

Greens/EFA action plan: Affordable and Accessible Medicines for All

Current regulations on the pharmaceutical sector are not appropriate to provide EU citizens with affordable and accessible medicines and treatments. The exclusivity system in the EU allows pharmaceutical companies to enjoy a monopoly position in the market to earn back investments in the development of medicines. However, in order to obtain these exclusive rights, the EU does not require pharmaceutical companies to be transparent about their actual costs of development and production. In other words: companies can charge excessive prices for medicines for years, even if they already earned back their initial investments.

At the same time, pharmaceutical companies receive public financial support – at both national and EU level – for the development of medicines. These grants or subsidies are not conditional on the accessibility or affordability of the medicines that are being developed with this support. Consequently, it is possible for the pharmaceutical industry to profit from public financial support and at the same time charge excessive prices when government institutions want to buy these products. By making strategic use of this system, the pharmaceutical industry is now one of the most profitable sectors in the world.

- The international intellectual property framework guarantees that pharmaceutical companies obtain protection on the medicines they are developing for 20 years (from the moment that research shows potential). When a patent has lapsed, pharmaceutical companies in the EU can opt for Supplementary Protection Certificates (SPCs), which can extend patent rights for a maximum of five years. An additional six-month extension is available if the SPC relates to a medicinal product for children (Reg (EC) No 1901/2006)
- In addition to patents and the SPCs, companies that develop treatments for rare diseases (so-called “orphan drugs”) can benefit from up to 10 years of exclusivities. To qualify for orphan designation, a manufacturer has to show that fewer than five per ten thousand people will use the medicine.

We need to alter the current innovation model for pharmaceuticals if we want to ensure accessible and affordable medicines for all. Ensuring access to all medicines for patients in need is a core human rights obligation, linked with the principles of equality, non-discrimination and transparency. As long as the EU system is solely based on exclusive rights- which lacks transparency about the actual costs of research and development- the system does not necessarily result in the medicines we need most urgently nor to better medicines, but to those medicines that make most business sense for pharmaceutical companies at often exorbitant prices. Over the years, the price of innovative medicines has been on the rise. For example, in the past ten years, the cost of

new cancer medicines has increased by 348%, showing only marginal benefits for the patients. This leads to difficult dilemmas for our society: should we keep reimbursing expensive medicines or deny patients access to medicines to limit healthcare spending.

Pharmaceutical companies refer to high costs of research and development, and the fact that they also have to take into account failures. Innovation does indeed have a cost, but it is currently impossible to determine a fair compensation because the research and development costs are a black box. Profits are often not reinvested in the further development of medicines, but are put in profitable financial constructions. This is problematic because in this way, EU funds that go into the development of medicines with the aim of improving public health, are partially flowing into the pockets of private shareholders.

The pharmaceutical strategy offers us an opportunity to change this system. The Commission and EU Member States have made themselves too dependent on the pharmaceutical industry for the research, development and production of essential medicines and medical devices. The new pharmaceutical strategy offers the opportunity to prioritize the public health needs of Europeans over the profits of shareholders. In order to ensure accessible and affordable medicines, now and in the future, the EU should take up the following actions:

1. Develop an EU research programme to fund and coordinate public research and clinical trials for the development of medicines and vaccines that address public health needs

- A European research programme should be set up to fund public research into medicines and vaccines that have a clear societal value. This includes funding not only for developing new medicines, but also for example 1) research of comparative effectiveness of different pharmaceutical treatment options, to identify the 'real' innovations 2) repurposing trials with old off-patent medical products and 3) development of medicinal products for children or for rare diseases.
- It would replace monopolies and high prices with alternative incentives based upon cash rewards, and would ensure expanded funding for research, drug development, and clinical trials ('delinking' the costs of research & development and the price of pharmaceuticals). Milestones and findings that are steps forward in the development of necessary medicines would be directly rewarded instead of linking the coverage of the R&D costs to the price that society and patients will pay afterwards.

2. Lay down requirements for public subsidies and oblige pharmaceutical companies to be transparent about the costs to develop medicines

- When using public funds or entering into price negotiations with EU countries, pharmaceutical companies should provide transparency about the share of public money they have used in the development of a medicine, the overall costs of R&D as well as other aspects of the supply chain. This would provide a clearer link between risk and reward.
-

- Transparency should equally be ensured in preclinical and clinical trial data as well as in prices paid across the public and private sectors. Confidentiality clauses in contracts have to be abolished: the public has the right to know the conditions and returns on public investments.
- The EU should equitably share intellectual property rights between the public and private sector to reflect the public contribution (through funding or publicly funded research) to the development of medicines. This could include only providing a non-exclusive license to a private sector entity for intellectual property (in this case: a drug discovery) generated through public sector contributions.

3. Do not extend pharmaceutical companies' exclusive rights if they have already earned back their investments

- The EU should make the granting of all extensions of monopoly positions, including Supplementary Protection Certificates (SPCs), conditional on applicants providing evidence that the period of effective protection under the patent is not sufficient to cover the investment put into the research. If an extension is granted, patent owners should be required to submit data on return on investment on a yearly basis, so that the SPC can be withdrawn once a manufacturer made enough profit to cover the costs of investment.
- In order to obtain additional exclusivity of 10 years for medicines for rare diseases (the "orphan drug status"), pharmaceutical companies should shoulder the burden of proof to demonstrate that they have not yet made sufficient profits to cover their research and development costs. This proof must be public so that society gains insight into the development costs of medicines. Policy should be based on sufficiency estimates related to transparency of costs and pricing. In addition, orphan exclusivity should be removed in cases where an orphan medicinal product already proved sufficiently profitable for the manufacturer.

4. Patients over patents: increases the possibilities for EU countries to use compulsory licenses

- Under the international TRIPS agreement, EU countries can use compulsory licenses to cancel the patent protection on a product if a national government deems it necessary for the public interest. In the case of orphan drugs it is often impossible for EU countries to use compulsory licenses because of European data protection and market exclusivity, even in cases of national emergency.
- In the spirit of the Doha Agreement, the EU has to introduce explicit data and market exclusivity waivers in the EU pharmaceutical regulation to enable national governments to facilitate effective use by governments of patents in the public interest, compulsory licensing or other measures needed for the advancement of public health and access to medicines for all within the European Union.

5. Step up action against abuses of dominant positions in the pharmaceutical sector

- The European Commission and national competition authorities can impose fines on companies that abuse their dominant position in the European market by charging excessively high prices. Enforcement to combat abuses of dominant positions by pharmaceutical companies need to be stepped up under article 102 of the TFEU: more investigations are needed and fines need to be imposed more quickly. In addition, the European Commission in close cooperation with national authorities must report annually on abuse of dominant positions in the European pharmaceutical sector.
- Companies in a monopoly position have a complete power over supply. They frequently limit the quantities of medicines supplied to national markets through very strict supply quotas policies. These supply restrictions are so tight that they are likely to cause medicines shortages. Companies in a dominant position should regularly provide European aggregate supply volume data for their products with a split by country.
- Invest in European non-profit pharmaceutical undertakings which operate in the public interest to manufacture medicinal products of health and strategic importance for healthcare, to ensure security of supply and prevent possible shortages of essential medicines.

6. Create an enabling environment for pooled procurement, joint price negotiations and more information exchange between EU member states

Drug manufacturers that operate on the international level currently have too much power over individual purchasing countries. There is a possibility at EU level to jointly procure medicines, but this opportunity is not widely used by member states. If implemented, EU joint procurement of medicines could strengthen the purchasing power of the Union in terms of joint price negotiations, and more information exchange between member states can ensure fairer prices, better conditions and increase patient access.