to become securitised in the early 2000s, the COVID pandemic has significantly accelerated this process (Godziewski and Rushton, 2024). In contrast to the national democratic contexts in which securitisation theory was developed, securitisation in a supranational, technocratic context like the EU has been described as more akin to building additional supranational competences – that is, further integration in health (Kittelsen, 2013). The pandemic has been an opportunity for the Commission to consolidate more power and leadership in health, visible amongst other things in the steady development of EU action on medical shortages outlined above. However, in the case of the recent CMA, the push for legitimating further supranational action predates the proposal. Here, the sense of urgency crafted by the

Commission is being used to legitimate the bypassing of due process. Making a credible case for the CMA's urgency, we would argue, is only possible because it is situated within the recent momentum towards health securitisation. That process unfolded during the pandemic and in response to wider geopolitical instability, and further consolidated the Commission's legitimacy in health governance. Arguably, what we are witnessing with the CMA proposal process is further capitalisation on crises and securitised governance, this time with the potential of weakening the Commission's own technocratic processes, many of which were developed in response to the (perception of) a democratic deficit within EU institutions.

Conclusion

The story of how and when the Commission published the CMA proposal is peculiar, not least because of the central, yet ill-fitting, references to urgency that justify its unusually swift process. For the reasons outlined above, we are not convinced by the Commission's assertion that the CMA is urgent in the same sense as other initiatives which have bypassed the procedures of the EU policy process. We do not mean, by this, that shortages of medicines are not important or pressing – this is an issue on which action should be prioritised, and there is clear added value to EU co-operation, as the Commission has been arguing for several years. Rather, our concern is that tools such as impact assessment and stakeholder consultation, however flawed, contribute to the legitimacy of EU policy outputs. That these processes are currently enacted in a way that disadvantages public interest representation is well documented (Lauber and Brooks, 2023; Smith et al., 2015). However, doing away with them altogether risks worsening this imbalance. Ultimately, publicly available impact assessment and stakeholder consultations provide a degree of structure and transparency meant to enhance the democratic legitimacy of EU policy-making. Bypassing these requirements should be possible only in truly exceptional circumstances.

At the same time, the story of the CMA proposal may be illustrative of the impacts of a broader drive towards securitisation of EU governance. Circumvention of due regulatory process has already been documented in other securitised areas, notably in migration governance (Cardwell and Dickson, 2023). We perceive risks in the case of health, too. The fragmentation of responsibilities in the health portfolio – in which responsibility for crisis and preparedness has been reallocated to the commissioner for equality, preparedness and crisis management, Hadja Lahbib, leaving the health commissioner with a reduced mandate – will force health actors to link their initiatives with the prevailing priorities, even where they have a tangential connection to security or defence. In the case of the CMA, national health ministers have already called for the proposal to be considered as part of the defence package, so as to utilise defence budgets to fund it (O'Neill, 2025). Though potentially effective in gaining attention in the short term, there are long-term social equity and human rights risks to securitising policy issues, including in health (Rushton, 2019). Eroding democratic processes is one such risk.

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