

Civil society urges Member States to support the Dutch EU Presidency's vision on access to affordable medicines

Call for backing comes as Health Ministers meet in Amsterdam today

AMSTERDAM—We strongly support the Dutch European Union (EU) Presidency's critique of the current over-protection and misuse of intellectual property and related rights for pharmaceuticals, and its goal to better balance the reward for innovation against the assurance of affordability of medicines.

Additional market exclusivity, data exclusivity, and supplementary protection certificates (SPCs) that add to the internationally-agreed 20-year period of patent protection delay price-lowering generic competition. Generic competition has proven central to massive treatment scale-up and cost containment everywhere, including Europe. The Dutch Presidency is right to address this and we support the proposal to critically analyse the impact and outcomes of these additional protections.

Without transparency of R&D costs to originator companies and information on the actual prices paid for medicines across EU Member States, any discussion about fair medicine prices remains impossible. The Presidency has correctly pointed out this problematic information asymmetry and we strongly support the call to better leverage Member States' collective action.

[We also support](#) the Dutch Presidency's initiative to explore other incentive mechanisms for pharmaceutical R&D that are needs-driven and deliver medicines at affordable prices. Ultimately, the current monopoly-based model of biomedical innovation steers research priorities away from the greatest health needs towards areas with the highest potential profitability. This is not only the case for antimicrobial resistance. There is [wealth of initiatives and ideas](#) regarding alternative incentive models, including from the [Dutch government themselves](#); what we need is the political will to scale these up.

2016 could be the year in which the Dutch Presidency propels the EU to seriously investigate and address the failures of the current pharmaceutical R&D model. This system leads to the development of 'me too' medicines, anti-competitive behaviours and high prices of new treatments that are not related to the costs of development.

We urge all Member States to support the Dutch Presidency in its ambitious proposals.¹

¹ At the same time, and linked to ongoing discussions on adaptive pathways, we caution against proposals to further expedite marketing authorisation for medicines which buy into arguments that this will contribute to medical innovation. In fact, what we need is a regulatory system that signals the importance of demonstration of added therapeutic value. Whilst acknowledging that timely access to medicines is important, it should not be at the expenses of thorough pre-market evaluation and patient safety.

Signatories:

BUKO Pharma-Kampagne (Germany)
Collectif Hépatites Virales (CHV) (France)
Commons Network
European AIDS Treatment Group
European Public Health Alliance (EPHA)
Global Health Advocates
Health Action International
Health Projects for Latvia
International Society of Drug Bulletins (ISDB)
Medecins Du Monde/Doctors of the World
Médecins Sans Frontières - Access Campaign
Medicines in Europe Forum (MiEF)
Mental Health Europe
No Gracias (Spain)
Nordic Cochrane Centre
PRAKSIS (Greece)
Salud por Derecho (Spain)
STOPAIDS (UK)
Ukrainian Network of People Living with HIV/AIDS
Universities Allied for Essential Medicines – Europe