

8 May 2024

### **Joint business statement on the EU Proposal on Compulsory Licensing**

We, a coalition of several European organizations, have been closely monitoring the developments regarding the EU Commission proposal for a regulation on EU compulsory licensing for crisis management<sup>1</sup>. As the Council prepares its position, it is important that the necessary time is taken to appropriately address key unresolved issues of the original proposal. While some improvements to the proposal were adopted by the European Parliament, including greater involvement of the rights-holder, a requirement for attempted voluntary licensing, and a reasoned approach to remuneration, there are other problematic provisions that remained, such as inadequate judicial review and forced technology transfer/trade secret sharing.

Business acknowledges and supports the need for preparedness in the face of future crises, which may take various forms such as health, environment, digitalisation, and climate change. It is crucial to ensure that society has access to crisis-relevant products or services. However, we firmly believe that, in its current form, this initiative will undermine innovation and competitiveness of European companies, ultimately impeding Europe's ability to tackle future crises effectively. Weakening IP in this way also sets a negative precedent internationally. It is important to address the myth that IP stands in the way of innovation when it is the opposite. The COVID-19 crisis was an example of the business community's willingness to contribute to a once in a century pandemic by having rightsholders voluntarily agreeing on licensing their rights. This was done under existing international, EU, and Member States frameworks which have largely demonstrated being fit to facilitate a quick solution to the crisis. Furthermore, knowledge-based industries need to be nurtured and protected should Europe want to strengthen its international competitiveness.

The current proposal raises fundamental concerns among the business community such as:

1. It needs to be made more prominent that a compulsory license is a last resort measure, where it "is the only means" to generate access to "indispensable," crisis-relevant products.
2. The inclusion of "additional measures complementing the Union compulsory license" which most likely includes trade secrets and know-how. Trade secrets and know-how must be explicitly excluded from the scope.
3. Definitions need to be clearer and well-defined (e.g., "crises,").

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<sup>1</sup> Regulation on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (Compulsory Licensing proposal).

4. The Advisory Board that will be advising the Commission on its decisions should necessarily include industry experts in both the European-level and national-level processes.
5. A thorough judicial review of a compulsory license must be made available. Right holders should always be given an opportunity to be heard prior to the adoption of any decision on compulsory licensing and to negotiate the “adequate remuneration” or to propose an alternative measure, for example around production capacity or cooperation agreements.

Quality should not be sacrificed for the sake of speed. This initiative should not mean reducing manufacturing standards that the Union has defined to ensure the right level of safety for EU patients and consumers, and for which competent authorities of the EU Member States are entrusted to supervise. We call on decision makers to ensure the principles of proportionality and subsidiarity, as well as legal certainty, are duly respected in this impactful legislation.

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#### **List of co-signatories:**

##### **BUSINESSEUROPE** (<https://www.businesseurope.eu/>)

BUSINESSEUROPE is the leading advocate for growth and competitiveness at European level, standing up for companies across the continent and actively campaigning on the issues that most influence their performance. The association speaks for around 21 million enterprises from all sizes from 36 European countries whose national business federations are our direct members.

##### **DIGITALEUROPE** (<https://www.digitaleurope.org/>)

DIGITALEUROPE is the leading trade association representing digitally transforming industries in Europe. It speaks over 45,000 businesses who operate and invest in Europe. DIGITALEUROPE's membership includes 109 corporations which are global leaders in their field of activity, as well as 41 national trade associations from across Europe.

##### **EFPIA** (<https://www.efpia.eu/>)

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. It represents 37 national associations, 38 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs).

##### **Eurochambres** (<https://www.eurochambres.eu/>)

Established in 1958 as a direct response to the creation of the European Economic Community. Eurochambres acts as the eyes, ears and voice of the Chambers and business community. The association represents more than 20 million businesses through its members and a network of 1700 regional and local chambers across Europe.

##### **MedtechEurope** (<https://www.medtecheurope.org/about-us/>)

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health.