

**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<sup>i</sup> in addition to national Compulsory License provisions, as it can significantly enhance the operationality of compulsory licenses within the European Union (EU).<sup>ii</sup> 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)<sup>iii</sup> 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.<sup>iv</sup> 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.<sup>v</sup> 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 Development, 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 Torrelee, 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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<sup>i</sup> 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>

<sup>ii</sup> 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

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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.

<sup>iii</sup> 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](https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_oth.pdf)

<sup>iv</sup> 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>

<sup>v</sup> 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](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>