

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

### **Chapter 1. Introduction: changing political context around high-price medicines**

#### **Unaffordable medicine is a problem for everyone**

The problem of prohibitively expensive medicines, and the resultant lack of access to them, has over recent years, shifted from being the concern primarily of the global south – disadvantaged for so long by rules written by rich countries in the interests (and under the influence) of their transnational corporations – to become a growing concern also for the world’s richest countries themselves. The *Financial Times*, for example, recently reported that in the US drug prices are rising at “four times the rate of inflation, causing concern for employers, health insurers and consumers”.<sup>1</sup> Meanwhile in Europe more and more medicines come with paralysing price tags, pushing public healthcare systems into financial crisis, and leaving patients without access to medicines they need. US company Gilead, for example, caused outcry with its pricing of Hepatitis C drug Sovaldi in Europe at around €55,000 per patient for a 12-week course, in contrast to production costs estimated at under €1 per pill.<sup>2</sup> Public health groups point out how the EU’s system of patent-based monopolies and exclusivities encourages companies to set such extreme prices, essentially blocking access to affordable treatments, as national health systems cannot afford the asking prices or are forced to ration costly drugs to a very limited number of patients at critical stages of a disease.<sup>3</sup> As a result, patients are left without access to life-improving and life-saving medicines, in the case of Sovaldi, causing great suffering to those denied access.<sup>4</sup>

In response to this problem some countries in Europe have teamed up to try to jointly negotiate prices with pharma companies (such as the Beneluxa Initiative and Valetta Declaration), aiming to address information and power asymmetries with the industry.<sup>5</sup> Pharma companies, meanwhile, often justify sky-high prices as reflecting research and development (R&D) costs, when in fact, public and charitable funding often both play a huge role in R&D (see Box 1). Drug company Vertex, for example, triggered headlines in the UK over its unwillingness to negotiate its colossal price tag for cystic fibrosis treatment Orkambi – £105,000 per patient per year – which was developed in part with charitable funding. Vertex’s Chief Executive, meanwhile, took home \$78.5m in 2017, with the company’s two UK directors pocketing over £15m from share options in the same year.<sup>6</sup>

## **WHO condemns pricing of cancer drugs for maximum profit**

A system of regulatory incentives that are highly beneficial for industry has, for example, enabled Novartis to earn billions beyond the R&D costs of its cancer drug Glivec. Meanwhile many patients cannot access it due to price tags in the realm of \$100,000 per year. In the EU, thanks to the orphan drugs regulation (ie designed to treat rare disease, see Box 1), Glivec was licensed for six rare diseases, in each case protected by ten years of market exclusivity, enabling it to charge more for longer. Glivec also benefited from a special type of patent extension called a 'supplementary protection certificate' (SPC), allowing it to extend its period of monopoly pricing (see Chapter 4). Novartis has made an incredible \$50.42 billion globally from Glivec since its launch in 2001.<sup>7</sup> In the US Glivec's price tripled in the first decade of its sale, something doctors lambasted as unjustifiable profiteering, bearing little relation to what the drug cost to develop and produce, instead charging whatever price the market will bear for a medicine that patients literally can't live without.<sup>8</sup> This kind of problem is recognised by the World Health Organisation (WHO) in its recent technical study on the pricing of cancer medicines. The study – notable for having maintained a firewall with Big Pharma in its preparation to prevent conflicts of interest – concludes that pharmaceutical companies do not set prices based on R&D costs, but according to “commercial goals, with a focus on extracting the maximum amount that a buyer is willing to pay for a medicine”. This “makes cancer medicines unaffordable”. In order to improve affordability and accessibility, the WHO recommends greater transparency around companies' pricing approaches, and a realignment of incentives for R&D.<sup>9</sup>

## **EU sits up and takes notice**

In light of the growing crisis of high-priced medicines, criticism of the model that has made the pharmaceutical industry one of world's most profitable – while more than two billion people still lack access to essential, life-saving medicines<sup>10</sup> – are coming from increasingly high-up. In Europe, the Dutch Presidency of the European Council in 2016 introduced a hitherto unimaginable step: political recognition that there is a problem with the profits-over-people model Big Pharma has worked hard to shape and maintain.

Sky-high prices were not the only catalyst; this was also spurred on by the glut of 'new' medicines coming to market with no clear added-value compared to existing medicines (ie despite costing more, they don't represent a therapeutic advance), whilst meaningful innovation (ie genuinely new or better treatments) in many vital areas lags behind. Under the chairmanship of Dutch Health Minister Edith Schippers, who recognised that medicines' prices have no clear relationship with R&D costs or even with the added value of a drug,<sup>11</sup> in June 2016 the Council issued ground-breaking conclusions on strengthening the balance in pharmaceutical systems in the EU and its member states.<sup>12</sup> They expressed concern about the abuse of some intellectual property (IP)-related incentives, and requested that the European Commission conduct a review of certain EU instruments that provide additional patent protection for the pharmaceutical industry (see Chapter 3).<sup>13</sup> The Council wanted to know if current rules were being used as intended, whether they were a fair distribution of incentives and rewards, and if they needed revision. Less than a year later the European Parliament mirrored

this, supporting “EU level action on access to medicines”, following a report by the Committee on the Environment, Public Health and Food Safety (ENVI).<sup>14</sup>

Committee member Nessa Childers described this report as subject to “an onslaught of lobbying”.<sup>15</sup> Although “some important lessons and policy goals survived”, says Childers – the final report called on the Commission to strictly limit the effects of monopoly price-extending SPCs, and for member states to make use of public health exceptions in trade-related intellectual property (IP) rules – this onslaught of lobbying was not a complete waste of effort for Big Pharma. Amendments that could have seen clinical trials – which test the safety and efficacy of a new drug – safeguarded, or national authorities’ ability to negotiate prices with pharma companies excluded from the scope of EU trade negotiations, were rejected.<sup>16</sup>

### **Big pharma gets its claws out to protect its profits**

The European Parliament has not been the only target of lobbying. As Yannis Natsis from the civil society group the European Public Health Alliance (EPHA) notes, Big Pharma was “taken by surprise by the disruptive Dutch Presidency”. It was the first time the industry had lost control of the narrative at the highest political level. Big Pharma’s lobbyists’ top priority since then has been to ensure that what they see as “the Dutch fiasco” is not repeated; and moreover that the Dutch Conclusions and the processes they triggered “will be weakened and/ or quickly forgotten”.<sup>17</sup> It is in this light that we might view Big Pharma’s ferocious lobbying and unrepentant PR war against any encroachment on the framework of IP and incentives that it profits so much from. The industry has fought tooth and claw against even the smallest tweak to the EU’s incentives regime. In particular it has sought to insert industry influence into EU attempts to gatekeep against medicines with high prices but low added-value.

### **Big Pharma's key lobbying issues**

This report takes a look at the Big Pharma lobbying scene in Brussels, and sets out some of the tactics being deployed by the industry’s main lobby group EFPIA (Chapter 2). It then considers some of the most significant events to follow the 2016 Council conclusions. First, the pharma incentives review the Commission was asked to undertake, which, unlike the WHO cancer pricing study, did not have a firewall to prevent conflicts of interest with the industry (Chapter 3). Next, we reveal how the ferocious lobbying against a minor change to the EU’s special patent extensions, called SPCs (which allow companies to charge high monopoly prices for longer), reflects Big Pharma’s attempt to close down debate (Chapter 4). We see worrying signals that Big Pharma may be fighting not only to preserve the existing regime, but to make it even more profit-friendly – at the expense (literally) of patients’ access to medicines. Next, we look at plans for joint European assessments of how effective new medicines are compared to existing treatments. These type of assessments help put governments in a better position to negotiate with Big Pharma over pricing (ie what they will pay for a medicine) and reimbursement (ie whether their health system will cover a particular drug). Robust and independent assessments could help tackle unjustifiably high-price medicines, so it is vital that

lobbying to make them too industry-friendly is resisted, whilst retaining the benefits of collaboration (Chapter 5). Finally, we make recommendations to the EU institutions on how to go forward, towards ensuring access to affordable, and effective, new medicines, including by safeguarding policy-processes from the undue influence of Big Pharma (Chapter 6).

### **Box 1: Issues affecting access to medicines**

There are many interweaving issues that affect access to medicines, and high prices, both in Europe and around the world. As well as the issues focused on in this report, namely the EU's pharma incentives review, patent extension rules like the SPC, and health technology assessment, these include:

- **Gaming the system - rare diseases and orphan drugs:** 'Orphan' drugs are those that are developed to treat rare diseases. They tend to be expensive to develop and unlikely to turn a profit, and so governments give incentives to drug companies to produce them to meet public health needs. According to EPHA, in Europe "incentives originally put in place to promote innovation in the field of rare diseases are being abused to maximise profit".<sup>18</sup> The misuse of orphan drugs regulation, whereby Big Pharma produces a growing proportion of drugs for rare diseases (where their products enjoy reduced regulatory requirements and can fetch exorbitant prices), comes at the expense of the healthcare needs of the entire population (ie as medicines to address other public health needs are neglected in favour of research into the now-more profitable rare diseases 'market'). Meanwhile, the high prices of 'orphan' drugs prevents many rare disease patients' access to them.<sup>19</sup>
- **Lack of public return on public investment:** Big Pharma argues that high prices reflect high R&D costs, but the data shows no link between price levels and the costs invested by the industry; at most only 15 per cent of a drug price is reinvested into medicines research and development.<sup>20</sup> Meanwhile public (and charitable) investments regularly play a major role in funding both medical research and clinical trials. Globally it is estimated that public bodies pay between one- and two-thirds of all up-front R&D investment.<sup>21</sup> This fact is massively downplayed by companies – aided by a lack of financial transparency – in order to obtain monopolies (and profit from monopoly pricing). There is a growing movement for public return on public investment, and to rethink frameworks to fund medical research.<sup>22</sup> The EU's biggest public private partnerships, the Innovative Medicines Initiative (IMI), helps demonstrates why; co-written and co-run by Big Pharma lobby group EFPIA, IMI has poured public money into the pockets of EFPIA's members – giant pharma corporations like Pfizer and GSK – for research they admit they'd do anyway.<sup>23</sup>
- **Industry-friendly European Medicines Agency (EMA):** Industry interests have increasingly permeated what should be the public interest agenda of EMA, which authorises ever more drugs with unclear added therapeutic value, based on premature evidence (see Box 3).
- **Trade deals:** Big Pharma uses trade policy to entrench its lucrative business model – as seen in the fight over TTIP and the EU-Japan trade deal<sup>24</sup> – but also in its lobbying against an SPC manufacturing waiver, by citing incompatibility with the EU's trade policy positions (see Chapter 4).

- **Clinical trials:** The WHO recognises that financial links influence the outcome of trials to test a drug's efficacy and safety. The likelihood a study funded by a company will yield favourable results is four times higher than for independent trials.<sup>25</sup> Together with the lack of transparency around clinical trials (we need public access to ALL results of ALL trials), this affects what medicines patients end up having access to, and how well their risks and benefits (the balance of desirable and undesirable effects) are understood by those prescribing and taking them.
- **Financialisation:** The pharmaceutical sector is becoming increasingly financialised, contributing to problems of accessibility and affordability. Pharma firms are investing more into financial strategies than into R&D; between 2006 to 2015, for example, 18 large pharmaceutical companies collectively spent US\$516 billion on share buybacks and dividends, and only US\$465 billion on R&D.<sup>26</sup> Product development, meanwhile, increasingly relies on buying up smaller labs; meanwhile, venture capitalists investing in biotech start-ups expect returns of three to five times what they put in.<sup>27</sup>
- **Wooing the medical profession:** By offering medical professionals bonuses and lucrative contracts, pharmaceutical companies have gained a level of influence over the prescriptions made and the decisions of health agencies. In France, for example, health professionals have received a total of more than €3.5 billion from the industry since 2012.<sup>28</sup>

- 1 *Financial Times*, Some drug companies are still imposing triple-digit price rises, April 2019, <https://www.ft.com/content/177f5df4-558b-11e9-a3db-1fe89bedc16e>
- 2 EPHA joins Europe-wide challenge to patent for Hepatitis C treatment, March 2017, <https://epha.org/press-release-epha-joins-europe-wide-challenge-to-patent-for-hepatitis-c-treatment/>
- 3 Doctors Without Borders Among 30 Groups to Challenge HCV Drug Patent in Europe, April 2017, <https://www.contagionlive.com/news/doctors-without-borders-among-30-groups-to-challenge-hcv-drug-patent-in-europe>
- 4 See eg *The Atlantic*, The True Cost of an Expensive Medication, 2015, <https://www.theatlantic.com/health/archive/2015/09/an-expensive-medications-human-cost/407299/>
- 5 See eg EPHA, BENELUXA: First results of multi-country cooperation on medicine price negotiations, 2017, <https://epha.org/discussion-paper-beneluxa/>
- 6 *The Guardian*, Directors of cystic fibrosis drug firm in NHS standoff made £15m, by Sarah Bosely, 29/02/19, <https://www.theguardian.com/society/2019/feb/19/directors-vertex-pharmaceuticals-cystic-fibrosis-orkambi-drug-firm-nhs-standoff>
- 7 *Politico*, Future of Pharma Incentives: Drug lobby's market protections, by Helen Collis, 10/5/17 <https://www.politico.eu/article/future-of-pharma-incentives-fine-line-between-incentives-and-favoritism-drug-research/>
- 8 CNN, Doctors blast ethics of \$100,000 cancer drugs, April 2013, <https://money.cnn.com/2013/04/25/news/economy/cancer-drug-cost/index.html>
- 9 Health Policy Watch: WHO Member States Call For Transparency, Access To Innovation On Cancer Drug Pricing, by David Branigan, 30/01/2019 <https://www.healthpolicy-watch.org/who-member-states-call-for-transparency-access-to-innovation-on-cancer-drug-pricing/>
- 10 WHO, Access to medicines: making market forces serve the poor, <https://www.who.int/publications/10-year-review/medicines/en/>
- 11 *Politico*, Future of Pharma Incentives, *ibid.*
- 12 Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, <https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/> Articles 46 and 47
- 13 EPHA, The top 5 issues in medicines policy for 2018, by Yannis Natsis, January 2018, <https://epha.org/the-top-5-issues-in-medicines-policy-for-2018/>
- 14 European Parliament, Report on EU options for improving access to medicines, 14/02/17, <http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A8-2017-0040&format=XML&language=EN>
- 15 Commons Network, 'Healthcare is not a business, but a fundamental human right', March 10, 2018, <http://www.commonsnetwork.org/news/healthcare-is-not-a-business-but-a-fundamental-human-right/> Text of Nessa Childers speaking at 31/01/018 event.
- 16 Commons Network, *ibid.*
- 17 EPHA, The top 5 issues in medicines policy for 2019: What will dominate the agenda this year, by Yannis Natsis, 5 February 2019 <https://epha.org/the-top-5-issues-in-medicines-policy-fo9r-2019/>
- 18 EPHA, New game, new rules: Pathways for better and affordable medicines in Europe, by Yannis Natsis, June 2017, <https://epha.org/new-game-new-rules-pathways-for-better-and-affordable-medicines-in-europe/>
- 19 See eg *Prescrire* <http://english.prescrire.org/en/81/168/51920/0/NewsDetails.aspx> and <http://english.prescrire.org/en/CF308C326563A64711049CB4876C0ACD/Download.aspx>; Medicines Law and Policy, <https://medicineslawandpolicy.org/2019/01/time-to-put-a-stop-to-the-abuse-of-orphan-drug-regulation-the-latest-scandal/>
- 20 Lazonick W, Hopkins M, Jacobson K, Sakinç ME, Tulum O., US Pharma's Financialized Business Model, Institute of New Economic Thinking, Working Paper No. 60, 13 July 2017, [https://www.ineteconomics.org/uploads/papers/WP\\_60-Lazonick-et-al-US-Pharma-Business-Model.pdf](https://www.ineteconomics.org/uploads/papers/WP_60-Lazonick-et-al-US-Pharma-Business-Model.pdf)
- 21 UCL Institute for Innovation and Public Purpose (2018) 'The people's prescription: Re-imagining health innovation to deliver public value', IIPP Policy Report, 2018-10. London: IIPP, Global Justice Now, Just Treatment, STOPAIDS. Available at: <https://www.ucl.ac.uk/bartlett/public-purpose/wp2018-10>
- 22 *Ibid.*
- 23 CEO, Policy Prescriptions, 2015, <https://corporateeurope.org/power-lobbies/2015/09/policy-prescriptions-firepower-eu-pharmaceutical-lobby-and-implications-public;>
- 24 ALTER-EU, Corporate Capture in Europe, September 2018, [https://www.alter-eu.org/sites/default/files/documents/corporate\\_capture\\_web\\_1.pdf](https://www.alter-eu.org/sites/default/files/documents/corporate_capture_web_1.pdf)
- 25 *BastaMag* and Observatoire de Multinationales, Entre les labos pharmaceutiques et les médecins, 14 millions de conflits d'intérêts potentiels!, 13 November 2018, <https://www.bastamag.net/webdocs/pharmapapers/l-argent-de-l-influence/entre-les-labos-pharmaceutiques-et-les-medecins-14-millions-de-conflits-d-interets-potentiels/>. See also <http://www.alltrials.net/>
- 26 Lazonick et al, *ibid.*
- 27 Based on comments by Jan Van den Bossche, Partner at Fund+, EPHA's Trailblazers event 20/11/18, <https://epha.org/epha-2018-a2m-forum/>
- 28 *BastaMag* and Observatoire de Multinationales, *ibid.*