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Answer given by Executive Vice-President Dombrovskis
on behalf of the European Commission
(13.4.2021)

Article 31bis of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) provides for a special compulsory licence to address difficulties of World Trade Organization (WTO) Members that have insufficient or no manufacturing capacity of medicines. This adds to the compulsory licence for the predominantly domestic supply under Article 31 of TRIPS, available to EU Member States.

The EU has extensive pharmaceutical manufacturing capacity, in particular for vaccines. The Commission is facilitating[1] the ramping up of production of COVID-19 vaccines and is not considering ending the opt-out at this stage. In coordination with Member States it continues to monitor the situation and will take all the necessary steps to ensure timely access to COVID-19 therapies and vaccines to EU citizens.

Compulsory licences are a means of last resort, but, if granted, they must be effective[2]. The Pharmaceutical strategy[3] foresees an assessment of the current system of incentives and obligations, including consideration of the possibility to waive current data protection rules in case of a compulsory licensing.

There is a need for better coordination of compulsory licensing in EU-wide emergencies, to avoid possible negative effects, including on EU joint procurement efforts. The Commission is exploring options based on principles, such as ensuring exchange of information and coordination between the Member States in crises, if resort to compulsory licensing is intended for critical products.

[1] https://ec.europa.eu/info/sites/info/files/communication-hera-incubator-anticipating-threat-covid-19-variants_en.pdf
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0760&from=EN
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN