Civil society letter calls on European Parliament to support global access to medical tools by removing export prohibition in Union compulsory license

Brussels, 5 March 2024

Dear Members of the European Parliament,

Ahead of the March 2024 plenary meeting of the European Parliament, we, the undersigned civil society organisations, call on you to support crucial amendments allowing the export of medical tools to third countries in the proposed Union Compulsory License.

As Civil Society Organisations, we support the creation of a Union Compulsory License[i] in addition to national Compulsory License provisions, as it can significantly enhance the operationality of compulsory licenses within the European Union (EU).[ii] By benefiting from economies of scale and overcoming legal barriers related to cross-border production and supply, a Union Compulsory License has the potential to foster a more effective response to public health challenges.

However, the current draft proposal put forward for a plenary vote of the European Parliament contains restrictive provisions (article 11 & 12) explicitly prohibiting the exportation of products produced under the Union Compulsory License outside the EU. Such prohibition goes against flexibilities enshrined in Article 31(f)[iii] of the World Trade Organization (WTO) TRIPS Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and against the EU's position on export restrictions at the WTO.[iv] This limitation is problematic, especially considering the use of a Union Compulsory License would likely be triggered by situations that would affect not only EU countries but also countries outside of the EU, either in the region or globally.

The COVID-19 pandemic has made clear that major health emergencies need to be addressed at local, national, regional and global level and showcased that the EU's advanced industrial capacity can be used to help protect EU citizens while also aiding and supplying non-EU countries, aligning with the principle that "*No one is safe until everyone is safe"*. It is therefore disheartening to note that, when preparing for the next crisis, the EU risks turning its back on the rest of the world, including non-EU countries in Europe, with this compulsory license proposal.

The European Commission maintains that the Union Compulsory License for export remains theoretically possible under Regulation 816/2006, Yet, this procedure, intended exclusively for export, is widely deemed cumbersome and has never been used. **More importantly, it currently cannot be used to simultaneously supply both EU countries and countries outside the EU**. Amending the Union Compulsory License proposal to allow simultaneous supply to EU countries and non-EU countries would not only promote global access to medical tools but also be invaluable during international health emergencies.

Article 31(f) of the TRIPS agreement allows the export of a non-predominant part of the supply produced under a compulsory license. Having this *option* included and available under a Union Compulsory License, to be used in case needed, is not just a matter of international solidarity but is also in the EU's interest. This can effectively help in controlling potential outbreaks and emergencies that could spill over into the EU, allowing EU-based manufacturers to respond promptly to the needs of non-EU countries.

Recognising the importance of this issue, the European Parliament Trade Committee has put forward amendments allowing export of a non-predominant part of the supply under a Union Compulsory License as well proposed updates to Regulation 816/2006 dealing exclusively with exports.[v] We urgently call for your support to these amendments to promote a more inclusive and effective response to global health challenges.

Sincerely,

National and regional civil society organisations
A.O. "Positive Initiative", Moldova
Access to Medicines Ireland, Ireland
All India Drug Action Network, India
Asociación por un Acceso Justo al Medicamento, Spain
Association of Women of Southern Europe AFEM, France
Australian Fair Trade and Investment Network, Australia
BUKO Pharma-Kampagne, Germany
CF "Patients of Ukraine", Ukraine
CO «100% Life» (former the All-Ukrainian Network of PLWH), Ukraine
Coalition for Research and Action for Social Justice and Human Dignity (CRASH), Finland
Consumer Association the Quality of Life-EKPIZO, Greece
Fundacion Ifarma, Colombia
Grupo de amigos con Vih AC, Mexico
Grupo de Trabalho sobre Propriedade Intelectual, Brazil
Health Action International Asia Pacific, South East Asia - Pacific Region
Health and Development Foundation, Thailand
Human Rights Research Documentation Centre (HURIC-Uganda), Uganda
Initiative for Health & Equity in Society, India
Innovarte NGO, Latin America
Institute for Health, Social Policy and Research Developmemt, Albania
ITPC Global, South Africa
JSA-Mumbai, India
Kamukunji Paralegal Trust (KAPLET), Kenya
Kerala Sastra Sahithya Parishad (KSSP), India
Madhira Institute, Kenya
Medico international, Germany
Medics for the People, Belgium
Misión Salud, Colombia
Network TB People Georgia, Georgia
People Health Movement South Africa, South Africa
People's Health Movement Uganda (PHMUGA), Uganda
People's Vaccine Alliance - Asia (PVA Asia), Asia
People's Vaccine Alliance Latin America (PVA LAC), Latin America
Pharmaceutical Accountability Foundation, The Netherlands
Public Citizen, United States
Salud por Derecho, Spain
Salud y Farmacos, United States
South African Non-Communicable Diseases Alliance, South Africa
Thai Network of People Living with HIV/AIDS (TNP+), Thailand
The Delhi Network of Positive people, India

World Vision Deutschland e.V., Germany

Global civil society organisations
AVAC
Consilium Scientific
Drugs for Neglected Diseases initiative (DNDi)
GI-ESCR
Global Initiative for Economic, Social and Cultural Rights
Harm Reduction International
Health Action International (HAI)
Health Global Access Project
Médecins Sans Frontières Access Campaign
NoGracias
Oxfam
Public Eye
ReAct- Action on antibiotic resistance (Europe)
Society for International Development (SID)
Wemos

Individuals
Anand Grover, Former UN Special Rapporteur on the Right to Health 2008-2014
Biswajit Dhar, Professor of Economics, India
Denis Joseph Bukenya, PHM and Consortium Against Privatisation, Uganda
Dinesh Abrol, TRCSS JNU, India
Diogo Lopes Nunes Galvao, Access to medicines expert, Brazil
Dr Gopal Dabade, Drug Action Forum – Karnataka, India
Dr Richard Stern, HIV and access to medicines activist, Costa Rica
Duncan Matthews, Queen Mary University of London, United Kingdom
Ellen't Hoen (PhD.), Director Medicines Law & Policy, The Netherlands
Els Torreele, Independent Global Health Researcher and Advisor, Belgium
Ganesh Acharya, TB survivor and TB/HIV Activist, India
Janis K. Lazdins-Helds, Retired WHO, Switzerland
Jyotsna Singh, Health Journalist, India
Kirsten Myhr, Independent expert, Norway
Narendra gupta, Prayas Centre for Health Equity, India
Olga Gurgula , Brunel University London, United Kingdom
Priya Anuragini, Dr Ram Manohar Lohiya National Law University, Lucknow, India
Professor Brook K. Baker, Northeastern University School of Law, United States
Ramya Sheshadri, Independent Researcher on Access to Medicines, India
Richa Chintan, Jan Swasthya Abhiyan Delhi, India
Salomé Meyer, Cancer Alliance, South Africa, South Africa
Santanu Kumar Tripathi, Professor Pharmacology, India
Warren Kaplan (PhD, JD, MPH), Boston University, United States

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[i] COM(2023)224 - Proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2023%3A224%3AFIN

[ii] The possibility to issue compulsory licenses is an important public interest safeguard provided in the TRIPS agreement allowing alternative production or importation of a generic version of a patented medical product without the prior consent of the patent

holder. Compulsory licenses are regularly used to protect public health, for example to ensure the supply of medical products which are not available or affordable, including during the COVID-19 pandemic.

[iii] Article 31(f) of the TRIPS agreement: "*any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;"* https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_oth.pdf

[iv] WTO WT/GC/W/823 Covid-19 and beyond: Trade and Health. 15 July 2021. https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/GC/W823.pdf
WTO WT/MIN(22)/31 WT/L/1142 Ministerial Declaration on the WTO Response to the Covid-19 Pandemic and Preparedness for Future Pandemics.17 June 2022.https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True

[v] OPINION of the Committee on International Trade for the Committee on Legal Affairs on the Proposal for a Regulation of the European Parliament and of the Council on Compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD)) https://www.europarl.europa.eu/doceo/document/INTA-AD-753730_EN.pdf
POLITICO*, MEPs, campaigners decry Europe-first health crisis plan*, 28 February, 2024. https://pro.politico.eu/news/176294