

High prices, poor access: What is Big Pharma fighting for in Brussels?

Chapter 6. Conclusion

Big Pharma, aided by a complacent or complicit Commission, has sought to sabotage any tackling of the crisis of access to medicines in Europe. The industry has been both relentless and multifaceted in its lobbying. As lawyer and IP expert Ellen' t Hoen notes, the “rules of the game have largely been drawn up by the pharmaceutical industry itself”, as shown by Big Pharma's heavy-handed response to any questioning of the paradigm it profits so much from.¹ The industry is not willing to cede even the slightest bit of ground. This is happening even as rich country governments – for so long pharma's allies in shaping global trade and IP rules in the industry's interest, at the expense of access to affordable medicines around the world – are waking up to the reality that this paradigm is causing access problems for them too.

The critique of a model that is failing public health whilst enriching Big Pharma's executives and shareholders has spread from civil society, academia, and public health advocates to gain high-profile political recognition. The time has come to focus on alternatives. And the opportunity to do so must not be lost merely because the Commission fails to take conflicts of interest or industry-influence seriously. The process started by the 2016 Council Conclusions must not be swept under the carpet by the lobbying and PR efforts of Big Pharma; policy-making processes need to be safeguarded to ensure they serve the public interest. This is particularly important for the incoming European Parliament and European Commission of 2019.

Our recommendations for Parliamentarians and policy-makers on how to go forward are as follows:

- **Ensure that medicines policy is protected from undue influence of Big Pharma:** As public health group EPHA notes, “Member States who are concerned by the threat high prices of medicines pose to the sustainability of health care systems will need to guarantee the European Commission's priorities and initiatives are not skewed by the pharmaceutical companies towards harmful deregulation in the disguise of innovation promotion.”² The Commission should recognise that hiring a consultancy with clear commercial ties to an industry, to produce studies intended to influence the regulation of that industry, may put public interest policy-making at risk.³ Policies should be put in place that take potential conflicts of interest seriously when outsourcing studies. The issue of undue influence of industry ‘stakeholders’, including in EU agencies like the EMA, also requires urgent attention. The WHO, when preparing its technical study into cancer drug pricing, did not consult industry “in

order to ensure there was no conflict of interest”.⁴ The Commission should learn from this kind of firewall.

- **Don't let Big Pharma's fear-mongering narrow the scope for transformative change:** With its exaggerated 'sky-is-falling' message and emotional PR campaigns, Big Pharma's lobbying against the SPC manufacturing waiver aimed to narrow the scope for greater change. As further aspects of the IP and regulatory incentives regime – such as the orphan drugs regulation – come under closer scrutiny, this may only be a taste of things to come. Policy-makers and parliamentarians should not let these scaremongering tactics close down broader debate, because the regime Big Pharma is trying to protect has led to a crisis of high prices, leaving patients without access to medicines they need, whilst more and more 'new' drugs have little-to-no added value, and vital but less profitable areas of research are neglected. Big Pharma's attempts to deflect criticism and reinforce this regime come at the expense (literally) of patients' access to medicines.
- **Keep working towards EU cooperation for robust and independent HTA:** EU collaboration on HTA can play a vital role in helping member states safeguard their public health systems from excessively-priced medicines, providing that policy-makers resist the push from industry for more sway over the process. The EU institutions should continue to work towards an agreement that ensures strong, independent assessments based on good, comparative data.⁵
- **Stop promoting expanded IP provisions through trade deals:** With the recognition that additional monopoly protections for Big Pharma have helped fuel the crisis of high-priced medicines in Europe, it is past time that the EU recognised the role they play in preventing access to medicines around the world, by ceasing to promote extra IP provisions in its trade deals.
- **Support discussions around public return on public investment:** Public health advocates and academics are developing new ideas about how to ensure public investment into medicines research actually serves the public interest (rather than the pockets of shareholders), and thinking of new ways of financing R&D. The European Parliament has a role to play in encouraging this debate, and the Commission – pending there is public willingness – to support research into these.

- 1 *De Volkskrant*, Vals spel in de farmacie: de pil is hetzelfde, de prijs een veelvoud, 15 /06/18, <https://www.volkskrant.nl/wetenschap/vals-spel-in-de-farmacie-de-pil-is-hetzelfde-de-prijs-een-veelvoud-b7518d05/> [google translated]
- 2 EPHA, Top 5 issues...2019, *ibid.*
- 3 This is an issue that has been identified in policy areas other than pharmaceuticals, including relating to studies relating to how to tackle corporate tax avoidance. See: CEO, Accounting for influence: how the Big Four are embedded in EU policy-making on tax avoidance, 2018, <https://corporateeurope.org/BigFourTax>
- 4 Health Policy Watch, *ibid.*
- 5 For more in depth recommendations about what will be needed to ensure this kind of robust, independent and transparent EU HTA, see, eg HAI, <http://haiweb.org/wp-content/uploads/2018/06/Health-Technology-Assessments-EU-Key-Recommendations-1.pdf>, BEUC, https://www.beuc.eu/publications/beuc-x-2019-004_beuc_position_on_hta_regulation.pdf, and EPHA, *ibid.*, as well as publications by payers like ESIF and AIM.