

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

Executive Summary

The pharmaceutical industry is one of the world's most profitable, benefiting from a highly problematic model which helps ensure that many people still lack access to essential, life-saving medicines. While this has been a major issue in the global South for decades, in recent years the crisis in affordable medicines has also spread to Europe. The emergence of extremely expensive medicines – with price tags in the tens and hundreds of thousands of euros, vastly disproportionate to the cost of developing and producing them – owes much to industry-friendly regulation and intellectual property (IP) rules. While civil society has been ringing alarm bells about these issues for years, in 2016 the European Council finally recognised the problem. It asked the European Commission to review whether the system of incentives and rewards for pharmaceutical companies was out of balance.

In the face of this review, Big Pharma's lobby machine ground into top gear to defend its privileges, doing its best to remove or weaken regulatory measures. A close relationship with the Commission – which fails to take undue industry influence seriously – has played a key role, as has the lobbying firepower of Big Pharma. The top ten biggest spending companies, for example, have increased their lobby budget by €2 million since 2015, and Big Pharma's main lobby group EFPIA (European Federation of Pharmaceutical Industries and Associations) sits on eight of the Commission's advisory groups. Big Pharma has also rolled out a PR offensive harnessing the powerful emotions around illness, designed to deflect criticism and narrow the scope for debate. Thanks to this lobbying arsenal, the industry has succeeded in influencing the review into pharma incentives and rewards (such as intellectual property rules), as well as a change to a type of patent extension called an SPC (supplementary protection certificate) which allows companies to extend the period of monopoly pricing. It has also affected a proposal for EU collaboration to assess how effective new medicines and health technologies are relative to existing ones, something which helps member states negotiate prices. Drug companies promote the use of 'new' drugs because they still have patent protection, and are therefore more expensive, over old ones that don't, even if the new product is not an improvement in medical terms.

Yet all is not lost. In response to a crisis of high prices, lack of access, and too few new medicines that represent real therapeutic advances, the appetite for radical change remains high. We urge the incoming European Parliament and Commission to ensure that medicines policy is protected from the undue influence of Big Pharma. Narrow commercial interests should not undermine public health priorities and the industry's fear-mongering must not narrow the scope for transformative change. The

EU institutions should keep working towards Europe-wide cooperation for robust and independent assessments of new drugs, stop promoting expanded IP provisions through trade deals, and support discussions around better ways to finance medicines research, ensuring a public interest return on public investment.

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”.¹ 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.² 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.³ 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.⁴

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.⁵ 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.⁶

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 Gleevec. 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), Gleevec was licensed for six rare diseases, in each case protected by ten years of market exclusivity, enabling it to charge more for longer. Gleevec 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 Gleevec since its launch in 2001.⁷ In the

US Gleevec'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.⁸

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.⁹

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 medicines¹⁰ – 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,¹¹ in June 2016 the Council issued ground-breaking conclusions on strengthening the balance in pharmaceutical systems in the EU and its member states.¹² 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).¹³ 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).¹⁴

Committee member Nessa Childers described this report as subject to “an onslaught of lobbying”.¹⁵ 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.¹⁶

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”.¹⁷ 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".¹⁸ 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.¹⁹
- **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.²⁰ 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.²¹ 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.²² 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.²³
- **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 deal²⁴ – 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.²⁵ 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.²⁶ 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.²⁷
- **Wooring 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 2012.²⁸

Chapter 2. EFPIA and Big Pharma's web of lobbying in Brussels

The firepower of EFPIA

Corporate Europe Observatory's 2015 report 'Policy prescriptions: the firepower of the EU pharmaceutical lobby and implications for public health', and ALTER-EU's 2018 book 'Corporate Capture in Europe' shone a spotlight on the immense influencing power of the pharmaceutical industry. This works through various channels, from Big Pharma's enormous lobby budgets and huge numbers of meetings (suggesting privileged access to Brussels' halls of power), to a revolving door that spins both ways, to its entrenched provision of 'expertise', and political debate framed by the industry to conflate its interests with that of the public's.²⁹

At the heart of Big Pharma's web of lobbying in Brussels is the European Federation of Pharmaceutical Industries and Associations (EFPIA). EFPIA has an annual lobby spend of €5.5 million; together with its two specialised sub-groups European Biopharmaceutical Enterprises (EBE) and VaccinesEurope, this rises to well over €6 million.³⁰ EFPIA and its two sub-groups have held a total of 42 meetings with commissioners, their cabinets or director-generals in the Juncker Commission, and have a total of 10 access passes to the European Parliament. EFPIA's standing as a trusted partner of the Commission is also evident in the fact that it currently sits on eight of the Commission's advisory groups, which provide expertise to legislators on policy-related issues, and so can be a channel for private interests to wield influence in the guise of expertise.³¹ EFPIA's chair Stefan Oschmann, the Chief Executive of Merck, recently spoke alongside a cluster of Commissioners, including President Juncker, at a High Level Commission conference.³²

Top 10 Big Pharma firms lobby spend increase

Many of EFPIA's member companies also engage in their own lobbying efforts, both directly and via lobby consultancies.³³ And Big Pharma's budget for lobbying appears to be going up. In September 2015 we reported that the then-top ten biggest spending pharmaceutical companies were splashing out between €12.5 million and €14.9 million. In April 2019, the now-top ten biggest spending Big Pharma firms – all members of EFPIA – have increased their budget by up to €2 million, spending between €14.6 million and €16.3 million.³⁴ Together they have had 112 top-level meetings with the Juncker Commission, and hold 60 access passes to the European Parliament. Johnson & Johnson (the seventh biggest spender, with six consultancies on its payroll,) has the second highest number (18) of Parliamentary passes out of all companies in the register.³⁵ And this is only an illustration of the industry's firepower. There are many other companies and pharma trade associations (including national members of EFPIA) in the lobby register, whilst many more meetings take place at the lower levels of the Commission.

Invoking emotions with strategic PR

In response to their long-established model coming under threat, Big Pharma has branched out from traditional lobbying. According to EFPIA's chairman, though the industry usually "talks about problematic issues or some legislative proposals... we thought it would be really useful to talk about the value we bring to society".³⁶ EFPIA's Director General Nathalie Moll points out that "to be effective in Brussels you need to have the outreach nationally and that includes media", adding that to unite politicians it is useful to find "a human element" to the industry.³⁷ EFPIA duly rolled out an evocative and emotionally-charged PR campaign called #WeWontRest. With tag-lines like "Disease never takes a break, so neither do we",³⁸ it responds to mounting criticisms of high-priced medicines by attempting to give Big Pharma a human face: a compassionate industry, dedicated to easing *your* family's suffering. By plugging into the emotions, it distracts from the profits-for-shareholders model that actually keeps prohibitively expensive medicines out of so many patients hands. EFPIA's website features a Pledge Wall full of photos of faces from EFPIA's member companies, together with motivational statements about why they do what they do (#WeWontRest until... "families are no longer torn apart by illness" or "cancer is no longer a scary word"). The message: medical breakthroughs are only thanks to "the passion, commitment and dedication" of people in our companies.³⁹ This is mirrored on EFPIA's corporate members' websites,⁴⁰ and plastered all over social media, for example, with a video informing viewers that "We were born to end patient suffering".⁴¹ Tweets under #ForTheChance⁴² show photos of patients with quotes like "For the chance to live without fear", to highlight "how many patients have grasped another chance at life because of treatments developed by the industry".⁴³

Attempt to close down debate

What is so perverse about this campaign is the way it attempts to close down the debate, insofar as it implies that when you criticise Big Pharma you're criticising the dedicated scientists researching medicines that improve and save people's lives. Implicitly if you, as policy-makers, change the rules for the industry, you're taking away patients' chances at a better quality of life. EFPIA's PR campaign has reportedly been translated into over 20 languages, and reached more than 50 million people around the world⁴⁴ with the message that Big Pharma is their tireless saviour. Implicitly, its critics then become the enemy of the sick and the suffering. This was the kind of message which EFPIA peddled at its December 2018 "premiere" of its #WeWontRest film at the Press Club in Brussels, which compiles interviews with the "people and companies" behind medical breakthroughs.⁴⁵

What is missing from this picture is that one- to two- thirds of pharmaceutical R&D is in fact publicly funded.⁴⁶ There is a growing discussion about the need for public return on public investment, responding to the pattern of part-publicly funded new medicines given exorbitant, prohibitive prices by Big Pharma (see Box 1). In light of this, EFPIA's #WeWontRest campaign resembles an attempt to co-opt the motivations and dedication of scientists (*whose work is of course vital and laudable*), and the hopes of patients to access better medicines (*which are of course legitimate*). This is particularly galling because the pharma lobby is doing so as part of its attempts to shape laws in the interests of

the shareholders of multi-billion euro companies, often at the expense of improving patients' access (which requires affordability) to better medicines (that are meaningful therapeutic advances, not just 'new' drugs that offer little to no improvement on existing treatments).

A parliamentary and media charm offensive

In May 2018 EFPIA held a four day exhibition in the Parliament, 'Unlocking tomorrow's cures', sponsored by three MEPs.⁴⁷ Promising to show how the industry transforms patients' lives,⁴⁸ it featured "escape room games", "fireside chats" and workshops with companies like Novartis and Pfizer on topics such as how to ensure the pharma industry "has the regulatory framework it needs". EFPIA followed this up with a manifesto for the 2019 European elections.⁴⁹ This sets out 'What Europe can do' to become a world leader in medical R&D, including: "Maintain and develop" its patent system, by "promoting strong IP protection, incentives and reward mechanisms" and creating "new incentives" for unmet medical needs. Again, the message is that industry wants even *more* incentives and protection, which would mean longer periods of monopoly pricing (ie unaccountable and unjustified high prices), and, potentially more 'new' drugs designed to reap the maximum profit from regulatory incentives rather than meet public health and patients' needs.

EFPIA also pays Brussels-bubble news outlet *Euractiv* for content that will be read by policy-makers and politicians. For example in October 2017 EFPIA sponsored a 'Special report' on Pharma innovation.⁵⁰ It included interviews with Health Commissioner Andriukaitis ("Supporting drug innovation is 'the only way'"), an official from the Estonian Presidency, a patient organisation (rare diseases group Eurordis – which receives significant industry funding (see below) – warning against any review of orphan drugs incentives), and a pharma boss (EFPIA's Nathalie Moll, who is quoted in three out of four of the other articles, warning that "Without incentives, innovations stop"). This report is clearly designed to give the impression of diverse support with the same message coming from many different mouthpieces – protect Big Pharma or else!⁵¹

Industry allies and corporate cross-over

EFPIA is not the only channel that Big Pharma lobbies through, and there are many interconnections between groups. The industry amplifies its voice through 'message multipliers', often pharma-linked organisations (that appear to represent different constituencies), which repeat messages aligned with Big Pharma's narrative, whilst omitting issues the industry does not want to talk about. Thus the industry orchestrates or convenes coalitions with a view to shaping the agenda.

For example in November 2018, EFPIA co-organised an 'EU Health Summit'⁵² together with a long list of groups with a "shared vision", including biotech lobby EuropaBio, medical technology association MedTechEurope, 'medium-sized' pharma lobby the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), and numerous patients representative groups (see Box 2). The event's first speaker was Robert Madelin, Chair of pharma-consultancy Fipra, who came through the revolving door from the Commission's health directorate (see Chapter 5).⁵³ Many of these groups pop up

repeatedly in interplaying lobbying efforts (as Chapters 4 and 5 show), and have links with EFPIA or its member companies, as funders, members or clients. EUCOPE, for example, shares around seven large corporate members with EFPIA,⁵⁴ whilst EuropaBio shares around 12, including AbbVie, Lilly, and Pfizer.⁵⁵ The Big Pharma company with the fifth biggest EU lobby budget, Amgen, is a member of all three. EFPIA's Director General used to head EuropaBio, and it is evident that the two groups work closely together.⁵⁶ What's more, not all pharma companies lobby through EFPIA; Gilead, for example, whose price for Sovaldi sparked outrage (see Chapter 1), is not a member of EFPIA, but it is of EuropaBio, EUCOPE, and US business lobby AmCham EU. It also recently set up its own EU affairs office in Brussels,⁵⁷ joining the many other Big Pharma companies already present.

Box 2: The importance of independence

The voice of patients is vital in policy debates around access to medicines. Yet there is also growing recognition of the importance of safeguarding the independence of patients' representative organisations, including their funding, to ensure they are in no way co-opted (knowingly or not) by Big Pharma to promote its interests. In some cases, patients organisations might face cuts in public funding and accept a greater proportions of industry funding as a result; and they may have strong enough firewalls to prevent undue influence from the industry. But in certain cases, there are warning signs that the interests of a particular group of patients are not the only interests being represented. For example EuropaColon has been gaining influence in Brussels' under the direction of Executive Director Stefan Gijssels, and has recently 'expanded' into Digestive Cancers Europe (which Gijssels also leads).⁵⁸ Gijssels, one of the speakers at the European Health Summit, is a professional lobbyist who was previously public affairs Vice President for Johnson & Johnson's pharma company Janssen. He also used to chair an EFPIA committee, has been a consultant at lobby firms Burson-Marsteller and Weber-Shandwick, and led European industry coalitions in the pharmaceutical and tobacco industries.⁵⁹ Gijssels also runs his own Brussels-based consultancy, Sebio, which offers clients expertise in "gaining control over their external environment... resulting in measurable business outcomes".⁶⁰ Sebio, which is not in the lobby register,⁶¹ lists GSK and Janssen as references, and has been commissioned by EFPIA to write a policy paper (focusing on the importance of "strong IP protection").⁶² EuropaColon's 'Funding Partners' include numerous pharma firms such as Pfizer, Lilly, and Merck, whilst EFPIA is a 'Collaboration Partner'.⁶³ Several Big Pharma arguments feature in a 2018 presentation by Gijssels: that high-prices are justified to encourage research, and that pricing of a drug should be determined by its value not its costs.⁶⁴ This contrasts with the findings of the WHO's recent study on cancer drug pricing; that we have been paying too much for too little meaningful innovation.⁶⁵

Chapter 3. Pharma-embedded consultancy reviews pharma model...

Commission employs consultancy with Big Pharma ties

Following the Council's request that the Commission critically review the balance of the EU's pharmaceuticals system, the Commission's directorate for the internal market, industry and enterprise, DG Grow, put out a tender for the study.⁶⁶ The study was to provide "an economic evaluation of the incentives and rewards for pharmaceutical innovation in Europe", including the effects of patent-extending SPCs. It was also to examine evidence on the overall impact on availability and accessibility of medicines for patients, and on the pressure on health systems across the EU. This was a very important mandate, mirroring the importance of the Council's recognition of the problem. Clearly, it would be vital for the Commission to choose a contractor whose independence would be unquestionable, and to avoid any actual or apparent bias towards the industry by rigorously ensuring balance in the stakeholders consulted by the contractor.

Yet the tender was won by consultancy firm Copenhagen Economics,⁶⁷ a firm which has had multiple Big Pharma clients. EFPIA, fiercely opposed to the pharma incentives review, previously hired Copenhagen Economics to produce a study on how beneficial the EU-US trade deal TTIP would be to the EU.⁶⁸ The resulting study, published in May 2016 (less than a year before DG Grow hired Copenhagen Economics) concluded that an "ambitious pharma chapter" in TTIP would do wonders for pharmaceutical exports and job creation in Europe.⁶⁹ It made wildly optimistic predictions that relied on models using overly-simplistic and ideology-driven assumptions.⁷⁰ What's more, the "ambitious pharma chapter" that EFPIA envisaged and lobbied for included the strengthening of IP laws (ie patent extensions like the SPC) of the very kind that Copenhagen Economics was hired by the Commission in April 2017 to evaluate. Copenhagen Economics was also hired by Novo Nordisk, Lundbeck, and Leo Pharma to produce a similar study on TTIP and Danish pharma.⁷¹ The consultancy boasts that it "has extensive experience performing economic analyses and providing advice" to "numerous" pharma clients,⁷² including helping with "Design and Advocacy", and producing materials to be used "in their dialogue with" ministries.⁷³ A Copenhagen Economics' staff member working on the incentives review has also been in charge of the firm's work for Novartis and Novo Nordisk,⁷⁴ whilst another described how part of the organisation's role is to advise "clients on pricing of pharmaceutical products and how to integrate pricing with market access and public affairs".⁷⁵ To spell it out, Copenhagen Economics regularly works for Big Pharma clients, produces materials that blatantly resonate with the industry's economic interests and lobbying strategies, and which are intended to be used directly in its pharma clients' lobbying of governments. Yet this is the consultancy that was chosen by the Commission to carry out what should have been a groundbreaking review that asked fundamental questions of the Big Pharma model.⁷⁶

Lack of stakeholder balance in review of system's 'balance'

Copenhagen Economics' study for the Commission says it conducted "more than 20 interviews with stakeholders",⁷⁷ but in a serious blow for transparency, a list of the interviewees is not included. The

report merely gives vague, unattributed input, such as how “some interviewees pointed out eg that the protection framework might signal to companies how 'innovation-friendly' a country or region is”. We therefore requested the list of interviewees from the Commission via the EU's access to documents laws. The results were disappointing. Twenty organisations were consulted, split into five categories, the biggest being 'Pharma' (Johnson & Johnson, Pfizer, Eli Lilly, Shire, Novartis and Novo Nordisk, the latter two have been clients of Copenhagen Economics). Add to this three 'Pharma organisations' - EFPIA (another client of Copenhagen Economics), EuropaBio, and EUCOPE (both the latter share many members with EFPIA). The 'Generic industry' had four industry representatives, and the 'Agricultural sector' (SPCs apply to plant protection products too) had three industry players. The category of 'Public organisation', however, had only one member: rare diseases patients' group Eurordis, which received €1.7 million funding from pharma and biotech companies in 2017 (see Box 2).⁷⁸ Out of the 20 interviewees, there are just three 'Other experts' representing non-industry interests.⁷⁹

This industry dominated list of 'stakeholders' is far from balanced, and a long way from what was stipulated in the European Commission's Technical Specifications for the study. These said that stakeholders should include industry, patients, healthcare professionals, consumer and public health organisations, payers and academia “in a balanced way”.⁸⁰ Yet they also said the contractor must provide the Commission with the list of experts for prior approval; does that mean the Commission approved this industry-skewed list? The dynamics between DG Grow and the Commission's health directorate, DG Sante, both involved in the study's oversight, might shed some light. As might the lobbying around it, which according to PR firm Hanover Communications (whose clients include pharma companies AbbVie, Gilead, and Vertex)⁸¹ said was “one of the most heavily lobbied items in Brussels”.⁸²

Industry lobbies the Commission over incentives review

In August 2017, upon request by DG Grow EuropaBio sent a series of case studies of medicines whose R&D “benefitted from the available set of IP incentives in the EU” to the Commission.⁸³ EuropaBio explained that additional patent protections like SPCs are “crucial to incentivise companies (and investors in general) to bring these medicines to market”. Moreover, it argued that even with all the existing protections, some discoveries don't make it to market; so not only will any reduction or recalibration of its patent protections “constrain and limit further medicines development in the EU”, it implies that “the current set of incentives are insufficient”. The biotech lobby clearly used the incentives review to try to get DG Grow on side for more IP protection. For example EuropaBio told DG Grow that fiddling with the existing system is “more than dangerous”; unless of course, it were to be strengthened even further in the pharmaceutical and biotech industry's interests.

Aside from EuropaBio, however, DG Grow told us it “did not have interactions with industry as regards this study”, since an objective of contracting it out was so “the (time-consuming) interactions with stakeholders are managed by the contractor”.⁸⁴ DG Grow also said that Copenhagen Economics' final report “includes all material sent to the Commission by the contractor (with the exception of purely

legal and administrative documents, such as contracts, invoices, meeting requests, etc.” Does this imply that DG Grow had not previously seen the list of interviewees? Or merely that it considered the details of who had been interviewed for the review as purely “administrative”?

DG Sante, on the other hand, had multiple meetings about the incentives review.⁸⁵ On the industry side, it met once with GSK and once with EuropaBio, whilst on the public health side it had several contacts with EPHA and Health Action International. EuropaBio peddled the same message as it did to DG Grow, and DG Sante “invited EuropaBio to contribute” to the study, “as input from of industry will be essential in keeping the study informed and balanced.” Sadly ironic in hindsight! Yet, it does appear DG Sante was concerned about balance: when chemicals and pharma giant Bayer (a member of both EuropaBio and EFPIA) requested a meeting about the ongoing review (noting that “the system is working”), Sante refused, on the grounds that Copenhagen Economics had already “consulted and interviewed” EFPIA, “of which Bayer is a corporate member”. Since stakeholders should be “consulted in a balanced way”, said Sante, it would not “be appropriate to organise a meeting as an appropriate consultation has already taken place”. Another indication that DG Sante wanted to avoid outright industry-domination comes from its correspondence with EPHA: DG Sante asked for “a short-list of experts” they’d recommend for interview, two of which did make it onto Copenhagen Economics’ list.⁸⁶

Disappointing results from disappointing review

Considering the pro-industry connections and input, the conclusions of Copenhagen Economics’ study into pharma incentives and rewards are not surprising, though they are deeply disappointing from a public interest perspective. Far from being a critical reflection of a skewed system, it concludes that “a longer effective protection period stimulates” R&D into new medicines, and that incentives like the orphan drugs regulation (see Box 1) bring more “innovation”.⁸⁷ The bulk of the report is a statistical analysis, but it does not examine whether the drugs in its datasets actually represent therapeutic advances – ie they may be ‘new’ but not have any meaningful added-value. Independent drugs-bulletin *Prescrire*, for example, conducted scientific assessments of over 50 orphan drugs authorised by the European Medicines Agency, and found that many fail to offer therapeutic advantages over existing drugs (and sometimes have disadvantages), or that there is insufficient evidence to tell.⁸⁸ Despite this, Copenhagen Economics review of whether EU pharma incentives and rewards are working as intended, steers clear of assessing the quality (or lack thereof) of the “innovations” the system is producing. The most radical of its conclusions is that there is a “trade off between innovation of new medicinal products and lower prices of medicinal products through faster availability of generics”. The best policy solution? To “circumvent” the trade off, by “finding other ways of curbing high prices” than targeting IP. Copenhagen Economics’ message is that everything is (more or less) fine, so don’t change things too much, as “a reduction of the effective protection period will negatively affect” EU investments in R&D. Bang on message with Big Pharma.

Chapter 4. Patent extensions: helping keep drug prices high for longer

Monopoly prices for longer threaten access to affordable medicines

Supplementary protection certificates (SPCs) are extensions to a patent, and like patents, they give the holder a monopoly on a drug. This means they are the only ones who can make and sell it, and therefore can set the price as high as they like. For example a preventative HIV treatment called Truvada made by US firm Gilead, shows how SPCs are geared towards corporate profits rather than public health. In France Gilead was granted a highly controversial SPC on Truvada, which non-profit group AIDES estimates will cost the French public health system an additional €815 million, directly threatening the country's preventive HIV policy.⁸⁹ SPCs are an EU invention, and can be awarded to pharmaceutical (or plant protection) products to “offset the loss of patent protection... due to the compulsory lengthy testing and clinical trials” required to obtain marketing approval.⁹⁰ Intended to woo pharma firms to the European market by promising more time supposedly to 'recoup' R&D investments, SPCs are granted by national patent offices. Patents normally last 20 years; SPCs can extend them by five. Weak criteria for SPCs however, means they are often routinely given, delaying the entry of generic competitors and the consequent drop in price. As Médecins Sans Frontières (MSF) points out, by prolonging monopolies, “SPCs lead to unaffordable medicines prices that prevail for longer periods of time – threatening the sustainability of national healthcare systems and delaying patients' access.”⁹¹

A faulty rationale

The very rationale for SPCs is faulty: Big Pharma companies are earning huge returns on drugs, not struggling to recoup their R&D costs. Monopoly drug prices do not reflect development costs, rather, they often exceed them wildly, whilst pharma companies are spending more on share buybacks and dividend payments than they are on R&D (see Box 1). As MSF explains, broad IP rules “facilitate the so-called 'evergreening' strategies of pharmaceutical companies”, that is they help extend market monopolies and maintain high rates of profit for longer, for example by filing multiple patents on a single medicine.⁹² Finally, the notion that companies need to be compensated for the time taken by the marketing authorisation process – necessary to determine a medicine's safety and efficacy – is itself highly questionable. Not least since companies often prolong this “by failing to provide quality data” or respond to queries in a timely way. But also because, as AIDES notes, the 20 years of patent protection was never intended as an effective 20 years of monopoly, only “to provide a sufficient period of monopoly on the market” whilst also “covering the various steps of the R&D process”, which it already does.

The distracting debate

Public health advocates like MSF argue that SPCs should be abolished.⁹³ Yet at the EU level, the debate around SPCs has not focused on such fundamental questions – as how they prevent access to affordable medicines, or whether the rationale for their existence is even justifiable. Instead, the lobby battle in Brussels has merely focused on how SPCs distort competition. The generics industry

has long argued that SPCs have the unintended effect of disadvantaging European generics manufacturers vis-a-vis their non-EU counterparts. EU firms cannot manufacture generic or biosimilar medicines for export to countries without an SPC (or where one has expired), but companies based elsewhere can. And, they argue that it is a competitive disadvantage to be unable to start making a drug whose SPC is due to expire, so that they are ready to enter the market on the day it expires in an EU country, whilst manufacturers from elsewhere can be. The idea of an SPC manufacturing waiver – allowing EU generics firms to manufacture an SPC-protected drug solely for export to a third country without an SPC – was designed to level the playing field for EU and non-EU generics firms. The Commission’s 2015 Single Market Strategy first floated the idea, and the Parliament, in 2016, “urged the Commission to introduce and implement before 2019 an SPC manufacturing waiver”.⁹⁴ Numerous studies, a public consultation and an impact assessment later, and the Commission published its proposal in May 2018. A pitched lobby battle between Big Pharma and generics characterised this process, with wins and losses on both sides. For many public health groups, however, the SPC manufacturing waiver barely scratches the surface of the real changes needed; as Dimitri Eynikel from MSF notes, it “primarily seeks to rebalance the competing commercial interests of originator and generic pharmaceutical industries in Europe” not address the issue of access to affordable medicines.⁹⁵

Big Pharma furious at even minor change to SPC

Patent-holding, name-brand drug ‘originator’ companies such as Novartis, GSK, and Pfizer have furiously lashed out at the SPC manufacturing waiver, even though it does not even alter the monopoly period provided by an SPC (so it doesn’t actually reduce their ‘reward’). EFPIA’s Nathalie Moll, for example, writes in Euractiv that the SPC manufacturing waiver sends a “damaging signal” that Europe is weakening its IP framework, whilst its competitors develop theirs, which could lead to a “perfect storm of disinvestment in R&D in Europe”.⁹⁶ This is the usual big business argument that if you regulate us in ways we don’t like, we’ll up sticks and leave. In a letter to Commissioner Beinkowska in February 2018 EFPIA said it had “reviewed various studies” and concluded an SPC manufacturing waiver could result in a negative EU trade balance.⁹⁷ But the “various studies” EFPIA cites as evidence are without exception funded or commissioned by Big Pharma. Namely, a report by consultancy firm Pugatch Consilium which was “commissioned by” AbbVie, F. Hoffmann – La Roche, and the US Chamber of Commerce”,⁹⁸ a study by QuintilesIMS study, funded by EFPIA,⁹⁹ and a report by the Office for Health Economics (OHE), also commissioned and funded by EFPIA.¹⁰⁰ In its letter, EFPIA does not mention any of these links.

Coordinated lobby efforts

EFPIA’s letter shares language with a host of other letters sent to the Commissioner from various national association members of EFPIA (Swedish LIF and Polish INFARMA) and EuropaBio (Belgian BIO.BE), which are scattered with near-identical phrasing.¹⁰¹ This cluster of apparently co-ordinated letters emphasise different, but converging elements of Big Pharma’s messaging. Arguments and tactics that are also used by other, interconnected groups in their lobbying against an SPC manufacturing waiver, include:

'A threat to jobs, growth, and patients': INFARMA told the Commission any adjustment to “existing IP incentives” could be “to the detriment” of jobs, growth and patients’ health in Europe. EBE also warned of job and investment losses, and lobby firm G+, on behalf of AbbVie (“in close coordination with” EFPIA), said “weakening” patent protection will undermine jobs, investments, and patient access.

'It will hurt small and medium size enterprises': EBE argued that an SPC manufacturing waiver “would be unfair” to EU biopharma SMEs which “larger companies” increasingly rely on “to secure their product pipelines”.¹⁰² But EBE does not represent SMEs’ interests; its members are the biggest of Big Pharma companies, with pockets full of the monopoly profits from SPCs.¹⁰³ Biotech lobby ICBA said “weakening the SPC” will “damage the viability” of European biotech SMEs, as SPCs provide ‘certainty’ to investors (“venture capitalists and larger companies”).¹⁰⁴ ICBA’s letter was signed by EuropaBio – which represents many Big Pharma firms – and nine of EuropaBio’s members.¹⁰⁵ EUCOPE, the association for pharma SMEs, claimed the Commission had “shown a fundamental disregard” for SMEs’ interests by “prioritising the input of larger market players”. This is despite the fact that Big Pharma also objected to the waiver, and that EUCOPE shares many large corporate members with EFPIA (Chiesi, for example, sits on the board of both).¹⁰⁶ EUCOPE’s members also include lobby firms with Big Pharma clients, such as Fipra (hired by EFPIA, Pfizer and Novartis) and Covington (hired by EFPIA, UCB and MSD).¹⁰⁷ Yet EUCOPE repeatedly tried to distance itself from Big Pharma, which often develops new drugs by buying or licensing molecules from smaller biotech firms (or buying the firms).¹⁰⁸

'It's incompatible with trade policy': LIF told the Commission that “patent exemptions” are incompatible with its trade policy. EUCOPE elaborated that since the “EU is trying to enforce its IP standards” globally, by promoting SPCs in trade talks with Mexico, and winning a WTO case against a stockpiling exemption in Canada, an SPC manufacturing waiver goes “against EU trade policy”.¹⁰⁹ G+, representing AbbVie further warned that the Commission’s draft proposal “already raised concerns in the United States, triggering deliberations about Section 301 measures.” This refers to the US’ annual reports identifying trade barriers (including IP laws) to US companies. Both the US Chamber of Commerce (which co-commissioned the Pugatch report with AbbVie) and PhRMA (EFPIA’s sister US group) lobbied the US to include the EU in its IP ‘Watch List’ over the pharma incentives review and SPC manufacturing waiver. The US Chamber warned that these “IP-degrading initiatives” could trigger “a race to the bottom in weakening global IP standards”.¹¹⁰ PhRMA meanwhile asked the US to “seek assurances” that the incentives review “will not result in measures to weaken” IP. And it seems they were successful at getting the US to stick its oar in. In October 2018, Brussels’ news outlets reported that the “U.S. Permanent Mission to the EU is holding a meeting with EU officials and IP attachés” to discuss the Commission’s SPC manufacturing waiver proposal, under the Chatham House Rule (meaning that no information on who said what can be reported publicly).¹¹¹

'It is incompatible with 'Better Regulation': EFPIA, INFARMA and G+, representing AbbVie, all invoked the Commission's big business-friendly and deregulatory so-called 'Better Regulation' agenda in their arguments.¹¹² EUCOPE went further, sending the Commission a document setting out "10 principles of Better Regulation the Commission has failed to respect".¹¹³ These include not considering "an industry self-regulation model", the benefits of which are "explicitly recognised" in the Commission's Better Regulation Toolbox.

'It ignores the benefits of self-regulation': EUCOPE urged the Commission to consider "successful voluntary industry agreements that achieve equal aims".¹¹⁴ By failing to do so, it argued, "the Commission is undermining the very credibility of its actions." A bold claim, given that Parliament had mandated the Commission to legislate for an SPC manufacturing waiver! LIF also berated the Commission for omitting "less intrusive mechanisms" like "soft-law" in its consultation.

'It will have dire effects... according to industry-funded studies': G+, on behalf of AbbVie (which co-commissioned the Pugatch study with Roche), sent the Commission materials full of references to Big Pharma-funded studies about how bad an SPC manufacturing waiver would be, including the Pugatch and EFPIA-QuintilesIMS studies.¹¹⁵ AmCham EU and ICBA referred to the Pugatch study as disproving its benefits,¹¹⁶ and EBE – in which AbbVie and Roche both hold important positions – also cited it.¹¹⁷ Meanwhile, when lobbying the US to intervene, PhRMA cited the Pugatch and EFPIA-OHE studies, plus a study commissioned by EuropaBio,¹¹⁸ as "debunking" the "belief" that an SPC manufacturing waiver would level the playing field for generics.¹¹⁹

'It's an unnecessary concession to a thriving generics industry': G+, on behalf of AbbVie, told the Commission that "there is no market failure" as the generics industry is thriving, a sentiment echoed by EBE. ICBA said an SPC manufacturing waiver would "favour of IP-infringing copycat products".¹²⁰ EUCOPE meanwhile berated the Commission for the "undue rush" between the public consultation and the proposal, implying the "evidence-light and politically driven" proposal was a "foregone conclusion" thanks to "a well-orchestrated campaign from the generic industry".¹²¹

Generic industry's wins and losses

Throughout the process, the generics industry lobbied intensely for the waiver, which is in its commercial interests.¹²² When the US got involved the EU lobby group for the generics industry, Medicines for Europe, responded by accusing it of "interfering in an EU domestic policy matter by trying to manipulate and influence the current debate" and to "convey the position of the US commercial bodies".¹²³ Medicines for Europe fought tirelessly for an SPC manufacturing waiver with provisions to stockpile for 'day-one' market entry, but they also made it clear they were not challenging the legitimacy of SPCs.¹²⁴ When the Commission's proposal did not include 'day-one entry', and delayed the date it would take effect for 10-15 years, Medicines for Europe – complaining that it would "not have any positive impact" as it would "hardly be used"¹²⁵ – were told by DG Sante that the proposal was "a reflection of different interests".¹²⁶ So Big Pharma's ferocious lobbying – including

growing pressure from increasingly mobilising US lobby groups¹²⁷ – *did* yield significant successes – though it did not derail the waiver altogether.¹²⁸

Big Pharma's fear-mongering narrows the scope for change

Despite Big Pharma's efforts, the European Parliament suggested amendments to the Commission's proposal that included stockpiling provisions. However negotiations with the Council diluted the period that these would apply, and brought changes that may pave the way for more litigation from Big Pharma towards generics firms.¹²⁹ But the February 2019 agreement on the draft SPC manufacturing waiver nonetheless seems to represent a 'win' for the generics industry and a 'loss' for Big Pharma. Certainly EFPIA complained the manufacturing waiver was a "gamble" that would turn Europe from "a knowledge-based region at the cutting edge of research, development and medical innovation to a Europe that is not competitive on the global R&D stage and fails to attract future investments".¹³⁰ Yet it is exactly this impression – that the SPC manufacturing waiver is a huge loss for Big Pharma – that is problematic. Big Pharma's tirade of lobbying and fear-mongering has depicted it as a massive industry setback, when in reality, it does not even reduce the period of monopoly protection.¹³¹ Yet Big Pharma's exaggerated 'sky-is-falling' message has narrowed the scope for real change of the current paradigm, which is designed to serve the interests of big companies' shareholders, to one that has access to new, better, and needed medicines at its heart. By fighting so hard against such a small reform, Big Pharma has deflected from the deeper issues at stake, and attempted to constrict the political space for debate.

This is illustrated by the way the Commission rushed to reassure the SPC manufacturing waiver's detractors. DG Grow reassured its critics that the "EU is actively trying to convince its trade partners... to upgrade or introduce IPR regimes similar to our own, including as regards SPC-like protection, something we recently succeeded in achieving in Canada".¹³² It also said the Commission was taking into account Big Pharma-funded studies,¹³³ and "by no means" intends to "weaken the exclusive rights that SPC holders enjoy in respect of the marketing of innovative medicines in the EU".¹³⁴ It is only the "unintended side effects" on the generics industry's global competitiveness that the waiver is intended to address. A narrow ambition indeed, from the perspective of public health and access to medicines. Yet, it seems clear that the Commission – despite being told by the Council that the whole edifice of pharmaceutical incentives and rewards needs reviewing – "remains fully committed to strong IPR and SPC protection and enforcement, both in the Single Market and in third countries".¹³⁵

All of this leaves us to wonder whether Big Pharma, far from bemoaning the SPC manufacturing waiver, is in fact congratulating itself for so far stemming the tide of more transformative change. For the sake of public health, it is vital that policy-makers, particularly the upcoming new Parliament and Commission, do not consider this minor tweak to a patent extension a sufficient follow up to the ground-breaking Dutch Council conclusions. A continued critical conversation, with scope for real, public-interest, regulatory changes, is urgently needed. (See Chapter 7 for further recommendations).

Chapter 5. EU HTA proposal: the need to safeguard against industry influence

A gatekeeper against high-priced drugs

A Health Technology Assessment (HTA) is the scientific analysis of the added therapeutic value of a new treatment. Put simply, HTA looks at whether a new drug or treatment is better, the same as, or worse than existing alternatives. Drug companies promote the use of new drugs that are covered by patent protection, over old ones that aren't, even if the new product is no better than existing ones. HTAs therefore help to indicate whether a new drug justifies the (often very high) price being asked for it.

With constraints on public spending and growing concerns over the sustainability of public healthcare systems, HTAs play a crucial role. They feed into national health systems' decisions about what price they are willing to pay for a new medicine being promoted by a pharmaceutical firm, and about which medicines should be reimbursed (and therefore made available to patients) under their national health systems. As more medicines without added therapeutic value (ie 'new' but not meaningful improvements on existing treatments, yet expensive thanks to being under patent) enter the market, HTA has grown in importance as a gatekeeper to protect public-interest public spending. It is a crucial part of the access to medicines debate in Europe.

Pricing and reimbursement decisions (including negotiations with companies over price) are taken by member states, and are a fiercely defended national competence. Yet the secrecy around them, and often the lack of good evidence available to health ministries (and other payers such as social healthcare insurers) about the benefits – or lack thereof – of a new drug, gives Big Pharma companies a lot of leverage. It becomes all too easy to rip governments off. However, with strong assessments of a new treatment's effectiveness relative to those already available – in other words, robust and independent HTA – governments are in a stronger position to negotiate. This can help curb Big Pharma's excessive power to secure sky-high and often unjustified prices.

Cooperation to ensure robust and independent assessments

Up till now, HTA has been conducted at national (or regional) level, but in January 2018 the Commission made a very open-ended legislative proposal for an EU-wide regulation on HTA.¹³⁶ Prior to this the EU had supported voluntary cooperation on HTA, for well over a decade (the EUNetHTA Joint Action¹³⁷). Low uptake of joint assessments at national level however meant the network's effectiveness remained limited. In addition, even after years of voluntary cooperation, differences in HTA capacity amongst Member States remained stark. The Commission's proposal, despite shortcomings, was intended to respond to this situation.¹³⁸ As the European Public Health Alliance notes, EU collaboration on HTA, if well-designed, could be a "powerful weapon to reduce inequalities and improve access". But if joint-EU HTA were too friendly to industry-interests – as is the case with the European Medicines Agency (see Box 3) – there is also a risk that rather than improve capacity it

could actually lead to “convergence towards the lowest common denominator in clinical assessments”.¹³⁹ Looking at the corporate lobbying towards the Commission around this file, we see that industry infiltration of the HTA process – with more control over what goes in and what comes out – has been central to the Big Pharma lobby’s wish-list. But all is not lost: despite considerable success with the Commission, the pharma lobby had a tougher time with the European Parliament, which strengthened the public interest aspects of the proposal.

Currently the proposal remains tied up in the Council. As member states debate thorny issues, a common position that it can take to negotiations with Commission and Parliament seems far off, leaving the fate of the HTA proposal uncertain, including whether and in what form it will survive with a new Parliament and Commission. Given the important role that EU collaboration on HTA could play in helping member states safeguard their public health systems from unjustified high-price medicines, we encourage the EU institutions to continue to work towards agreement. We need European cooperation that helps ensure robust and independent HTAs, that improves on the Commission’s proposal, and that resists industry pressure for undue influence over the process.

Box 3. The European Medicines Agency: Lessons for EU HTA

HTA has increasingly been seen as a way to deal with problems caused by an inadequately functioning and industry-friendly European Medicines Agency (EMA). More and more drugs are being approved by the EMA with low or uncertain value, as documented by *Prescrire*,¹⁴⁰ based on premature data or a weak evidence base. For example, between 2009 and 2013 the EMA authorised new cancer drugs in most cases without clear evidence that they improved patients’ quality of life and their life expectancy.¹⁴¹ HTA can help respond to this “weak evidence-high prices conundrum” believes EPHA, but only if “HTA itself does not become subordinated to the EMA”.¹⁴² Subordinated to, or modelled on, since the EMA is a regulatory agency with a too-close relationship with the industry it is supposed to regulate. This is due to the revolving door between regulator and regulated, dependence on industry funding, and an institutional culture that sees the pharma industry as its partner or even client. This isn’t helped by the weak interpretation of conflict of interest rules, which the EMA renamed “competing interests” in 2017, replacing “terminology such as conflict, risks, etc” with “more neutral language”, in order to “address the perception issue”.¹⁴³

Revolving door: The EMA has a well-established revolving door with Big Pharma.¹⁴⁴ For example, the EMA’s Head of Legal Affairs Stefano Marino joined after two decades in the pharma industry. EMA’s former Legal Head Vincenzo Salvatore joined the ‘European life sciences regulatory practice’ of law firm Sidley Austin LLP. After leaving his job overseeing medicines’ safety and efficacy at EMA, Xavier Luria became a consultant for the pharmaceutical sector. EMA’s ex-Director Thomas Lönngren went on to set up Pharma Executive Consulting Ltd.¹⁴⁵ These appointments reflect lack of stringency in EMA conflicts of interest rules and risk blurring the interests of regulator and regulated, which are fundamentally different: the industry being regulated seeks to maximise its profits, but the job of the regulator is to safeguard public health, by ensuring strict safety and efficacy conditions are met before a drug can be sold in the EU.

Reliance on industry experts, funding and data: As of December 2017 nearly one thousand of EMA's European experts have direct or indirect interests in the pharmaceutical industry.¹⁴⁶ Direct interests include financial interests or employment with, consultancy to, or a strategic advisory role for a company. And even indirect interests – which include being an Investigator or Principal investigator (in an industry instigated/ sponsored clinical trial), or organisational grants or funding from the pharma industry – are rather direct!¹⁴⁷ EMA is also reliant on the pharmaceutical industry for its funding (for example, through fees for giving scientific advice), and reliant on clinical trials data provided by the industry, which it doesn't have the means to verify. All these things contribute towards a power imbalance in favour of Big Pharma. The EMA at times has been too willing to serve or capitulate to the industry's interests. When the EMA made moves towards greater clinical trials data transparency, for example, the then-president of EFPIA (and Chief Executive of Sanofi) warned this would discourage critical investment in crisis-hit Europe, and threatened that Sanofi's "next euro of investment would go to the United States or to emerging markets."¹⁴⁸ Following this, and other industry pressure (including a lawsuit by AbbVie, ending in a deal over access to clinical study reports about their drug Humira)¹⁴⁹, the EMA backtracked, shifting to a more restrictive transparency approach that raised concerns with the European Ombudsman, payers, and civil society.¹⁵⁰ Although there have subsequently been some welcome developments in this area (with, for example, the EMA starting to publish clinical reports for new medicines, the first regulator to routinely do so), there is still much to improve.¹⁵¹

Corporate influence: Industry often appears to be overwhelmingly represented at EMA's events. In October 2018 EMA held a 'multi-stakeholder workshop' to launch a consultation on regulatory science:¹⁵² EFPIA sat on five out of six panel sessions. The dominance of industry (or industry-funded) groups (including EFPIA, EBE, VaccinesEurope, EuropaBio, EUCOPE, and MedTechEurope) was combined with the absence of consumer or public health groups.¹⁵³ The organising committee for this workshop included EMA's Head of Human Medicines R&D Support, who came to EMA from a long career at Merck-Serono (whose Chief Executive is President of EFPIA),¹⁵⁴ while EMA's 'Industry Stakeholders' Liaison was formerly a Senior Regulatory Affairs executive at Pfizer.¹⁵⁵ In recent years, the EMA has held annual meetings with industry groups like EFPIA and EuropaBio, covering topics such as HTA and early-stage "multi-stakeholder engagement".¹⁵⁶ It also produces annual reports on EMA's interaction with industry, which, ironically, are "not intended to provide a comprehensive overview of all contacts".¹⁵⁷ One such reveals that 51 per cent of all EMA stakeholder events in 2017 were industry only, and of the 39% multi-stakeholder events, industry participated in 83%.¹⁵⁸

Ombudsman's concerns over industry influence: In July 2017 the European Ombudsman opened a strategic inquiry into EMA's pre-submission activities. The utter lack of transparency around the EMA's early dialogues with, and scientific advice given to, industry led the Ombudsman to conclude that "there is a risk that the eventual decisions by EMA on the authorisation of medicines may be influenced – or be reasonably perceived to be influenced – by what has been discussed during the meetings with medicine developers prior to receiving their formal submission".¹⁵⁹ The inquiry is ongoing, with results expected in 2019.

All in all, the EMA's industry-friendly ecosystem offers warnings for what the proposed joint EU HTA must avoid. It shows why clear, enforceable rules on independence, conflict of interests, transparency, and public funding are vital from the outset. Yet the pharmaceutical industry has been eager to promote the EMA as a model for EU HTA. EFPIA told the Commission the EMA is "a good model for a successful and scientifically based secretarial/organization support".¹⁶⁰ EUCOPE lobbied to grant "a more prominent role to the EMA" to ensure "joint HTA work is well-integrated with the existing regulatory framework".¹⁶¹ This is hardly surprising, given the "ever-closer partnership" Big Pharma has with EMA, but as EPHA notes, allowing EU HTA to "become a subdivision of the EMA" would lead to "an excessive concentration of power" and undercut HTA's potential to mitigate problems caused by the EMA's approvals.¹⁶² Thankfully, there is little appetite in the Council for this. As for the EMA itself, "a mindset shift is necessary – one that treats pharmaceutical companies as a business sector in need of regulation and not as clients or partners, as they are currently viewed."¹⁶³ And this is a lesson that joint EU HTA must learn, in order to be a successful gatekeeper against high-priced medicines of questionable therapeutic value.

Industry singled out for special input

Big Pharma had a big presence in the Commission's preparatory phase for the HTA regulation. Individual companies like Sanofi and Lilly lobbied DG Sante,¹⁶⁴ whilst a Commission focus group with pharma companies including Johnson & Johnson, Pfizer, and Lilly, makes it clear that Big Pharma anticipates EU HTA could mean lower standards of evidence than those they are currently required to provide in some member states.¹⁶⁵

This lends credence to fears that a mandatory EU HTA system – if overly-influenced by industry-interests – could actually weaken the gatekeeper role played by the most robust national HTA bodies. Given this, it was worrying that Commission invitations to HTA stakeholder meetings placed more emphasis on industry's input than on that of patients/consumers. Only letters to industry stakeholders contained this addition (in bold):

It is my utmost priority to meet all stakeholders organised at EU level, to hear your views on the matter and discuss this proposal with each of you, **in particular issues regarding the production of joint clinical assessments (process and outcomes) and the governance, including the involvement of stakeholders.**¹⁶⁶

It is of great concern that the Commission appears to have wanted to speak only to the pharma/med tech industry about the "involvement of stakeholders" in the governance of European HTA!

Industry infiltration of HTA process

EFPIA also lobbied the Commission over its HTA proposal, with indications of a close and cooperative relationship: for example, an email from EFPIA shared the "first batch of compromises" from the Parliament's ENVI committee with the Commission.¹⁶⁷ In addition there was an invitation to DG Sante to join an EFPIA board meeting and "engage at the level of senior leaders of our industry, in particular

regarding next steps in the legislative process and the role industry should play moving forward”, which was welcomed by DG Sante as “a very good idea”.¹⁶⁸ Once the Commission’s proposal was out, EFPIA lobbied for assessments to be based on a “submission dossier” from the industry, warning that without this, “HTA bodies would compile the evidence and assess it without any input from the companies”. In other words, they want a greater role for companies on what they are assessed over, giving industry more control.¹⁶⁹ And whilst EFPIA welcomed the Commission’s proposal, it also pushed for the “inclusion of a scoping meeting,” for companies to “carry out a 'fact checking' of the final report”, and for stakeholder involvement to include industry.¹⁷⁰ This is all about giving industry more control over what goes in to and what comes out of the HTA process.

Attempt to extract the teeth from the proposal

In a meeting with DG Sante, “EFPIA expressed serious concern about the terminology ‘Relative effectiveness assessment’”. The pharma lobby group’s argument was that HTAs ‘mainly’ use evidence from clinical trials, which relate to a medicine’s efficacy (ie whether a drug produces the results expected in a lab setting), not its effectiveness (ie the degree of benefit a drug has in more normal clinical settings).¹⁷¹ This might sound technical, but a lot is at stake with this argument. The rationale of HTAs is to assess whether a treatment is more or less effective than other available treatments. It is precisely the *relative* effectiveness – this aspect of *comparative* evaluation – which is the whole point of HTA, in order to help governments decide what is worth paying for. So in contrast to EFPIA’s argument, it is not enough to only have data on a drug’s efficacy compared to, for example, a placebo it was tested against in a lab (ie in a non-comparative clinical trial).

EFPIA’s explicit demands echoed by US business lobby

EFPIA also sent the Commission a “technical” position paper setting out its article-by-article demands,¹⁷² which is longer and more explicit than its publicly available HTA position paper.¹⁷³ This paper pushes for important details of how the EU HTA would function not to be written into the law, but rather to be left until afterwards to be developed, in EFPIA’s words, “between all stakeholders”, essentially leaving the door open for the industry to influence the details. It talks of “the necessity of a scoping meeting”, of protecting all “confidential data”, and for industry to be responsible for “managing the exchange” between joint HTA and the EMA. Unlike its public paper, which says only there should be “clear rules” for determining stakeholders, EFPIA’s non-public paper says they should “explicitly” include “the health technology developers of the medicinal products” in the preparation of assessments.¹⁷⁴ Many of EFPIA’s messages were mirrored by AmCham EU, whose members include many Big Pharma companies.¹⁷⁵ The Commission promised to read AmCham EU’s position paper “with great interest”.¹⁷⁶ It also asked for “formalised stakeholder input” with “health technology developers”, emphasised the importance of confidentiality, pushed for a “scoping meeting”, and for an “appeal mechanism” to challenge decisions. In other words, both EFPIA and AmCham EU want an EU HTA system that is as porous to industry’s influence, and as difficult to audit, as possible,¹⁷⁷ to prevent it from being an effective gatekeeper against high-priced medicines.

Industry wants less oversight of most expensive medicines

Another demand from industry actors such as EUCOPE, EuropaBio, and US biotech firm Biogen was that orphan drugs for rare diseases get special (more 'flexible') treatment in HTA.¹⁷⁸ The misuse of the orphan drugs regulation (which gives faster market access with less stringent evidence requirements at the EMA) is of major concern (see Box 1). Demands from industry that may be intended to weaken the assessment of orphan drugs' effectiveness relative to other treatments are, therefore, also a concern for access to affordable and effective medicines. And it seems likely the lobbying did not stop at the Commission, given that the Parliament added amendments which focused on orphan drug specificities. This caused *Prescrire* to flag concerns that it must not risk paving the way for orphan drug HTAs to be dealt with by the more industry-friendly EMA (see Box 3).¹⁷⁹

Revolving door-lobby firm running 'stakeholder' roundtables

Notably, DG Sante presented its HTA proposal at an event organised by lobby firm Fipra.¹⁸⁰ This was followed-up with two more Fipra 'stakeholder roundtables' in June 2018, also attended by Sante officials. The first was sponsored by EFPIA, Pfizer, Amgen, and Roche,¹⁸¹ and the second by EFPIA, EUCOPE, EuropaBio (and several of their corporate members).¹⁸² The latter focused on HTA of treatments for rare diseases, and noted that the Commission had been lobbied "to consider methodological flexibility for rare conditions in HTA".¹⁸³ It is astonishing that these 'stakeholder' roundtables (which don't appear to include any consumer or public health groups) on these subjects have been *de facto* privatised into Big Pharma's hands via a consultancy firm. And not just any consultancy firm; Fipra's clients include EFPIA, EuropaBio, Pfizer, Amgen, Novartis, and many other pharma companies.¹⁸⁴ Fipra's Chair, Robert Madelin, meanwhile, came through the revolving door after 12 years in "senior leadership" positions at the Commission, including as Director General for Health and Consumer Policy.¹⁸⁵

MedTech lobby keen to avoid stricter oversight

The medical technology industry has been one of the most vociferous in lobbying the Commission,¹⁸⁶ in particular EU trade association MedTech Europe.¹⁸⁷ The International Consortium of Investigative Journalists (ICIJ) has exposed how inadequately tested medical devices, thanks to insufficient regulatory oversight, have caused harm - , including injuries and deaths - to patients across the globe.¹⁸⁸ ICIJ warns that the industry is pushing for speedier regulatory approvals, which go hand in hand with demands for lower evidence thresholds.

In line with this, the med tech industry has lobbied for medical technology to be treated differently in EU HTA (either by not being included, being voluntary, or facing different assessment conditions) and for 'stakeholder' ie industry involvement in the details of how the regulation will be implemented. MedTechEurope sent DG Sante a confidential article-by-article "Input for consideration to strengthen the proposal".¹⁸⁹ They also admitted that its fingerprints were recognisable in DG Sante's proposal, which "reflect[s] some of the points made by MedTechEurope", particularly "the differentiation between

pharma and medical devices”.¹⁹⁰ COCIR, another med tech lobby,¹⁹¹ also said “the majority” of its concerns had been considered in the proposal, and sent further proposed amendments to the Parliament’s responsible committees.¹⁹² Prior to the inter-service consultation between all Commission directorates, the med tech industry also lobbied DG Grow,¹⁹³ warning that DG Sante’s plans “might block innovation” and “create additional burden” to industry.¹⁹⁴ The European Consumer Organisation (BEUC), on the other hand, argued that medical devices need strong HTA, as they have “huge significance for consumers’ lives, as well as healthcare budgets”.¹⁹⁵ Patients group EPF also called for their inclusion.¹⁹⁶

Industry gains and loses ground

Industry won a number of its asks from the Commission, whose proposal for a HTA regulation left so many core aspects and important details about the set-up, methods and processes of joint EU HTA to be decided at a later date, that it has been likened to being asked to sign a contract blindfolded. By leaving the details to be sorted out in implementing acts (which enable the Commission to clarify how the regulation shall be implemented), the door is left wide open for industry to influence the details to reflect their interests (this is why this was one of their key demands). In contrast, BEUC argued that “[p]rocedural rules for ensuring the independence and transparency of HTA processes should be included in the Regulation and not be relegated to implementing acts.”¹⁹⁷ Other issues with the proposal (or wins for the industry) included not stringent enough requirements to provide all evidence (ie all data from all trials) and the absence of explicit conflicts of interest rules. The association of non-profit healthcare payers, AIM, also expressed their concern at the Commission’s proposal for HTA funding to come in part from industry fees, as it could “lead to conflicts of interest”.¹⁹⁸

Fortunately MEPs strengthened the Commission’s proposal, adding improvements in transparency, independence, governance, and standards.¹⁹⁹ As *Prescrire* notes, the Parliament called for EU HTA to require comparative trials, public (not industry) funding, and guarantee the highest quality standards (rather than the lowest common denominator).²⁰⁰ Health Action International also welcomed the transparency requirement that scientific consultation reports on health technologies that have undergone joint clinical assessments should be made public (which relates to the Ombudsman’s investigation of the EMA – see Box 3).²⁰¹

It wasn’t only public health groups who were pleased with MEPs’ improvements: the European Social Insurance Platform (ESIP), which represents public health care payers, also welcomed provisions for broader public access to information, as well as for a mechanism to require companies to provide information in cases of non-compliance.²⁰² To EFPIA’s disappointment, MEPs did not pick up its proposal for “scoping meetings” with companies, which it lamented as “a lost opportunity for the health technology developer to... jointly define the scope of the assessment and the evidence to be submitted”.²⁰³ In other words, a lost opportunity for companies to have more sway over the assessment. Not everything was rosy however, as MEPs also added in more protections for “commercially sensitive data”, and capitulated to industry wishes for a “less rigorous approach for

medicines which treat rare diseases”, even though these, as BEUC points out, “are precisely the drugs which can be the most expensive and which need the most investigation”.²⁰⁴

Tricky talks in Council leave EU HTA with uncertain fate

The picture is more complicated in the Council, where member states’ health ministers must negotiate and agree a compromise. Some – particularly those with stronger national HTA systems – are concerned an EU HTA might erode their standards. Mandatory participation and uptake of EU HTA therefore crosses their red lines. Many are unwilling to see the freedom over reimbursement choices of their health ministries and payers limited in any way (by a weak *or* by a strong EU HTA – as not all member states are keen to have strong, independent HTA). Big Pharma meanwhile, as EPHA notes, is already “used to doing business with the current fragmented European HTA landscape”,²⁰⁵ and is not unhappy with the status quo (though it is clear from its lobbying that it would be delighted to get an industry-porous EU HTA, similar to the EMA). Discussions are still with the Council but agreement is not expected any time soon.²⁰⁶ And with both a new Parliament and a new Commission arriving in 2019, the fate of Joint EU HTA – whether as an independent and strong gatekeeper against Big Pharma’s high prices, or as a one-stop-shop for Big Pharma’s influence, or even as a proposal that gets buried by new political dynamics – is uncertain.²⁰⁷

EU cooperation on robust and independent HTA could help member states curb high prices

One thing is clear: member states have serious and legitimate concerns about extremely high-priced medicines. Whilst it is true that a ‘bad’ EU-wide HTA – based on poor methodology/lack of comparative data, and that too easily gives a positive assessment – could hamstring decision-makers in pricing and reimbursement decisions, putting further pressure on public spending, it is also true that ‘good’ EU HTA – strong, independent assessments based on good, comparative data and all relevant evidence – can empower national authorities to make sound pricing and reimbursement decisions. This would help to improve access to better and more affordable medicines, and provide doctors and patients with the evidence they need to discuss which therapy would be better for which patient. The devil may all be in the details. But the details add up to fundamentally different choices. And rather than letting EU collaboration on HTA fizzle out, the new Parliament and Commission, as well as the ministers negotiating in the Council, should recognise the important role of EU-level cooperation on HTA in enabling member states to curb high prices, providing it reflects the choice for robust, independent, and transparent joint assessments.

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.²⁰⁸ 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.”²⁰⁹ 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.²¹⁰ 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”.²¹¹ 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 to continue to work towards an agreement that ensures strong, independent assessments based on good, comparative data.²¹²
- **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.

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