



April 25, 2023

The Honorable Stella Kyriakides  
Commissioner of Health and Food Safety  
Rue de la Loi / Wetstraat 200  
1049 Brussels, Belgium

The Honorable Sandra Gallina  
Directorate-General for Health and Food  
Safety  
Rue de la Loi / Wetstraat 200  
1049 Brussels, Belgium

Dear Commissioner Kyriakides and Directorate-General Gallina:

The Alliance for Biosecurity appreciates the opportunity to submit comments in response to the European Commission's proposed revisions to the European Union's general pharmaceutical legislation. Specifically, the Alliance is concerned that the Commission's proposal in its current form could significantly impede Europe's – and, in fact, the entire world's – ability to prepare for future public health crises.

The Alliance is a coalition of biopharmaceutical companies, laboratories, and academic partners that promotes a strong public-private partnership to ensure medical countermeasures (MCMs) – like vaccines, diagnostics, and other emergency supplies – are available to protect public health, enhance national health security, and support governments' ability to respond to chemical, biological, radiological, and nuclear (CBRN) threats, including pandemics.

While the Commission's proposed reforms seem to be rooted in a desire to ensure Europeans have timely and equitable access to the newest biopharmaceutical innovations – a goal the Alliance wholeheartedly shares – the proposal attempts to achieve this admirable objective by reducing intellectual property (IP) protections for newly launched medicines. However, IP protections are what incentivize biopharmaceutical companies to develop new therapies in the first place – without a period of market exclusivity, innovators would not be able to earn back the massive investments required to develop new medicines.

Curtailing IP protections would force European biopharmaceutical companies to make harmful cuts to ongoing biopharmaceutical research and development (R&D) investment, thus hindering Europeans' access to cutting-edge medical advances. This is profoundly concerning as relates to CBRN threat readiness, especially given that there are already relatively few companies working to develop new MCMs for naturally occurring, deliberate, or accidental CBRN threats. Indeed, numerous large pharmaceutical companies decline to participate in this sector due to lack of adequate incentives.

In addition to across-the-board cuts to IP protections, several provisions in the Commission's proposal fail to take into account the unique market dynamics of CBRN MCM development.

For example, the Commission hopes to penalize companies who are unable to launch new medicines in all 27 European Union member states. This well-intentioned policy ignores the fact that governments are often the sole purchasers of CBRN MCMs. A member state's government could decline to purchase a particular MCM, in which case the MCM's developer would have no reason to launch there.

Similarly, there is considerable uncertainty around which potential CBRN MCMs would qualify for additional incentives under the proposal's narrow definition of "unmet medical needs." MCMs are sometimes developed in anticipation of future CBRN threats, rather than those that already exist. Similarly, we worry that the proposal's approach to unmet medical needs could end up discouraging companies working to develop multiple effective MCMs for the same threat.

More broadly, the proposed reforms would severely threaten growth prospects for Europe's more than €200 billion pharmaceutical market by sending a message that future R&D investment is not welcome. Europe's share of global biopharmaceutical R&D investment is already on the decline, and the misguided revisions to existing law would only accelerate that trend.

There is no doubt that the Commission shares the Alliance's goal of bolstering global readiness for future public health threats, whatever form they take. However, reducing IP protections will solely serve to undermine this goal, leaving Europe and its allies far less prepared to face CBRN threats. As such, the Alliance respectfully requests that the Commission please reconsider this harmful proposal.

Sincerely,

A handwritten signature in black ink that reads "Jack Kingston". The signature is written in a cursive, slightly slanted style.

The Honorable Jack Kingston  
Squire Patton Boggs  
Secretariat, Alliance for Biosecurity