

A scoping review of the EU's impact on access to medicines in low- and middle-income countries

Katrina Perehudoff

K Perehudoff^{1,2,3}, *C Durán*⁴, *I Demchenko*⁵, *V Mazzanti*⁶,
P Parwani^{1,2,3}, *F Suleman*^{7,8}, *A de Ruijter*^{1,2,3}

¹Law Centre for Health & Life, University of Amsterdam, Amsterdam, Netherlands

²Amsterdam Institute for Global Health & Development, Amsterdam, Netherlands

³Amsterdam Centre for European Law and Governance, University of Amsterdam, Amsterdam, Netherlands

⁴Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht, Netherlands

⁵Department of Forensic Medicine and Medical Law, Bogomolets National Medical University, Kyiv, Ukraine

⁶Department of Public Health & Primary Care, Ghent University, Ghent, Belgium

⁷Discipline of Pharmaceutical Sciences, University of KwaZulu-Natal, Durban, South Africa

⁸WHO Collaborating Centre for Pharmaceutical Policy and Evidence Based Practice, University of KwaZulu-Natal, Durban, South Africa

Contact: katrina.perehudoff@gmail.com

The European Union (EU) has a potential major influence on patients' global access to medicines. Historically, this influence most notably came through the EU's trade and aid agendas that intentionally targeted foreign markets. Now, the EU's own internal pharmaceutical policy appears to indirectly shape global access to medicines (ex. EU's large-scale Covid-19 vaccine procurement and export bans). To understand the ways the EU's internal and external policies impact on global access to medicines, this Scoping Review synthesises evidence of the EU's global regulatory influence and its impacts on access to medicines in non-EU low- and middle-income countries (LMICs). By searching 8 databases and grey literature, documents published in English, Spanish, Portuguese, or Russian between 1995-2021 that addressed an EU law, regulation, or policy in relation to access to medicines in LMICs were included. This review identifies three mechanisms through which EU action impacts on medicines in LMICs. One, the EU's external, treaty-based agreements with LMICs can affect their pharmaceutical trade, sales, and use. Two, EU's internal market regulation, standards, and methods are used as models or sources of inspiration for pharmaceutical governance in LMICs. Three, 'soft' forms of EU influence manifest through the EU's technical assistance, its research and development (aid) funding, and its 'capacity building' activities towards LMIC actors in the field of pharmaceuticals. Examples of impacts of EU action ranged from the development of new medicines primarily for LMICs, to changes in the availability of generics and on medicines spending in LMICs, and the potential for a more efficient yet less autonomous local market approval process. Most evidence of impact was not peer reviewed. This study raises the question of how to support resilient and efficient global pathways for drug development and regulation while still being responsive and accountable to the local public interest.

Key messages:

- There are 3 mechanisms through which EU action impacts on medicines in LMICs: treaty-based agreements, EU internal market regulation, and 'soft' EU influence.
- EU decision makers need a reliable understanding of how the EU's internal and external policies impact on pharmaceuticals globally.