

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

### 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.<sup>1</sup> 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,<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> It made wildly optimistic predictions that relied on models using overly-simplistic and ideology-driven assumptions.<sup>5</sup> 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.<sup>6</sup> The consultancy boasts that it "has extensive experience performing economic analyses and providing advice" to "numerous" pharma clients,<sup>7</sup> including helping with "Design and Advocacy", and producing materials to be used "in their dialogue with" ministries.<sup>8</sup> 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,<sup>9</sup> 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".<sup>10</sup> 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.<sup>11</sup>

### **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",<sup>12</sup> 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).<sup>13</sup> Out of the 20 interviewees, there are just three 'Other experts' representing non-industry interests.<sup>14</sup>

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".<sup>15</sup> 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)<sup>16</sup> said was "one of the most heavily lobbied items in Brussels".<sup>17</sup>

### **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.<sup>18</sup> 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”.<sup>19</sup> 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.<sup>20</sup> 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.<sup>21</sup>

### **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”.<sup>22</sup> 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.<sup>23</sup> 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.

- 1 DG Grow, Contract notice, [http://ec.europa.eu/Growth/content/study-economic-impact-supplementary-protection-certificates-pharmaceutical-incentives-and-0\\_en](http://ec.europa.eu/Growth/content/study-economic-impact-supplementary-protection-certificates-pharmaceutical-incentives-and-0_en)
- 2 Copenhagen Economics was awarded the study by the European Commission in April 2017: see <https://www.copenhageneconomics.com/publications/publication/study-on-the-economic-impact-of-supplementary-protection-certificates-pharmaceutical-incentives-and-rewards-in-europe>
- 3 CEO, Policy Prescriptions, *ibid.* Copenhagen Economics, How A Strong Pharmaceutical Chapter in TTIP Will Benefit the EU, May 2016, <https://www.copenhageneconomics.com/dyn/resources/Publication/publicationPDF/3/353/1464075718/how-a-strong-pharmaceutical-chapter-in-ttip-will-benefit-the-eu-policy-brief.pdf> and <http://www.efpia.eu/uploads/Modules/Documents/2188-02-efpia-ttip-study-23may2016.pdf>
- 4 EFPIA, TTIP Report Study Highlights the Positive Benefits of Ambitious Pharmaceutical Provisions in the Proposed Agreement for Europe's Economy and Society, 24/05/16, <http://www.efpia.eu/mediaroom/332/43/TTIP-Report-Study-Highlights-the-Positive-Benefits-of-Ambitious-Pharmaceutical-Provisions-in-the-Proposed-Agreement-for-Europe-s-Economy-and-Society>
- 5 Copenhagen Economics-EFPIA TTIP study extrapolated from figures in earlier study by CEPR (see [https://www.efpia.eu/media/25874/how\\_a\\_strong\\_pharmaceutical\\_chapter\\_in\\_ttip\\_will\\_benefit\\_the\\_eu\\_policy\\_brief.pdf](https://www.efpia.eu/media/25874/how_a_strong_pharmaceutical_chapter_in_ttip_will_benefit_the_eu_policy_brief.pdf)) which used computable general equilibrium (CGE) – for critique of assumptions and CGE see eg Ferdi De Ville & Gabriel Siles-Brugge (2015), The Transatlantic Trade and Investment Partnership and the Role of Computable General Equilibrium Modelling: An Exercise in 'Managing Fictional Expectations', *New Political Economy*, 2015, Vol. 20, No. 5, 653 – 678, <http://www.tandfonline.com/doi/pdf/10.1080/13563467.2014.983059> and Friends of the Earth, Briefing, The Transatlantic Trade and Investment Partnership (TTIP), November 2015, <https://www.foe.co.uk/sites/default/files/downloads/briefing-transatlantic-trade-investment-partnership-91913.pdf>
- 6 Copenhagen Economics, The Danish pharmaceutical industry and TTIP, <https://www.copenhageneconomics.com/publications/publication/the-danish-pharmaceutical-industry-and-ttip>
- 7 See eg Copenhagen Economics <https://www.copenhageneconomics.com/publications/publication/the-value-of-clinical-trials-in-denmark> and <https://www.copenhageneconomics.com/news/313/new-study-danish-fertility-industry-is-big-business>
- 8 Copenhagen Economics, Healthcare & Life Sciences, <https://www.copenhageneconomics.com/services/healthcare-life-sciences>
- 9 Copenhagen Economics, Christian Jervelund, <https://www.copenhageneconomics.com/our-experts/expert/christian-jervelund>
- 10 Copenhagen Economics, Kristoffer Jensen, <https://www.copenhageneconomics.com/our-experts/expert/kristoffer-jensen> [Linked-in](#), [Linked-in, Kristoffer Jensen, https://www.linkedin.com/in/kristoffer-jensen-90a1977/?originalSubdomain=dk](https://www.linkedin.com/in/kristoffer-jensen-90a1977/?originalSubdomain=dk)
- 11 DG Grow also commissioned a related study, on the economic impacts of possible SPC exemptions, from another consultancy that regularly works for Big Pharma: Charles River Associates (CRA), which has "long standing relationships with most leading pharma organisations" including EFPIA and its US counterpart PhRMA (see <http://www.crai.co.uk/industry/life-sciences>). Through its economic assessment of possible changes to patent protections, CRA helped the Commission narrow down from more radical policy options to merely an SPC manufacturing waiver. (CRA concluded a waiver would have positive benefits for Europe, as increased export sales for the generics industry outweigh negative impact on the branded pharma industry - see <https://publications.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en>
- 12 Copenhagen Economics, Study on the economic impact of SPCs, pharmaceutical incentives and rewards in Europe, <https://www.copenhageneconomics.com/dyn/resources/Publication/publicationPDF/5/445/1527517171/copenhagen-economics-2018-study-on-the-economic-impact-of-spcs-pharmaceutical-incentives-and-rewards-in-europe.pdf> The study also says "all input, including comments and relevant studies provided by Member States and other stakeholders have been considered by Copenhagen Economics".
- 13 Eurordis' top five donors in 2017 were Pfizer and Shire (each €130,000), Celgene (€100,000), Vertex (€90,000) and Novartis (€80,000). Eurordis, Financial Information, <https://www.eurordis.org/financial-information-and-funding> and <https://www.eurordis.org/financial-information-and-funding#tabs-4>
- 14 Bangor University's Centre for Health Economics & Medicines Evaluation, Medicines Law & Policy, and Harvard University
- 15 European Commission, Call for tender: Study on the economic impact of SPCs, pharmaceutical incentives and rewards in Europe, Technical specifications, p.25, <https://etendering.ted.europa.eu/cft/cft-document.html?docid=21827>
- 16 Transparency Register, Hanover Communications, <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=712987314570-57> last modified on: 24/09/2018
- 17 Hanover Communications, Is the EU in danger of undermining medicines investment in Europe? 22/06/17, <https://www.hanovercomms.com/2017/06/22/is-the-eu-in-danger-of-undermining-investment-in-the-development-of-new-medicinal-products-in-europe/>
- 18 Documents released from DG Grow (hereafter 'Grow docs'), FW: Case Studies \_ IP incentives \_ EuropaBio, 07-0817
- 19 Reply from DG Grow to access to document request, <https://www.asktheeu.org/en/request/6012/response/20225/attach/3/Reply%20GESTDEM%202018%205805.pdf>
- 20 See replies to request GestDem 2018/5864, [https://www.asktheeu.org/en/request/dg\\_Sante\\_contacts\\_re\\_pharma\\_ince](https://www.asktheeu.org/en/request/dg_Sante_contacts_re_pharma_ince) for documents quoted from in this paragraph.
- 21 Namely, Medicines Law & Policy, and Centre for Health Economics & Medicines Evaluation.
- 22 Copenhagen Economics, Pharma incentives study *ibid.*
- 23 Articles published in *Prescrire International* between 2004 and 2017; see also, *Prescrire* (2016) New drugs, new indications in 2015: little progress, and threats to access to quality healthcare for all, [english.prescrire.org/en/3D3B93E1C3DE20A599FBA073C5442463/Download.aspx](http://english.prescrire.org/en/3D3B93E1C3DE20A599FBA073C5442463/Download.aspx)