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European Federation of Pharmaceutical Industries and Associations

# EFPIA's Response on the Compulsory Licensing Framework Proposal

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In its Compulsory Licensing ("CL") proposal, the European Commission ("EC") posits a new EU-wide CL for crisis response. This harms innovator IP rights and is a dramatic expansion of the EC's role into Member State ("MS") remit, where viable CL provisions already exist.

CLs are a last resort, all attempts at voluntary licensing having failed. CLs undermine IP and prevent the choosing of preferred partners to rapidly bring goods to market. Undue willingness to employ CLs erodes investor confidence in IP, harming innovation pipelines, and impeding voluntary measures' speed to bring goods to the public in times of crisis. Little in the proposal, however, limits CLs to measures of last resort. Lessons from COVID are clear: CLs were not needed. Voluntary models launched vaccines in a year and rapid scale-up made supply quickly exceed demand. Vaccine delivery challenges were related to trade, *eg* export bans, or issues of logistics and uptake. CLs would have only diverted scarce resources, hampering supply.

The proposal fails to provide compelling evidence for an EU-wide CL, despite the clear request from the RSB for both concrete examples and impact on future R&D investment. It disregards the public consultation, which favors a coordinating role for the EC. There is no reason for why this was rejected nor a showing of MS CL provisions as inadequate. An EU-wide CL is simply not required, as coordination is preferable and achieves better harmonisation: it employs existing MS CL practice with EC oversight, channeling communication and evidence among MS facing a crisis. It avoids legal pitfalls facing the EC proposal and allows agile response to crises affecting limited numbers of MS.

It sends the wrong signal globally, incorrectly implying that IP is a barrier in a crisis. It is already having negative effects on global IP discourse, harming the ability to address the actual, multifaceted issues impeding crisis response.

It faces broad legal hurdles:
**TRIPS:** The ability to ignore the: 1) ID of the rights-holder, 2) ID of patents, 3) assessment of alternatives, and 4) negotiation with the rights-holder, violates Art. 31(a)&(b). Broad "additional measures" without safeguards, possibly including know-how transfer, violate Art. 39. Extension to patent *applications* violates Art. 31. A remuneration cap at 4%, divorced from a true economic value analysis violates Art. 31(h). Lack of a clear, thorough legal redress violates Art. 31(i)&(j).
**EU Law:** An EU-wide CL interferes with the Right to Property under Art. 17 of the EU Charter of Fundamental Rights. Legislation must limit interference to what is proportionate and strictly necessary. By failing to include safeguards, *eg* by extending CLs to include know-how, allowing CL issuance without: 1) ID of or negotiating with rights-holders, 2) ID of the relevant patents, or 3) providing adequate remuneration or rights of appeal, the proposal fails proportionality and violates Charter Art. 17, 41 & 52.

Lack of clarity also renders the framework impractical, likely to impede crisis response. Problems include:
-No clear crisis definition, only limited references to other legislation.
-Inadequate rights-holder CL notification.
-An EC trigger for the CL procedure, with an unclear licensee role.
-No clear process for first negotiating voluntary licences.

-Unclarity of advisory body composition, the effect of its recommendation, and scope of rights-holder consultation.
-Overbroad CLs can apply to all rights attached to a product, without clear ID, including pending rights.
-Broad EC powers for "complementary measures," which may lead to forced disclosure of know-how/trade secrets.
-Limited judicial review of a CL; precise avenues for/scope of redress are unclear.
-Remuneration capped too low to be "adequate;" cooperation penalties capped *far* higher, exceeding those in the General Pharmaceutical Legislation.

These issues call for meaningful stakeholder discussion, with serious reflection on proposal purpose and legality.