

To: Ms. Lowri Evans, Director General DG GROW
M. Xavier Prats-Monné, Director General DG SANTE

cc:

Ms. Aude l'Hirondel, DG SANTE
M. Fabio Domanico, DG GROW
Ms. Olga Solomon, DG SANTE
Ms. Amaryllis Verhoeven, DG GROW

Brussels, 8 September 2017

Subject: Open submission on supplementary protection certificates for medicinal products in the European Union

Dear Madam, Sir,

As civil society organisations working on access to medicines and public health, we would like to share with the European Commission and draw your attention to an open submission on supplementary protection certificates (SPCs) for medicinal products in the European Union and their impact on access to affordable medicines for patients. The submission addresses the European Commission's current review of Regulation EC 469/2009 concerning SPCs for medicinal products, requested under the 'Council Conclusions on Strengthening the Balance in the Pharmaceutical System in the EU and its Member States', adopted in June 2016 (point 47).

The prices charged by companies for new medicines have increased steeply over the past decade, to the point they have become unaffordable for many European patients and threaten the financial sustainability of national healthcare systems. Monopolies reinforced through intellectual property and other market exclusivities, such as SPCs, have disproportionately empowered commercial interests over public health needs. Prolonged exclusivity through SPCs has enabled companies to avoid generic competition and to charge unaffordable prices, as demonstrated – in detail and with concrete examples – in the full submission text.

SPCs are counterproductive to stimulating innovation as they create incentives for companies to focus on prolonging monopolies through evergreening strategies. At the same time, companies continue not to invest in areas of unmet public health need.

We therefore recommend that the European Commission i) abolish the SPC mechanism, ii) improve transparency, flexibility and public health impact assessment in the current SPC review process, and iii) stop encouraging the inclusion of SPCs – or similar mechanisms, such as patent term extensions – in free trade agreements with other countries.

We thank you in advance for your consideration and we look forward to hearing from you.

Co-signing organisations

1. Médecins sans Frontières (MSF) Access Campaign
2. Wemos
3. STOPAIDS UK
4. Global Health Advocates France (GHA)
5. Just Treatment

6. Health Action International (HAI)
7. PRAKSIS
8. Global Justice Now
9. Médecins du Monde
10. Commons Network
11. EKPIZO
12. UAEM Europe
13. Salud por Derecho
14. All-Ukrainian Network of PLWHA
15. "AGEPC" Kazakhstan
16. Prescrire
17. Aktionsbündnis gegen AIDS - Action against AIDS Germany
18. AIDES
19. Public Eye
20. Health Projects for Latvia
21. Altroconsumo
22. Access to Medicines Ireland (AMI)
23. BUKO Pharma-Kampagne
24. AIDS Action Europe
25. IPPNW Germany
26. AIDES
27. The International Society of Drug Bulletins (ISDB)
28. Grupo de Ativistas em Tratamentos (GAT)
29. Hepatitis Scotland
30. Aids Hilfe (Austria)
31. Oxfam
32. European AIDS Treatment Group (EATG)
33. MEZIS e.V. Germany

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