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From Brussels to the World: The Diffusion of EU Pharmaceutical Legislation towards Developing Economies

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Abstract

Regulatory norms, rules, and arrangements enshrined in and established by EU pharmaceutical law travel internationally and influence foreign legal systems, regulatory practices, pharmaceutical company conduct, health systems' functioning, and ultimately patient access to medicines and human health worldwide. This paper applies the mechanisms of Europeanisation (conditionality, socialisation, externalisation, and mimicry) to explain *how* these EU norms, rules and arrangements are diffused globally, with a focus on developing economies. Using the ongoing revision of the EU's pharmaceutical legislation as a case study, this paper selects three innovative legislative proposals therein (i.e. environmental risk assessments for antimicrobials; reporting of public funding for medicines R&D; revised clinical test data and market protection, including a transferrable exclusivity voucher). Through the lens of Europeanisation, this paper postulates how these three legislative proposals, if adopted, would travel globally to developing economies, under which conditions, and with which likely impacts. This paper addresses several gaps in the literature, namely by introducing a global lens to the existing analyses of the EU's revision of pharmaceutical law, by revealing the theory behind the emerging evidence of the EU's influence over global pharmaceutical markets, and by positioning the case of pharmaceutical regulation in low- and middle-income countries among the scholarship on the global regulatory influence of EU internal market law.

Keywords: Europeanisation; low- and middle-income countries; pharmaceutical law; pharmaceutical regulation

I. Introduction

Ensuring equitable access to innovative medicines within and between regions and countries, and regulating environmental pollution caused by pharmaceuticals are global challenges.[1] European Union (EU) lawmakers have establish harmonised standards

[1] See generally: A Fundytus et al., "Access to cancer medicines deemed essential by oncologists in 82 countries: an international, cross-sectional survey" (2021) 10 Lancet Oncol 1367; M Stolbrink et al., "The availability, cost, and affordability of essential medicines for asthma and COPD in low-income and middle-income countries: a systematic review." (2022) 10 Lancet Glob Health e1423; Francine Brinkhuis, et al., "Added Benefit and Revenues of Oncology Drugs Approved by the European Medicines Agency between 1995 and 2020: Retrospective Cohort

applicable to all twenty-seven EU Member States to regulate the safety and quality of medicinal products, and to promote the functioning of the Union single market, primarily through the adoption of five Regulations and a Directive (hereafter: EU pharmaceutical law).[2] In 2023, the European Commission (hereafter: Commission) initiated a revision of the EU laws governing the main aspects of the authorisation and supervision of medicinal products sold on the EU market for human use.[3] These laws also govern the establishment of the European Medicines Agency (EMA) and the specificities of paediatric, orphan, and advanced therapies regulation. In this reform process, the Commission asserts that the "EU pharmaceutical legislation can be an enabling and connecting factor for innovation, access, affordability and environmental protection."[4] This paper argues that this potential of the EU's pharmaceutical legislation is not only true within the Union's borders, but also globally, specifically in low- and middle-income countries (LMICs). This paper seeks to explain *how* existing and proposed EU norms, rules or arrangements for regulating pharmaceuticals are or may be diffused globally to LMICs through the mechanisms of Europeanisation. This paper also critically examines which conditions facilitate the foreign uptake of EU pharmaceutical norms, rules and arrangements by lawmakers and the potential impact of EU-inspired rules, standards and models on industry, regulators and patients located outside the EU. This paper is therefore relevant for policy makers and stakeholders in the EU and all LMICs, particularly those latter countries in privileged relationships with the EU as candidate countries for Union membership (i.e. countries in the Western Balkans, Turkey, Georgia, Moldova, Ukraine), countries neighbouring the EU (e.g. in North Africa and the Middle East), EU trading partners (e.g. Kenya, Colombia, Peru, Brazil, Paraguay, Indonesia), and countries with whom the EU has cooperation and development agreements (e.g. African, Caribbean, and Pacific countries).[5]

Study" (2024) 384 BMJ 5–7. Wilkinson JL, et al., "Pharmaceutical pollution of the world's rivers" (2022) 119 Proc Natl Acad Sci USA 1–10.

[2] EU competence is based on Art 168(3)(a) TFEU. A medicinal product is "a substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action." These six EU laws constituting 'EU pharmaceutical law' are: Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [2000] OJ L18/1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use [2006] OJ L378/1. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products [2007] OJ L324/121. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use [2014] OJ L158/1.

[3] Commission, "Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006" COM (2023) 193 final. (Hereafter: "Regulation Proposal");

Commission, "Proposal for a Directive of the European Parliament and of the Council on the Union Code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC" COM (2023) 192 final. (Hereafter "Directive Proposal").

[4] Ibid, Proposal for a Regulation.

[5] See generally: Sandra Lavenex, 'Concentric Circles of Flexible "EUropean" Integration: A Typology of EU External Governance Relations' (2011) 9 Comp Eur Polit 372.

1. Internal market regulation of pharmaceuticals

The Union promotes and safeguards the functioning of the single market and the safety of the EU's pharmaceuticals supply by harmonising the pre-marketing authorisation procedures and post-authorisation supervision (i.e. pharmacovigilance) of medicinal products through Directive 2001/83/EC and Regulation 726/2004. For example, to enter the EU's single market, a new medicinal product must receive approval from a designated regulatory body through the decentralised, mutual recognition, or centralised authorisation procedures.[6] The EMA, governed by Regulation 726/2004, is the technocratic body competent to discharge some of these regulatory responsibilities at the Union level, including the evaluation of medicinal products in the centralised authorisation procedure. The EMA's global role as a collaborator (alongside Member States) in international harmonisation and standardisation for pharmacovigilance, and a source of scientific and technical support for cooperation on the evaluation of medicines with international organisations and third countries is codified in the same Regulation.[7] Additionally, the EU has adopted legislation to incentivise and regulate the peculiarities of orphan medicinal products (Regulation 141/2000/EC), medicinal products for children (Regulation 1901/2006), and advanced therapeutic medicinal products (Regulation 1394/2007). Together with the Clinical Trials Regulation 536/2014, these six laws are the primary instruments regulating the EU's internal pharmaceutical market.

2. Global transfer of EU pharmaceutical regulation

The EU's internal market norms, rules, and regulatory arrangements travel the globe through a process of Europeanisation of third countries (i.e. non-EU member states, hereafter: foreign countries), also known as the domestic influence or impact of the EU.[8] Europeanisation scholarship proposes various theories and conditions under which EU standards and governance models travel, from which Frank Schimmelfennig's review of the literature distils four general diffusion mechanisms that guide this paper: conditionality, socialisation, externalisation, and mimicry.[9] These four mechanisms are shown in Figure 1 and they guide the analysis in Section II of this paper. To date, the Europeanisation of regulatory norms and arrangements in third countries is often addressed in sectors besides health, and literature has only cursory references to the case of pharmaceuticals.[10]

This paper builds on the emerging evidence that EU internal market regulation of pharmaceuticals travels internationally and influences foreign legal systems, regulatory practices, pharmaceutical company conduct, and ultimately patient access to medicines and human health worldwide.[11] An earlier scoping review documented limited but

[6] Certain medicinal products must be centrally evaluated. See Regulation 726/2004 supra, n 2, Arts 3(1) and 3(2)(b) and Annex I.

[7] Ibid, Arts 28(d) and 57(j).

[8] See generally: Ulrich Sedelmeier, "Europeanisation in new member and candidate states" (2011) Living Reviews in European Governance 6/1.

[9] See generally: TA Börzel & T Risse, "From Europeanisation to Diffusion: Introduction" (2012) 35 West Eur Politics 295; Sandra Lavenex, "The Power of Functionalist Extension: How EU Rules Travel" (2014) 21(6) J Eur Public Policy 885; Anu Bradford, *The Brussels Effect: How the European Union Rules the World* (Oxford, Oxford University Press 2020); Frank Schimmelfennig, "Europeanization beyond Europe" (2015) Living Reviews in European Governance 10/1.

[10] Joanne Scott, "The global reach of EU law" in Marise Cremona & Joanne Scott (eds.), *The Global Reach of EU law* (Oxford, Oxford University Press 2020) 30. See generally: Ibid, Bradford; ML Flear, "Clinical trials abroad: the marketable ethics, weak protections and vulnerable subjects of EU law" (2014) 16 Cambridge Yearbook of European Legal Studies 75–107.

[11] Katrina Perehudoff, et al., "Impact of the European Union on access to medicines in low- and middle-income countries: A scoping review" (2021) 9 Lancet Reg Health – Eur 1.

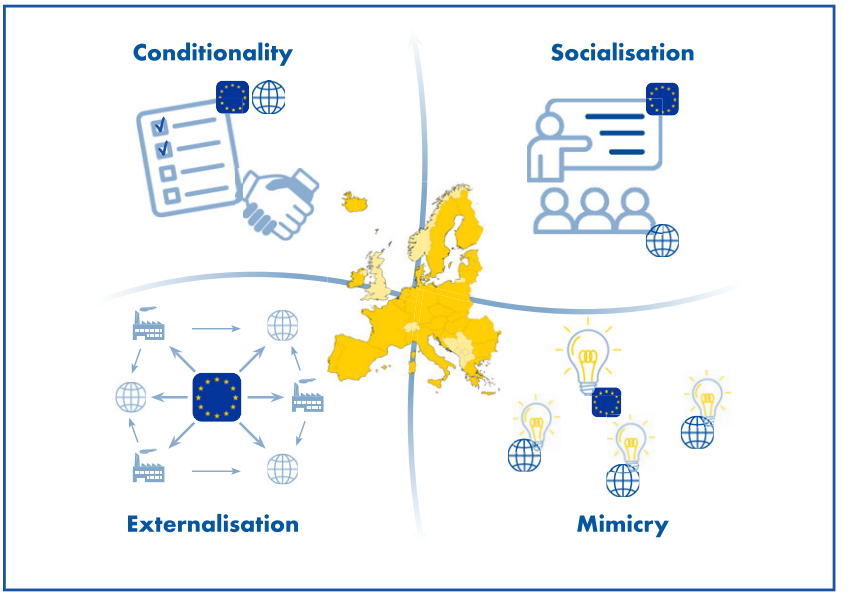

Figure 1. The four mechanisms of global diffusion of EU norms, rules, and regulatory arrangements. Graphic by Crescendo Consulting.

growing evidence of the EU's empirical impact on medicines innovation, availability, affordability and access for consumers in LMICs.[12] One example of the possible external impacts of the EU's internal legislation is that an estimated 380 million people are served by Latin American regulators who rely on, mirror or adapt the EU's decisions (among other regulators) when licensing medicines for sale on foreign markets.[13] In the absence of systematic empirical studies of the EU's external impact on pharmaceutical markets, this paper applies existing theories of Europeanisation to postulate how the EU's norms, rules and arrangements for regulating pharmaceuticals are likely to travel globally, and under which conditions, following the Union's revision of its pharmaceutical legislation.

3. Revision of EU pharmaceutical legislation

The review of the EU's pharmaceutical legislation was first announced in the 2020 Pharmaceutical Strategy for Europe as a response to the unaffordability of some innovative medicines, unequal access and shortages of certain medicines across the EU, and European patients' unmet medical needs. The Commission's adoption of its proposal for a new Directive (hereafter: Directive Proposal) and a new Regulation (hereafter: Regulation Proposal) in April 2023.[14] These two proposals would repeal and replace or incorporate components of the abovementioned six EU pharmaceutical laws.[15] The primary impetus for this far-reaching legislative review is to address the shortcomings of the existing pharmaceutical law, which include the unmet medical needs of patients, the shortages and unaffordability of certain medicinal products, the unequal access to them

[12] Ibid.

[13] Carlos Durán, et al., "Regulatory reliance to approve new medicinal products in Latin American and Caribbean countries" (2021) 45 Rev Panam Salud Publica 1–10.

[14] Directive Proposal supra, n 3; Regulation Proposal supra, n 3.

[15] Ibid, Directive Proposal, Explanatory Memorandum, 3.

across the EU, as well as the negative impacts of pharmaceuticals on the environment and the insufficiency of the existing regulation to "cater for innovation."[16]

In 2023, the European Parliament, under the leadership of the Environment and Health (ENVI) Committee, debated the Commission's proposals. ENVI adopted its reports proposing amendments to both instruments in March 2024, which were subsequently integrally adopted without changes by the plenary of the European Parliament in April 2024.[17] As the legislative process continues at the level of the Council, this paper analyses three key proposals by the Commission and/or the Parliament for new regulatory standards, rules, or arrangements that would be a first-of-their-kind worldwide: a revision to the Environmental Risk Assessment to include a new requirement for the assessment of the risks of antimicrobial supply chains, including in third countries; a new transparency rule requiring manufacturers to disclose public contributions to the R&D of new medicines; revised periods of clinical test data and market protection for originator medicines in the EU, including a new transferable exclusivity voucher to incentivise antimicrobial development.

To date, relatively few foreign actors have expressed detailed views about the potential global influence of the proposed revisions to EU pharmaceutical law.[18] In the absence of these views, this paper extends the mechanisms of Europeanisation to anticipate the influence the revision of the EU's pharmaceutical law on medicines markets and health systems in LMICs. In this way, this paper contributes a deeper global perspective to the existing analyses of the revision of the EU pharmaceutical legislation, which has been primarily through a European lens to date.[19]

4. The case of pharmaceuticals in developing economies

The case of pharmaceuticals is a relevant, yet understudied, example of the EU's global regulatory influence over human health. In the medicines sector, the Union is a global regulatory heavyweight, and the EU's pharmaceutical sector possesses numerous traits (e.g. regulatory capacity, market size, ...) that facilitate its regulatory reach externally.[20] The global dimension is also prominent in the Commission's Pharmaceutical Strategy for Europe, where the Union's ambition to ensure "a strong EU voice globally" is advanced

[16] Ibid, 8–10.

[17] Parliament, "Legislative Resolution of 10 April 2024 on the Proposal for a Regulation of the European Parliament and of the Council Laying Down Union Procedures for the Authorisation and Supervision of Medicinal Products for Human Use and Establishing Rules Governing the European Medicines Agency, Amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and Repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM(2023)0193 – C9-0144/2023 – 2023/0131(COD))" (2024). Hereafter "Amendments to Regulation Proposal"; Parliament, "Legislative Resolution of 10 April 2024 on the Proposal for a Directive of the European Parliament and of the Council on the Union Code Relating to Medicinal Products for Human Use, and Repealing Directive 2001/83/EC and Directive 2009/35/EC (COM(2023)0192 – C9-0143/2023 –2023/0132(COD))" (2024). Hereafter "Amendments to Directive Proposal"; Parliament, "Revision of the EU's Basic Pharmaceutical Legislation" (20 May 2024) <https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-revision-of-the-pharmaceutical-legislation> (accessed 4 June 2024).

[18] 59 (of the 478) responses received to the Commission's Public Consultation on revising the pharmaceuticals legislation are from non-EU entities. <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation/public-consultation_en> (accessed 17 August 2024)

[19] See generally: Astrid Berner-Rodoreda et al., "Transferable Data Exclusivity Vouchers Are Not the Solution to the Antimicrobial Drug Development Crisis: A Commentary on the Proposed EU Pharma Regulation" (2024) 9 BMJ Glob Health 1; I Heikkinen et al., "Role of Innovation in Pharmaceutical Regulation: A Proposal for Principles to Evaluate EU General Pharmaceutical Legislation from the Innovator Perspective" (2023) 28 Drug Discov Today 1; J Wested, "Imaginaries of the EU Commission Proposal for New Pharmaceutical Regulation" (2023) 7 Eur J Health Pharmaceut Law 85.

[20] Bradford supra, n 9, Ch. 2.

through "open dialogue with other regions and countries," including with LMICs, cooperation with non-EU markets to facilitate access to medicines abroad, and (global) "regulatory cooperation, and where possible, convergence" through multilateral fora. Moreover, the EU is a regional government where Member States' health and economic systems are dependent on companies to import active pharmaceutical ingredients (often from China and India) and/or medicinal products into the Union's single market.[21] As such, the EU has a strong own interest in leveraging its foreign influence to the advantage of its strategic autonomy over a supply of medicines. Additionally, the EU has treaty-based responsibilities established in Article 168(1) TFEU to ensure a high level of health protection through *all* its policies and activities, regardless of their internal or external character. In its interactions with the global community, the EU should demonstrate solidarity, and respect for human dignity and rights, as enshrined in Article 3(5) TEU. These objectives and principles, combined with the globalised pharmaceutical market and the 2023 revision of the EU's pharmaceutical legislation, make a case study of the mechanisms facilitating the EU's worldwide regulatory reach over pharmaceuticals a timely and pertinent investigation.

While several analyses have compared the EU's health-related legislation and risk regulation vis-à-vis that of other (mostly) high-income countries, comparatively little has been explored between the EU and LMICs.[22] Although this paper focuses on the foreign influence of EU pharmaceutical legislation, similar legislation from the United States or other global economies may also shape law, policy and practice regarding pharmaceuticals in other regions or LMICs. This potential is acknowledged, and for reasons of brevity, not specifically examined in this paper.

II. Mechanisms of Europeanisation: the EU's global influence over pharmaceutical markets

This section explains how the four mechanisms of conditionality, socialisation, externalisation and mimicry (shown in Figure 1) promote the EU's internal market norms, rules or arrangements internationally. This section focuses on the implications of the migration of EU norms, rules or arrangements on local industry, health systems, and patients in LMICs.

1. Conditionality

Conditionality involves offering third countries certain rewards or incentives that are contingent upon those countries' compliance with EU requirements.[23] Third countries voluntarily enter into legal agreements with the EU, such as accession or trade agreements, that stipulate these and other benefits, and the conditions for obtaining them.[24] Rewards or incentives for third countries may include but are not limited to membership of the EU, access to the EU market for its producers and manufacturers,

[21] Eurostat. Medicinal and pharmaceutical products in extra-EU trade, 2002–2023. <https://ec.europa.eu/eurostat/statistics-explained/index.php?title=File:Medicinal_and_pharmaceutical_products_in_extra-EU_trade,_2002-2023.png≥ (accessed 23 July 2024).

[22] See generally: Katharina Biedenkopf, "Hazardous Substances in Electronics: The Effects of European Union Risk Regulation on China" (2012) 3(4) Eur J Risk Regul 477; Chapter 6 of Anu Bradford, supra, n 9; Sandra Lavenex, "The External Face of Differentiated Integration: Third Country Participation in EU Sectoral Bodies" (2015) 22(6) J Eur Public Policy 836; Perehudoff, supra, n 11; Pramiti Parwani, *EU's impact on access to vaccines in LMICs*, presentation at University Association for Contemporary European Studies (UACES) Annual Conference (2022) Lille.

[23] Schimmelfennig supra, n 9, 8.

[24] Ibid.

receipt of EU financial aid, and/or other benefits such as visa-free travel in the Union.[25] Conditionality is observed in action when, for example, the EU's foreign trading partners and accession states have signed agreements with the EU requiring them to strengthen their domestic intellectual property and data exclusivity laws (among other requirements) in exchange for favourable trading terms with, or even membership to, the EU.[26]

The EU is sometimes said to use conditional agreements to "coerce" third country authorities into adopting behaviour desired by the EU that the authorities would not otherwise adopt.[27] Nevertheless, foreign governments voluntarily choose to be bound by these agreements because they seek to maximise their own estimated costs and benefits, and conclude that complying with EU requirements offers a net benefit.[28] EU capacity-building incentives, such as "technical and financial assistance" may accompany conditional agreements.[29] Ultimately, conditional agreements with the EU may impact upon the autonomous governance and sovereignty of foreign states to determine their own pharmaceutical regulation and policy.[30]

The EU uses conditionality to strategically extend the Union's regulatory influence externally by leveraging its market and regulatory power to shape pharmaceutical markets in third countries. Introducing or lengthening the period of clinical test data protection of pharmaceuticals is an example of an EU conditionality. Test data protection prohibits regulators from relying on (clinical) test data (i.e. collected by testing an originator product) for granting market approval to competing products (i.e. generics). Consequently, generic competitors of a given pharmaceutical product are unable to provide the regulatory test data required for market approval, and therefore generic competition is delayed.[31] EU trading partners or candidate countries may be required by their agreements with the Union to introduce or increase the number of years of test data protection offered on their domestic markets for pharmaceutical products. This practice allows a first product (i.e. a new medicine, commonly imported from outside the developing economy) to limit or block the availability of competing alternatives for consumers on the local market. From a public health perspective, this practice can contribute to high medicines prices and lower availability of medicines for people in LMICs.[32] From the perspective of local industry, this practice can delay the production and marketing of lower-priced alternative (generic) products, thereby harming consumers and restraining the development and proliferation of local generic industry.[33]

In the case of Turkey, an EU candidate country since 1999, local lawmakers introduced a period of six years of test data protection for pharmaceuticals in 2005.[34] Semin and Güldal report that the impetus for this legal revision was a complaint by members of the trade

[25] Börzel & Risse supra, n 9, 295.

[26] Gabriel Michael, "International Coercion and the diffusion of regulatory data protection" (2016) 19 The Journal of World Intellectual Property 2.

[27] Ibid.

[28] Börzel & Risse supra, n 9, 293.

[29] Ibid, 295.

[30] See generally Michael supra, n 26.

[31] Directive 2001/83/EC supra, n 3, Art. 10(1)(a)(iii).

[32] Oxfam International, "All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines" (Oxfam Briefing Paper 102, March 2007) <https://policy-practice.oxfam.org/resources/all-costs-no-benefits-how-trips-plus-intellectual-property-rules-in-the-us-jord-113932/> (accessed 4 June 2024) 9. See generally: N Kessomboon et al. 'Impact on access to medicines from TRIPS-Plus: a case study of Thai-US FTA' (2010) 41 Southeast Asian J Trop Med Public Health 667.

[33] S Semin & D Güldal, "Globalization of the Pharmaceutical Industry and the Growing Dependency of Developing Countries: The Case of Turkey" (2008) 38 Int J Health Serv 379.

[34] Turkish Regulations on Licensing the Human Medical Products 2005, Art 9(3), English version available at: <https://www.ifpma.org/publications/data-exclusivity-encouraging-development-of-new-medicines/> (accessed 11 July 2024).

association, European Federation for Pharmaceutical Industries and Associations, to the Commission regarding the companies' lost revenue of €250 million due to the absence of test data protection in Turkey.[35] Although the EU–Turkey customs agreement of 1999 did not require the latter to introduce test data protection, the prospect of joining the EU may have influenced the Turkish authorities to pre-emptively harmonise local law with EU law.[36] In general, conditional agreements with the EU influence the foreign adoption of EU-like norms or rules on average four years before these countries join the Union.[37] Such a policy change can have a substantial financial impact on foreign health systems, as observed through evidence from other LMICs. For example, introducing five years of data exclusivity on pharmaceuticals in Peru and Colombia triggered an estimated 5.4 million to 10.7 million USD (respectively) in lost cost savings for the local health systems, likely because of delayed competition from lower-priced generics.[38] Therefore, this practice may have important local public health and industrial implications even before the foreign state can enjoy the other advantages of full EU membership.

2. *Socialisation*

Socialisation is a form of co-option in which EU regulatory norms, rules or arrangements are actively promoted abroad and assimilated by foreign actors.[39] Socialisation occurs when the EU deliberately seeks to persuade foreign governments or private companies operating abroad, about the "legitimacy and appropriateness" of the EU's regulatory approaches.[40] Through this process, the EU's ultimate aim is to convince the foreign actor to adopt norms, rules or arrangements consistent with those of the Union.[41] To persuade or teach foreign actors, EU institutions such as the Commission and/or EU regulatory agencies participate in "dialogues, information exchanges, training and capacity-building exercises with third country regulators promoting approximation to EU rules."[42]

An example of socialisation in pharmaceutical regulation is the EU-Medicines4all procedure that allows the EMA, cooperating with the World Health Organization (WHO) and foreign regulators, to provide scientific opinions on medicinal products intended only for use in third countries.[43] This procedure is distinct from the central authorisation procedure because the EMA may use it to apply the EU's evaluation standards to medicines to be used by patients and consumers abroad. Foreign regulators may be observers to the EMA's evaluation process. The EMA describes the participation of foreign regulators in the EUMedicines4All process, explaining that by November 2019:

> . . . regulators and experts from Brazil, Burkina Faso, Democratic Republic of Congo, Ghana, Kenya, South Africa, Tanzania, and Thailand have been involved in one or more EUM4all opinions. Training and support is given to maximise the impact of their role. This involvement is also instrumental in building regional trust in the

[35] Reported in Semin & Güldal, supra, n 33, citing footnotes 29 and 30 (in Turkish, not retrievable in English).

[36] Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union.

[37] Michael supra, n 26, 7.

[38] IQVIA. Impact of free trade agreements (FTAs) on generic & biosimilar medicines markets. 2020. < https://igbamedicines.org/doc/IQVIA-IGBA_Impact%20of%20FTAs%20on%20generic%20and%20biosimilar%20markets_Final%20Deck%20-%20October%202020.pdf> (accessed 23 August 2024)

[39] Lavenex supra, n 9, 890.

[40] Börzel & Risse supra, n 9, 294–296.

[41] Schimmelfennig supra, n 9, 9.

[42] Lavenex supra, n 9, 890; Bradford supra, n 9, 74.

[43] Regulation 726/2004 supra, n 2, Art 58.

scientific opinions and for ensuring that local knowledge is incorporated in the outcomes.[44]

When this procedure results in a positive opinion, foreign regulators may choose to accept or reject the EMA's opinion based on their own rules and assessments of the same medicines on their local markets. According to authors from the EMA, between 2004 and 2019, the EUMedicines4All procedure led to ten positive opinions on medicines, which were followed by 138 approvals by non-EU drug regulatory authorities.[45] One of these medicines, fexinidazole for African sleeping sickness, was evaluated by in cooperation with the WHO and regulators from the Democratic Republic of the Congo (DRC) and Uganda. The product received a positive opinion in November 2018 from the EMA's Committee for Medicinal Products for Human Use (CHMP), which was followed "by the rapid national authorisation of fexinidazole by the DRC authorities in December 2018 on the basis of the CHMP scientific assessment."[46]

The EMA's positive opinion of a medicine, and involvement of foreign regulators in that process, may not only promote the EU's norms, rules or arrangements abroad, but may also improve public health outcomes externally. Timely market approval of safe and effective therapies for infectious diseases that have plagued certain developing economies is an important first step towards improving public health outcomes. The EUMedicines4All procedure may play a role in reducing the common delays in the market launch or failure to launch new, innovative medicines in developing economies. According so some clinical experts, the decades-long stride to eliminate African sleeping sickness is entering the "last mile" owing, in part, to the introduction of fexinidazole, the first all-oral treatment, in LMICs.[47]

Overall, socialisation is a unique mechanism of Europeanisation because it is driven by the EU's intentional promotion of its norms, rules or arrangements and foreign actors' conviction that they are appropriate solutions to challenges experienced abroad.[48] In contrast to socialisation, the forthcoming sub-sections on externalisation and mimicry illustrate how these mechanisms use indirect influence.

3. Externalisation

The externalisation of EU norms, rules or arrangements occurs when they are copied by foreign actors (e.g. foreign pharmaceutical companies or regulators) because doing so offers these actors certain rewards or generates efficiencies for them that could not otherwise be had.[49] The EU's presence offers a template of rules or institutional arrangements that may help actors reduce their net costs or generate net benefits.[50] Examples of rewards or net benefits are a more efficient regulatory decision making process (for foreign regulators)[51] or access to the EU market (for foreign companies). Schimmelfennig explains that foreign actors may adopt and/or follow EU norms, rules or

[44] Maria Cavaller Bellaubi et al., "The European Medicines Agency facilitates access to medicines in low- and middle-income countries" (2020) 13 Expert Ver Clin Pharmacol 321, 324.

[45] Ibid.

[46] E Pelfrene et al. "The European Medicines Agency's scientific opinion on oral fexinidazole for human African trypanosomiasis" (2019) 13 PLoS Negl Trop Dis 3.

[47] MP Barrett et al. "Elimination of human African trypanosomiasis: The long last mile" (2024) 18 PLOS Negl Trop Dis 2.

[48] As compared to conditionality, which relies on a functional logic and the EU's capacity to govern outside of its borders. Börzel & Risse supra, n 9, 297.

[49] Schimmelfennig supra, n 9, 9.

[50] Ibid; Börzel & Risse supra, n 9, 293.

[51] Pramiti Parwani, *External Trust and Regulatory Reliance on the EMA: Implications for Vaccine Access in LDCs*, University Association for Contemporary European Studies (UACES) Annual Conference (2024) Trento.

arrangements is "because ignoring or violating them would generate net costs."[52] An example of net costs for a manufacturer is having to establish a separate production line that meets EU standards (when those standards are different than other jurisdictions where the product is sold).[53] In other words, externalisation is driven by foreign actors' desire to seek or avoid the potential consequences of following or not following the EU's example. Unlike socialisation, where the EU actively promotes its norms, rules or arrangements abroad, externalisation relies on the EU's sheer presence to inspire foreign actors to adopt EU rules or models because they are seeking ways to improve their "economic performance in a globalised world."[54] Externalisation is distinct from conditionality because the latter mechanism requires foreign actors to adopt EU rules out of legal obligation, usually in the form of an explicit legal agreement, whereas externalisation is not propelled by a legal agreement between the EU and a foreign actor.

Two theories exemplify how externalisation can work in practice. The first theory is that of Scott's "territorial extension," which rests on a legal link between the EU's internal market and the conduct of third parties outside of Union borders.[55] Territorial extension relies on a connection between the interests of EU consumers (e.g. the safety or effectiveness of a product) and the circumstances in which the product is developed or produced in a third country.[56] This relationship between foreign conduct and the safety and wellbeing of EU consumers justifies EU lawmakers in extending the EU's legal authority to cover product developers' or producers' conduct outside the Union when the end product is ultimately destined for the Union's single market.[57]

One example of externalisation in EU pharmaceutical law is the requirement that clinical trials (whether conducted within or outside the Union) supporting an application for EU market authorisation comply with good clinical practice standards and ethical principles.[58] This means that investigators must declare that all clinical testing, including at testing sites outside the EU, was carried out in accordance with the ethical principles in the current revision of the Declaration of Helsinki and that the trial protocol and documentation was reviewed by a relevant ethical committee before the study/ies started.[59] Complying with this requirement generates rewards for pharmaceutical companies, namely eligibility to receive an EU market authorisation for their products. By extending the EU's clinical and ethical standards to certain trials in foreign jurisdictions, this rule potentially adds an additional layer of protection for trial participants abroad, which may be especially important in jurisdictions with weak or absent clinical testing regulations.

The second theory is that of Bradford's "Brussels Effect," which proposes that the EU exerts unilateral regulatory power over global markets by virtue of its "market size, regulatory capacity, stringent standards, inelastic targets, and non-divisibility."[60] These conditions motivate foreign actors, such as transnational companies, to align their practices with the EU's norms, rules or arrangements for the ease of business operations and to take advantage of the EU's rewards, such as access to the single market. This is

[52] Ibid, Schimmelfennig.

[53] Bradford supra, n 9, Ch. 2.

[54] Börzel & Risse supra, n 9, 298.

[55] See generally Joanne Scott, "Extraterritoriality and territorial extension in EU law" (2014) 62 The American Journal of Comparative Law, 1, 87–126.

[56] Lavenex supra, n 9, 892–895.

[57] IG Bercero & K Nicolaïdis, "Europe's power surplus: Understanding legal empathy and the trade/regulation nexus" in Elaine Fahey (ed.) *Understanding the EU as a Good Global Actor* (Edward Elgar Publishing 2022) 24.

[58] Directive 2001/83/EC supra, n 2, Annex 1, part 4.

[59] A market authorisation application "must include a statement to the effect that clinical trials carried out outside the European Union meet the ethical requirements." Regulation No 726/2004 supra, n 2, Art 42(1).

[60] Bradford supra, n 9, 25.

known as the de facto Brussels Effect. The incentive to adopt the EU's norms, rules or arrangements is sometimes so strong that transnational companies may even lobby foreign governments and regulators to align their standards with those of the EU. The *de jure* Brussels Effect occurs when foreign lawmakers adapt their local laws to permit the adoption or reliance on the EU's norms, rules or arrangements when regulating their home markets.

Externalisation, and specifically the Brussels Effect, is the most likely driving force behind the regulatory harmonisation and reliance of pharmaceutical systems worldwide. Foreign regulators' reliance on the EMA's evaluations and/or the EU's market authorisation decisions (among other reference regulators) for new chemical entities has been observed among at least thirteen Latin American regulatory bodies serving thirty-four countries, thereby affecting an estimated 380 million people.[61] Some of these Latin American regulators recognise the Commission's market approval decisions without an additional assessment by local regulators, which raises questions about the sovereignty, accountability, and quality of foreign regulators' decision making vis-à-vis their publics.[62] Amending domestic law to allow reliance on the EU's internal market decisions, as Latin American regulators have done, arguably allows these regulators to avoid the costs of conducting a full product assessment and instead reap the net benefits of reliance, which WHO asserts may be "more predictable, faster approval to improve access to quality-assured medical products for patients worldwide."[63]

The externalisation of EU regulation through regulatory reliance also evokes potential drawbacks for governance, regulation, public health, and health system sustainability. For example, Parwani's case studies of vaccines reveal that regulatory reliance (i.e. between Global North and Global South regulatory authorities) should not replace activities to maintain and build the capacity of authorities in Least Developed Countries.[64] Moreover, it is unclear to what degree regulatory decisions adopted by LMICs (relying on authorities in high income countries) are made through informed, independent and evidence-based choice free from geopolitical, industrial, or other undue influences.[65] A notable potential detriment for public health is the externalisation of pharmaceutical benefit-risk assessments made by the EMA based on "poorly performed clinical trials," which may cause a product to appear more favourable (and worthy of market approval) than it is.[66] Consequently, LMIC health systems and patients may be spending their scarce resources on medicines with limited or no benefits for overall survival or quality of life, for example. Finally, the global promotion of regulatory reliance also has a significant market-making effect whereby pharmaceutical companies with innovative products (usually based in the Global North) can more easily gain approvals in non-EU markets (compared to without regulatory reliance).[67] Besides the *de jure* Brussels Effect, the fact that transnational pharmaceutical companies promote regulatory reliance of third country regulators on the EMA's assessments suggests that the *de facto* Brussels Effect is also at play.[68]

[61] Perehudoff supra, n 11, 7; See generally Durán supra, n 13.

[62] Carlos Durán et al., "Potential negative impact of reputed regulators' decisions on the approval status of new cancer drugs in Latin American countries: A descriptive analysis" (2021) 16 PLoS One 1.

[63] WHO Expert Committee on Specifications for Pharmaceutical Preparations. Annex 10 of "Fifty-fifth report." (2021) WHO Technical Briefing Series 1033, 256.

[64] Parwani supra, n 51.

[65] Ibid.

[66] Durán supra, n 62, 1.

[67] Parwani supra, n 51.

[68] Pharmaceutical trade associations organised a webinar "Regulatory Reliance Tools Unveiled: A Practical Guide by EMA" (19.03.2024) <https://www.efpia.eu/news-events/events/efpia-event/regulatory-reliance-tools-unveiled-a-practical-guide-by-ema/> (accessed 25 July 2024).

4. Mimicry

Foreign actors make the unilateral decision to emulate or mimic EU norms, rules or arrangements because they offer a "role model of governance."[69] Similar to socialisation, foreign actors are motivated to imitate the EU because it is perceived as offering appropriate responses and foreign actors "perceived them as legitimate or normatively superior" for addressing local challenges.[70] However, unlike the EU's intentional socialisation of its norms among foreign actors, mimicry is the sole decision of the foreign actor, which may imitate to demonstrate its membership in a particular community, or to legitimise "their own political agenda."[71] Mimicry therefore has a normative objective, as compared to the functional objective of conditionality and externalisation.

The EU's definition of a rare disease, enshrined in Regulation 141/2000, has been emulated in foreign laws. In EU law, a rare disease is a "life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the Community".[72] Amid the growing global recognition that patients with rare diseases have inadequate therapeutic options, domestic lawmakers worldwide are experimenting with different legal interventions for the development and marketing of new pharmacotherapies in this field, including the legal definition of a rare disease and corresponding regulatory and other incentives.[73] Several non-EU countries (e.g. Argentina, Chile, Mexico) have modelled their own legal definition from EU law, particularly by mimicking the EU's threshold for a rare disease, being a condition affecting not more than 5 per 10,000 patients in the Union.[74] Lawmakers from these non-EU countries appear to have aligned their definitions with the EU's despite the fact that the US FDA was the first regulator to adopt a definition of orphan diseases and related regulatory incentives (1983 Orphan Drug Act). In Chile, the EU's threshold appears to have inspired the domestic definition in the Ricarte Soto Law, which provides funding (i.e. a grant of 200 billion pesos for four years) towards the care needed by rare disease patients.[75] In this way, the EU's internal market standards for defining a rare disease help shape the social protections offered to rare disease patients beyond Europe's borders.

Besides foreign lawmakers, foreign judges may also seek to imitate EU lawmakers' response to unmet patient needs for orphan medicines. In the Indian case *Mohd vs. Union of India & Ors.*, a patient sought access to government-funded supply of the expensive yet effective enzyme replacement therapy, Cerezyme®, for Gaucher's disease- a rare, debilitating condition.[76] In its decision, the Delhi High Court highlighted that the Indian government has neither a policy nor incentives in place similar to the EU's Orphan Drug Regulation that entices "Indian manufacturers to develop local alternatives to orphan medicines" that may be more affordable than Cerezyme.[77] The Court suggested that a revision of Indian laws to follow the approach of the EU's Orphan Drug Regulation (namely, the financial incentives it offers to orphan drug developers) would be appropriate

[69] Schimmelfennig supra, n 9, 10.

[70] Lavenex supra, n 9, 891; Biedenkopf supra, n 22, 477–478.

[71] Börzel & Risse supra, n 9, 298; Schimmelfennig supra, n 9, 10.

[72] Regulation 141/2000 supra, n 2, Art 3(1)(a).

[73] For example, D Wainstock & A Katz, "Advancing rare disease policy in Latin America: a call to action" (2023) 18 Lancet Reg Health–Americas 1–7; Neil Khosla & Rodolfo Valdez, "A compilation of national plans, policies and government actions for rare diseases in 23 countries" (2018) 7 Intractable Rare Dis Res 213.

[74] These include Law 26.689 (2011, Argentina), Ricarte Soto Law (Chile), and Art. 224 revision (2012, Mexico) cited in Khosla & Valdez supra, n 73, 219.

[75] Generally, Khosla & Valdez supra, n 73.

[76] *Mohd. Ahmed (Minor) v Union of India & Ors* [2014] Del HC, 17 April.

[77] Ibid, para 42.

policy options to stimulate the domestic development of alternatives to high-priced orphan medicines and/or a reduction in their "prohibitive" cost.[78]

III. Extending the EU's regulatory reach over global pharmaceutical markets

The EU's global regulatory reach over pharmaceuticals touches law and practice in developing economies through conditionality, socialisation, externalisation and mimicry. This paper contends that these same four mechanisms will globalise the new and revised norms, rules or arrangements adopted in the revision of the EU's general pharmaceutical legislation. This section introduces three legislative proposals by the Commission and the Parliament: expanded environmental risk assessments for antimicrobials; reporting of public funding for medicines R&D; revised periods of test data and market protection for new medicines. By applying the four mechanisms to these proposals, this section critically analyses how they, if adopted, would be disseminated to developing economies, and which factors would influence their uptake by foreign lawmakers and the potential impact on companies active in third countries, foreign regulators and patients.

1. Externalising environmental risk assessments to non-EU markets

Currently, applications for market authorisation must include an Environmental Risk Assessment (ERA) of the candidate medicinal product, which documents the risks of its use, storage and disposal to the environment and public health.[79] The Commission's proposal stands to externalise revised ERA requirements for antimicrobials through territorial extension. This is the same mechanism that already externalises EU rules for ethical conduct in clinical trials and good manufacturing practices in third countries.

The Commission's proposal requires the ERA to address the risks of antimicrobial resistance (AMR) during the "entire life cycle" of antimicrobials and, in an innovative turn, to account for risks in supply chains internal and external to the EU because AMR is a "global concern regardless where the emissions and discharges [from manufacturing sites] take place."[80] The Commission's proposal also stipulates that incomplete, insufficiently substantiated, or insufficiently addressed risks in the ERA are grounds to refuse a centralised market authorisation, which strengthens the enforceability of the ERA.[81] Through these requirements, the EU conditions single market access for antimicrobials on the identification, prevention and mitigation of environmental and public health risks inherent in their production within and outside the Union.

EU norms, rules or arrangements are externalised through a unilateral decision by manufacturers acting abroad or by foreign lawmakers who draw lessons from observing the Union's choices and their own cost-benefit assessments.[82] The ERA, a regulatory requirement for marketing new medicines in the EU, may indirectly influence company conduct abroad and foreign lawmaking. As a comparatively large single market for pharmaceuticals in the world, the EU lawmakers are able to introduce rules for the Union's market (i.e. the ERA rule for antimicrobials) that influence companies' manufacturing

[78] Ibid, para 43.

[79] Directive 2001/83/EC supra, n 2, Art 8(3)(g); Regulation 726/2004 supra, n 2, Art 6(2)(c); Committee for Medicinal Products for Human Use, *Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use* (EMEA/CHMP/SWP/4447/00 Rev 1, 15.02.2024).

[80] Directive Proposal supra, n 3, recital 72 and Arts 4(33) and 22(4).

[81] Regulation Proposal supra, n 3, Art 15 (1)(d). Currently under EU law, a medicine with an ERA showing it has deleterious environmental effects and/or inadequate measures to address them, may still receive centralised market approval.

[82] Schimmelfennig supra, n 9, 9.

processes abroad. Moreover, the EU also possesses sizable technical and enforcement capacity for pharmaceutical regulation, namely through the Union's regulator, the EMA, which further supports the global dissemination of EU regulatory rules.[83] Recognised as a "global reference authority," the EMA serves as an example to other foreign agencies (i.e. in developing economies) as they develop their regulatory capacities.[84] The Commission's proposal to permit refusing a market approval application in case of an insufficient ERA only strengthens the enforcement capacity of EU regulators.

Extending the EU's norms, rules or arrangements externally may fill the gap in global and state-level regulation on the matter. For example, in 2021, scholars reported that no international organisation (e.g. WHO) nor national regulatory authority had established regulatory standards or laws for controlling antibiotic emissions in pharmaceutical manufacturing, although norms were being drafted in several legal orders.[85] Among these jurisdictions are the EU and India, where the latter is a major global producer of antibiotics.[86] Whether or not a manufacturer chooses to comply with the AMR prevention and mitigation measures listed in an ERA will not be legally enforced under EU law; however, the act of identifying these risks and approaches to reduce them is a first step towards better environmental protection at manufacturing sites in third countries.

An ERA stipulating prevention and mitigation measures with which manufacturers comply may be especially beneficial in jurisdictions where little or no regulation exists (including in many LMICs). Transnational manufacturers producing antimicrobials in those jurisdictions for local sale and for export to the EU will likely have to commit to an ERA (as part of an EU market authorisation). Consequently, higher environmental protection standards will be applied to local manufacturers serving the foreign market than producers serving only the local market. In some cases, foreign lawmakers may also use EU law as a template or source of inspiration to adopt stricter EU-style risk assessment standards for antimicrobials.[87]

Drawing on the socialisation mechanism, the global dissemination of ERA regulatory requirements may also be aided by "social" interactions and contacts between Union and third country authorities.[88] In general, third countries that are close EU trading partners and/or have a high exposure to the EU will facilitate learning and extension of EU norms, rules or arrangements.[89] Pertinent examples are the existing EMA cooperation schemes with China and India, and the EMA's "training and capacity-building in countries with less-developed regulatory systems" such as candidate countries and non-EU LMICs. These activities sustain and expand close contacts and lesson learning that may ultimately support the transmission and adoption of EU norms, rules or arrangements abroad.[90]

[83] Ibid.

[84] See the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. <https://www.ich.org/page/members-observers> (accessed 22 August 2024); EMA, International Agreements. <https://www.ema.europa.eu/en/partners-networks/international-activities/international-agreements> (accessed 22 August 2024)

[85] A Kotwani, J Joshi, & D Kaloni, "Pharmaceutical effluent: a critical link in the interconnected ecosystem promoting antimicrobial resistance" (2021) 28 Environ Sci Pollu Res Int 32111, p 32116–32117.

[86] N Shafiq et al. "Shortage of essential antimicrobials: a major challenge to global health security." (2021) 6 BMJ Global Health, 1, 2

[87] Bradford supra, n 9, Ch 2.

[88] Schimmelfennig supra, n 9, 9; Lavenex supra, n 9, 891.

[89] Ibid, Schimmelfennig.

[90] Ibid; Lavenex supra, n 9, 891; Bradford, supra, n 9, 74. Cooperation schemes with EMA are generally focused on compliance with good clinical and manufacturing practices. See International Agreements supra, n 84. Examples of capacity building are the webinar supra, n 68, and the EMA's assistance to enlargement countries through the Instrument for Pre-Accession Assistance I, II, and III, presented at the WHO Policy Dialogue in Trieste (18 April 2024).

2. Global reach of reporting public funding of medicines R&D

Requiring manufacturers to report the public contribution towards the R&D activities of a particular medicine seeking or covered by a national or central market authorisation is an entirely new transparency norm proposed by the Commission to "help maintain or improve access to affordable medicinal products."[91] If adopted, this norm may be mimicked by foreign regulators facing similar affordability challenges.[92] Moreover, an EU requirement for the public disclosure of public R&D contributions in new medicines would help elucidate the actual worldwide investment in R&D, which could inform the pricing setting procedures by medicines purchasers worldwide.

According to the Commission, this reporting should concern "any direct financial support received from any public authority or public body to carry out any activities for the research and development of medicinal products" regardless of which legal entity received the support and whether the R&D was successful or unsuccessful.[93] As proposed, any information reported will become publicly available in an EU database.[94] Similar measures are proposed by the Commission in relation to antimicrobials (as part of the transferrable exclusivity voucher, see sub-section 4 below) to help prevent establishing prices that overcompensate developers for their investments in the new product.[95]

If adopted, this responsibility of manufacturers could be embedded into the regulatory rules of foreign jurisdictions because the EU's precedent demonstrates the political will to regulate corporate conduct. The global transfer of regulatory rules is more likely when foreign lawmakers perceive the EU as legitimate or normatively superior.[96] Moreover, EU law provides a clear template to imitate. To date, there has been little political appetite to take legal, policy, and other steps for greater transparency of the components of a pharmaceutical's price (including investment in R&D) in line the World Health Assembly (WHA) Resolution 72.8 on increasing the transparency of pharmaceutical markets.[97] Italy and France are the only known states worldwide to have adopted similar legal requirements for the disclosure of public funding of medicines R&D as a condition of reimbursing the medicine.[98] If adopted, these revisions to EU pharmaceutical legislation may create a template for the disclosure of public investments in pharmaceutical R&D that is consistent with the commitments states made in WHA Resolution 72.8. The Commission's proposal is the first worldwide initiative to use a different legal hook, namely require such disclosures as a condition of the product's market authorisation. If adopted, the EU's rules requiring public disclosure of R&D financing may signal the growing global acceptance of new transparency norms in the pharmaceutical sector. Third countries may mimic the EU's rule to signal the (external) legitimacy of their domestic political agenda and/or their membership of a global community espousing these norms.[99]

[91] Directive Proposal supra, n 3, recital 131 and Art 57(1).

[92] Ibid.

[93] Ibid and Art 57(2(a)); Directive Proposal, Explanatory Memorandum supra, n 3, 17. The Parliament's amendments to this article widen the scope of reporting to include not only direct financial support received from public authorities, but also a "publicly funded body or philanthropic or not-for-profit.

Organisation or fund, irrespective of its geographic location, and any indirect financial support received from any public authority or publicly funded body of the Union or its Member States" in Amendments to Directive proposal supra, n 17, Art 57(1), amendment 169.

[94] Directive Proposal supra, n 3, Art. 57(2); Explanatory Memorandum of Directive Proposal supra, n 3, 17.

[95] Ibid, Directive Proposal, recital 81.

[96] Lavenex supra, n 9, 891.

[97] World Health Assembly, *Improving the Transparency of Markets for Medicines, Vaccines, and Other Health Products* (WHA72.8, 28 May 2019) <https://www.who.int/publications/m/item/wha72.8> (accessed 5 June 2024); K Perehudoff, K Mara, and E 't Hoen. *What is the evidence on legal measures to improve the transparency of markets for medicines, vaccines and other health products?* (WHO 2021) <https://europepmc.org/article/nbk/nbk572572> (accessed 23 July 2024).

[98] Ibid, Perehudoff, Mara & 't Hoen, Annex 3.

[99] Börzel & Risse supra, n 9, 298.

3. Global export of EU rules for test data and market protection

Revisions to the periods of clinical test data protection and market protection applicable to all originator medicines in the EU is another example of the potential global reach of EU norms and rules through emulation and conditionality. Market protection or exclusivity prevents competing protects from entering the market, thereby delaying competition for a given product, and often sustaining high prices of that product.

The Commission proposes to reduce the existing duration of exclusivity to six years of base protection for all originator medicines with optional extensions, while the Parliament's amendments propose to limit protection to seven and a half to eight and half years.[100] Moreover, the Commission has proposed to grant one additional year of data exclusivity in the form of a "transferrable exclusivity voucher" to medicinal products offering "significant clinical benefit" for antimicrobial resistance.[101] Such a voucher would be transferable to other authorised products or manufacturers, and test data protection may be revoked in cases of unfulfilled supply, procurement or purchase request for the antimicrobial.[102] Through these proposals the Commission seeks to incentivise the R&D of products for unmet medical needs and priority antimicrobials.

Additionally, the Commission has introduced a waiver for test data protection of originator medicines, which would facilitate the rapid registration of the generic product in the event of public health emergency.[103] Although this is the first proposal by EU lawmakers to introduce a waiver to data and market protection, it is preceded by support from experts and, interestingly, examples of legal texts from developing economies (i.e. Malaysia, Colombia).[104]

Data and market protection provisions in pharmaceutical regulatory regimes are permitted but not required by international trade law.[105] Transnational pharmaceutical companies have highlighted that, if adopted, the voucher would be the first policy measure of its kind worldwide.[106] If adopted by the EU, these data and market protection standards may be unilaterally mimicked by foreign lawmakers or purposely exported by the EU in conditional trade and accession agreements with third countries.[107] As this paper has shown in sub-section III(1), a global transfer of these norms may have implications for indigenous pharmaceutical companies operating in developing economies and the availability and affordability of medicines for foreign health systems and patients.

V. Conclusion

The Union's revised pharmaceutical legislation is likely to sustain and extend the EU's regulatory influence over foreign pharmaceutical markets in developing economies through the mechanisms of externalisation, socialisation, conditionality and mimicry. This analysis of key proposals for reform – namely ERAs, transparency of public R&D contributions, and changes to clinical test data and market protection rules – applies the four mechanisms to illustrate how these proposals, if adopted, may travel internationally.

[100] Regulation Proposal supra, n 3, Ch. III; Directive Proposal supra, n 3, Ch VII; Amendments to Regulation Proposal supra, n 17, amendments 149–165; Amendments to Directive Proposal supra, n 17, amendments 196–217.

[101] Regulation Proposal supra, n 3, Art 40.

[102] Ibid, Art 42(2).

[103] Data and market exclusivity would be suspended in relation to the party that is granted a compulsory license for a relevant authority in the EU. See Directive Proposal supra, n 3, Art 80.

[104] For example, E 't Hoen, P Boulet, & B Baker, "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation" (2017) 10 J Pharm Pol Pract 1–9.

[105] Art 39.3 of the Agreement on Trade Related Aspects of Intellectual Property.

[106] See generally Commission's Public Consultation supra, n 18.

[107] See Michael supra, n 26.

By drawing on existing mechanisms of dissemination from European studies and international relations, this paper reveals the conditions that facilitate the exportation of EU norms, standards and arrangements in the pharmaceutical sector, and suggests some of their potential effects on foreign lawmakers, indigenous industry, regulators, and health systems and patients in developing economies. This analysis reveals that EU norms, rules and arrangements, when externalised, may fill legal gaps in the regulatory regimes of third countries lacking robust environmental regulation, may influence manufacturers' conduct in third countries, may affect the competitiveness of indigenous industry, and/or may impact on the availability and affordability of medicines for LMIC health systems and patients. New regulatory norms, rules or arrangements adopted in the EU's revision of its legislation may inspire the unilateral adoption of similar norms, rules or arrangements in third countries facing comparable challenges regarding environmental degradation or high medicines prices. This analysis shows that a single mechanism may drive the dissemination of an EU norm, rule or arrangement abroad, or two or more of these mechanisms may function together. The size of the EU's pharmaceutical market and the perception of the Union internationally, together with its regulatory capacities for scientific-technical assessments, external capacity building of regulators, and enforcement of EU standards on the single market, facilitate the foreign reach of EU norms, rules and arrangements. Future research should investigate those factors that influence the implementation or resistance to the adoption of EU pharmaceutical standards in LMICs.

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