Response to European Consultation on Compulsory Licensing

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Health Action International (HAI) welcomes the step taken by the European Commission towards an enhanced use of Compulsory Licenses (CL) in European Union (EU) territory. Such a measure will have a positive impact on access to medicines and health technologies, strengthening the ability of governments to fulfill the human right to health beyond crisis or exceptional circumstances.

The policy objectives seem to be well identified, even though they may have been too narrowly framed. Regarding Art. 31 bis of the Trade Related Aspects of Intellectual Property (TRIPS) agreement, the discussions around a proposal for a waiver for COVID-19 related health technologies have revealed dissatisfaction with the current legal framework from a number of parties to the World Trade Organisation (WTO). This includes how countries with no pharmaceutical manufacturing capabilities may make use of TRIPS flexibilities. During deliberations, the EU expressed repeatedly that enhanced CL was the answer to limited production capabilities. It is important to add that, as part of this consultation, some sort of proposal for reform or amendment of the TRIPS agreement is considered.

National disparities on regulation of CLs pose a challenge to any EU-wide policy, therefore we would support a combination of legislative and non-legislative changes aimed at achieving a greater legal and administrative coherence among Member States. Any kind of proposed “EU-level compulsory license” should not negatively affect the possibility of a Member State enacting more health-oriented measures allowing, for instance, more legal grounds to issue a CL.

Such harmonisation should be extended to EU regulation on data and market exclusivity that go beyond what is prescribed by the TRIPS agreement, and seriously hinder the exercise of flexibilities including CLs. Here, we call on the European Commission to ensure that there is no contradiction between the several discussions currently under way, notably the revision of the pharmaceutical legislation within the European Pharmaceutical Strategy and some components of the Intellectual Property Action Plan, as well as the EU COVID-19 vaccine strategy.

CLs should not be perceived nor labelled as last-resort measures but as part of a wider framework of public interventions. Mainstreaming the use of CLs as part of the legitimate policy options at the disposal of governments facing excessively high prices of medicines and/or other anticompetitive practices can contribute to fairer, more efficient markets and ensure the economic sustainability of public health systems.

Clarification and consolidation of CL as a public policy instrument should also be brought

into negotiations with EU trade partners, to avoid previously reported cases of TRIPS+ clauses being inserted into international agreements with low- and middle-income countries (LMICs). At the WTO, the EU should resist efforts by other parties to weaken TRIPS flexibilities and cast doubt about the relevance of the Doha Declaration by publicly stressing the legitimacy of CL as policy instrument.

As part of the consultation to carry out the impact assessment of this measure, the European Commission should support initiatives from civil society and academia aiming at a wider dissemination and knowledge of TRIPS flexibilities among EU stakeholders, including lawmakers, academics, advocates, policy makers and researchers.

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