

Civil Society Open Letter to the Council of the European Union Concerning Transferable Exclusivity Vouchers for Antimicrobials

05 December 2022

Dear Ministers,
Dear Ambassadors,

We, the undersigned civil society organisations, are concerned about the European Commission's intentions to introduce transferable exclusivity vouchers (TEVs) for the development of effective antimicrobials. We strongly urge the Council to reject such a proposal at the upcoming Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) meeting on 8-9 December 2022, and call on the Commission to explore, identify and develop alternative proposals with no negative impact on people's access to medicines and without putting the economic sustainability of national healthcare systems at risk.

The European Commission is developing a proposal for TEVs as part of its revision of the EU's pharmaceutical legislation. According to a leaked draft impact assessment,ⁱ the proposed voucher would apply one year of exclusive protection on regulatory data of a medical product of the developer's portfolio, which may be sold/passed on to another company. Small pharmaceutical companies and academic groups are leading the antibiotic development field, but larger pharmaceutical companies would be the likely buyers of the vouchers. In practice, TEVs will function as an additional year of market monopoly on the TEV-holder's bestselling products, yielding high levels of revenue for the company but delaying generic competition that could bring prices down to more affordable levels for people and healthcare systems.

Independent research contests the effectiveness and efficiency of TEVs in supporting the development of antibiotics.ⁱⁱ Such measures and incentives tend to lead to higher prices for health products. Rather than addressing the dearth of antibiotics, TEVs would further cement and validate a model which has failed to bring forward a new class of effective antibiotic drugs for the last 34 years.ⁱⁱⁱ

The development of medical tools, including new and effective antibiotics, is urgently needed, particularly in light of the ever-growing threat posed by antimicrobial resistance (AMR). The development will entail a significant cost for the public sector either in the form of upfront investments and/or through sales prices. However, the awarding of TEVs, whereby companies can extend monopolies on their products, will amount to handing over a blank cheque to the private sector with the public sector having no control over the final cost. The Commission's draft impact assessment indicates that the public payer costs of TEVs may be three times higher than the R&D reward/compensation for the developer. Independent research estimates the cost may be five times higher than other forms of incentives, rendering this tool highly inefficient.^{iv}

This proposal runs counter to concerns from the European Council^v and the European Parliament^{vi} over financial sustainability of healthcare systems and high prices of medicines. In our view, the high cost related to the introduction of a TEV carries a risk for significant opportunity costs, where healthcare systems may be impeded from investing in and/or procuring other medicines and medical devices, delivering services, or assuring quality of care. In addition, it could make it harder

for national authorities to make use of flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO), as compulsory licensing does not apply to exclusive protection on regulatory data.

The development of new medical tools to tackle AMR should not rely on a model that increases inequity. We therefore urge you to call on the Commission to develop and explore alternative proposals to support the development of antibiotics that do not rely on extending or expanding monopolies on pharmaceuticals. Sales revenue (both prices and sales volumes) should be fully delinked (or separated) from the cost and incentives to develop relevant antibiotics as recognised in the 2016 UN General Assembly High Level political declaration on AMR.^{vii} The development of antibiotics and other medical tools to tackle AMR should be enabled through support for multiple tailored push funding and pull incentives that better ensure the affordability, sustainable access and rational use of antibiotics. The Commission should also be urged to fully explore the role of the EU and its institutions to exercise better management of research priorities and outcomes, including by providing greater support and deployment of public capacities for a more effective collaborative R&D ecosystem.

Sincerely,

Signatories:

1. Médecins Sans Frontières Access Campaign
2. Health Action International (HAI)
3. ReAct Europe
4. Consumer Association the Quality of Life-EKPIZO, Greece
5. Medicines Law & Policy, The Netherlands
6. Asociación por un Acceso Justo al Medicamento, Spain
7. Salud por Derecho, Spain
8. Consilium Scientific, UK
9. European Public Health Alliance (EPHA)
10. Coalizione Italiana per le Libertà e Diritti civili (CILD)
11. Access to Medicines Ireland
12. Oxfam
13. Observatoire de la transparence dans les politiques du médicament (OTMeds)
14. Médecins du Monde Germany, Ärzte der Welt e.V.
15. France Assos Santé
16. CNDC – 11.11.11, Belgium
17. BUKO Pharma-Kampagne, Germany
18. Universities Allied for Essential Medicines Europe e.V.
19. Prescrire, France

ⁱ European Commission impact assessment report on the revision of EU pharmaceutical legislation, published by Politico, 29 August 2022. <https://pro.politico.eu/news/153448>

ⁱⁱ Årdal C, Lacotte Y, Ploy MC, on behalf of the European Union Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI). Financing Pull Mechanisms for Antibiotic-Related Innovation: Opportunities for Europe, *Clinical Infectious Diseases*, 2020 Oct; 71(8):1994–1999. <https://doi.org/10.1093/cid/ciaa153>

Rome BN, Kesselheim AS. Transferrable Market Exclusivity Extensions to Promote Antibiotic Development: An Economic Analysis. *Clinical Infectious Diseases*. 2020 Oct;71(7):1671-1675. <https://doi.org/10.1093/cid/ciz1039>
DRIVE-AB Report. Revitalizing the antibiotic pipeline: Stimulating innovation while driving sustainable use and global access, 2018. <http://drive-ab.eu/wp-content/uploads/2018/01/CHHJ5467-Drive-AB-Main-Report-180319-WEB.pdf>

ⁱⁱⁱ Aagaard H, Malpani R, Zorzet A. “Ensuring sustainable access to effective antibiotics for everyone, everywhere – How to address the global crisis in antibiotic Research and Development”. <https://www.reactgroup.org/wp-content/uploads/2021/09/ReAct-Report-Ensuring-sustainable-access-toeffective-antibiotics-for-everyone-everywhere-How-to-address-the-global-crisis-in-antibiotic-Research-andDevelopment-March-2021.pdf>

^{iv} Årdal C, Lacotte Y, Ploy MC, on behalf of the European Union Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI). Financing Pull Mechanisms for Antibiotic-Related Innovation: Opportunities for Europe, *Clinical Infectious Diseases*, 2020 Oct; 71(8):1994-1999. <https://doi.org/10.1093/cid/ciaa153>

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^v Council of the European Union. Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (2016/C 269/06). Luxembourg: OJ C269/31; 2016. <https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/>

^{vi} European Parliament. Resolution on EU options for improving access to medicines (2016/2057(INI)), 2017. https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061_EN.html

European Parliament. Report on a pharmaceutical strategy for Europe (2021/2013(INI)) 2021. https://www.europarl.europa.eu/doceo/document/A-9-2021-0317_EN.html

^{vii} UNGA. Resolution adopted by the General Assembly on 5 October 2016 (A/71/L.2) 71/3. Political Declaration of the High-Level Meeting of the General Assembly on Antimicrobial Resistance. <https://digitallibrary.un.org/record/842813>