

# IN THE NAME OF INNOVATION

INDUSTRY CONTROLS BILLIONS IN EU RESEARCH FUNDING, DE-PRIORITISES THE PUBLIC INTEREST

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REPORT 1 (OF 2)

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**More private than public:**  
the ways Big Pharma  
dominates the Innovative  
Medicines Initiative



Corporate  
Europe  
Observatory

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# Contents

Introduction	3
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## **PART 1 – IMI: diverting public funds for commercial purposes?**

1. Is IMI fulfilling its mandate and adding value?	5
a) The myth of tackling market failures	5
b) Public subsidies for industry’s pre-existing R&I strategies	7
2. IMI’s research priorities: addressing priority health needs?	9
a) How does IMI live up to the WHO list of priority research areas?	9
b) IMI’s late Ebola investments	13
3. IMI’s impact: equal benefits to society?	16
a) Missing accountability mechanisms	16
b) Evaluations show lack of impact for patients and society	18
c) No concrete evidence on economic benefits	19
d) A bias towards big partners and corporations	20
4. Under the spotlight: IMI projects with questionable public interest	23
a) IMI projects give industry opportunities to directly lobby regulators	23
b) IMI project gives industry direct opportunity to lobby patients	27
c) Pharma dominates agenda setting and sidelines public partners in Anti-Microbial Resistance projects	29
d) IMI: improving access to medicines or entrenching a system with skyrocketing medicines’ prices?	35
e) Big decisions over health data behind IMI’s closed doors	40

## **PART 2 How and why was the public interest sidelined?**

1. Incoherent public and private goals on a collision course	44
2. Private interests dominate IMI governance structures	45
a) Imbalance of private over public in IMI’s Governing Board	45
b) Is the European Commission defending the public interest in IMI?	47
3. Big Pharma dominates in IMI’s agenda-setting processes	50
a) Industry dominates IMI Strategic Research Agenda, work programmes, calls, and topics...	51
b) ...An imbalance that the IMI’s Scientific Committee does little to correct	52
c) Civil society missing in action	53
4. IMI decision-making a black box	54
5. Accountability: a litany of problems with industry in-kind funding	56

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<b>Conclusions</b>	58
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## **Recommendations**

1. GOVERNANCE that ensures less industry dominance and more public ownership	63
2. AGENDA-SETTING that responds to a needs-driven research agenda	64
3. ACCOUNTABILITY to ensure impact for society	64

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# Introduction

The European Union's Research and Innovation policy (R&I) is one of the key areas that can help us deliver both a better future for EU citizens and meet our international commitments, especially the UN's Sustainable Development Goals. R&I is integral to addressing the many challenges faced by society, whether in health and wellbeing, food and farming systems, climate change, energy, or democracy and digitalization.

The European Commission sees the R&I policy as a core tool to “help create growth and jobs and tackle our biggest societal challenges”.<sup>1</sup> To help achieve these policy objectives, the Commission, among others, has established partnerships with the private sector to pool “Europe's resources to tackle the biggest challenges, support competitiveness, deliver high quality jobs, and encourage greater private investment in research and innovation.”<sup>2</sup>

One of those partnerships, the Innovative Medicines Initiative (IMI), is a large-scale public-private partnership between the European Commission and pharmaceutical trade association and lobby group EFPIA (European Federation of Pharmaceutical Industries and Associations). The first partnership, IMI, ran from 2008-2013, and was renewed as IMI2 to run from 2014-2020. IMI is up for renewal again in 2020, with plans to shift its focus to digital health.

While its stated aim is to drive innovation in pharmaceutical research in the EU and improve health, IMI has been criticised as embodying a model by which the public sector foots a large part of the bill for research, while the private sector is able to set the research agenda in its own interests, and reap the rewards.

The EU's policies ought to be shaped to achieve direct and tangible benefits for citizens and society, including equitable access to healthcare both within Europe and globally. In the case of the IMI, this means ensuring the agenda is needs-driven, rather than set by commercial interests.

As such, **this report critically examines any structural weighting of IMI towards private sector interests.** For example, we examine whether the IMI is setting research priorities for pharmaceutical innovation that may be more about business-as-usual market priorities, than about compensating for ‘market failures’ (the latter is a key rationale for such a public private partnership). **We investigate, in particular, what value IMI adds, and whether its set priorities are really addressing public health needs** such as HIV/AIDS and poverty-related and neglected tropical diseases.

**We examine whether the IMI delivers – on its own stated terms – of increasing competitiveness in the European’s pharmaceutical sector,** given some of the misgivings of project partners such as small and medium enterprises. **The report looks at concerns over whether public, non-profit, and smaller partners have equal access to data produced in IMI projects,** or whether the influence of the private pharmaceutical sector is placing undue limits on intellectual property.

The question of whether the IMI awards the private industry unwarranted influence in the formation of regulations for the health sector – such as medicines safety, or privacy of patients’ data – is also crucial. **And it is equally important to assess whether an imbalance towards industry is reflected in the IMI’s governance, finance, and accountability structures.**

Overall, this report asks whether the IMI’s health research truly delivers tangible benefits for citizens, such as better access to health innovations, or whether it is rather focused on enhancing the competitiveness of the largest pharmaceutical corporations?

Both Horizon 2020, the current R&I framework programme, as well as IMI2, end in 2020. At the time of writing, the European institutions are in the process of designing Horizon Europe to succeed Horizon 2020, as well as the successor of IMI2 to be called “Innovative Health Initiative”.<sup>3</sup> It is an important moment, then, to investigate the societal impact of IMI, particularly in terms of public health goals, in order to meaningfully feed into the discussions and the processes around the future of the programme. The future shape of IMI’s successor is of interest to all European citizens, and especially given the large sums of taxpayers’ money to be spent on such a research framework, we believe this should be a topic of wider public discussion.

The methodology of the report has included desk and literature review and interviews, and Freedom of Information requests to the European Commission. We have compared the IMI’s research areas to those identified by the World Health Organisation as priority areas for medicine and interviewed former participants in IMI projects. We have examined the governance structure, accountability, and evaluation processes of IMI. This was an attempt to assess both whether IMI delivers positive societal impacts, and to understand whether its stated claims of enhancing EU competitiveness stand up to scrutiny. Furthermore, we made a critical assessment of what governance and accountability mechanisms were in place to ensure that public money spent through IMI focuses in areas where there was a clear and real need for public funding. **Billions have been spent on IMI to date, and it is likely that billions will be invested in the next partnership. It is therefore critical to analyse whether IMI is truly equipped to achieve its own stated aims and deliver benefits for society.**

The report aims to answer to these and other questions that arose as we carried out our investigation into IMI.

# IMI: diverting public funds for commercial purposes?

## 1. Is IMI fulfilling its mandate and adding value?

### a) The myth of tackling market failures

#### Box 1: IMI origins – industry sets the agenda from the start

The IMI's origins lie in the Lisbon Strategy, an EU plan which in 2000 set the goal of making the EU “the most competitive and dynamic knowledge-based economy in the world”.<sup>4</sup> As part of this process the European Commission set up ‘Technology Platforms’, which were industry-led advisory structures for setting research priorities at a European level.

These platforms were charged with coming up with strategic research agendas (SRA) intended to address major economic, technological, or societal challenges.<sup>5</sup> However, as documented by Corporate Europe Observatory, they were flawed in the way that they offered “privileged access to industry in shaping the EU research direction and spending of the research budget”.<sup>6</sup> Many of these advisory structures were heavily dominated by, or exclusively composed of, representatives of large corporations with a direct commercial interest in the area on which they were to formulate proposals.

Incredibly, this prioritisation of corporate interests was no accident but the Commission's explicit intention. As the then-Research Commissioner Janez Potočnik put it, “platforms can play a key role in better incorporating industry's needs into EU research priorities”.<sup>7</sup>

IMI itself began as a European Technology Platform called Innovative Medicines for Europe (InnoMed) in 2004. The Commission brought in as the main partner pharmaceutical trade association and lobby group the European Federation of Pharmaceutical Industries (EFPIA), whose members include Big Pharma giants such as GSK, Novartis, Pfizer, Lilly, and Johnson & Johnson. EFPIA was asked to identify the “main barriers to innovation” in health research in Europe, and duly created a strategic research agenda which “laid the foundations for IMI”, and set out how to “reinvigorate the European biopharmaceutical sector and to make Europe more attractive for private R&D investment”.<sup>8</sup>

The very origins of the Innovative Medicines Initiative (IMI) are rooted in a model which, from the get-go, was designed to allow corporations to set the agenda for public research funding in the European Union (see [Box 1](#)).

The Innovative Medicines Initiative was established as a Joint Technology Initiative (JTI) in 2007.<sup>9</sup> JTIs are public-private partnerships between the European Commission and industry, and they must meet several criteria:

- address an area of strategic importance for Europe, with clearly identified outcomes;
- address an identified market failure;
- demonstrate the added value of action at European level;
- and muster a long-term commitment from the industry concerned (ie have a leverage effect).

The Joint Technology Initiatives, of which IMI was one of the first two to be launched, were intended to focus on “areas where research and technological development can contribute to European competitiveness and quality of life”. For example, in order to “promote industry-driven research” in Europe, they would implement a research agenda developed by the industry concerned. The IMI, which is a partnership with trade association and lobby group the European Federation of Pharmaceutical Industries (EFPIA), had the stated aim of improving the environment for pharma research, and maintaining Research and Development (R&D) investment, within Europe.<sup>10</sup>

One key goal of IMI is to focus in part on ‘bottlenecks’ in the drug development process. This is intended to address a problem that the pharmaceutical industry identifies as the failure rate of its products in late stages of development: a relatively high number of medicines in development turn out, after several years of investment in their R&I, to be ineffective or too harmful, at a big cost to industry. Reducing this proportion – and so reducing the industry’s costs and therefore (the argument goes) increasing its competitiveness – is a core goal of the IMI.

IMI addresses this goal by focusing on what it calls “pre-competitive research”. It is important to note that this does not mean early stage research, as it is not focused on the development of medicines, but on “the tools, information and data that facilitate their development”.<sup>11</sup> When we asked IMI’s Executive Director to elaborate, we were told that it is “not possible to define the precompetitive space because it changes over time”.<sup>12</sup> Thus it can be defined only as whatever topics industry players agree to work on together.

There is growing recognition that this term appears to warrant further scrutiny, because what is “pre-competitive”, “might vary between industries”.<sup>13</sup> Academics have noted that what is “pre-competitive” is always guided by “private strategic interests and informed by competitive goals”.<sup>14</sup> This can have an especially negative impact on Small and Medium Enterprises (SMEs), when what is “pre-competitive” for Big Pharma is in fact core business for SMEs (see [Part 1, 3d](#)).

It is worth noting in this context that shaping regulation is a key area where pharma companies agree they should work together, via what IMI calls “a partnership with regulators”.<sup>15</sup> Indeed the pharmaceutical trade association EFPIA identified “safety regulations” as a bottleneck to getting medicines approved for market, and introduced this ‘issue’ into the IMI’s strategic research agenda, complaining that “regulatory authorities are becoming more risk-averse,” thanks to “increased public and media scrutiny of pharmaceuticals and regulatory decision-making”.<sup>16</sup> Closer and earlier engagement with regulators thus became an explicit aim of all IMI projects,<sup>17</sup> and as we will see, has remained a core funding priority. However, while it’s clear what industry gains from this, it’s less clear how this is in the public interest. For example, getting medicines to market faster by lowering the initial “safety standards” required for approving new medicines means patients will have an earlier access to medicines. But these might have implications for the rigour of clinical safety tests, and there is a considerable debate about whether it is safe for patients.

As well as increasing industry’s competitiveness, the IMI’s mission is to address ‘market failures’ and to focus on areas of “unmet medical or social need”.<sup>18</sup> These ‘market failures’ are a key political justification for the public-private partnership. Big Pharma is not investing in research in numerous areas where there is an urgent public health need, because they are not deemed profitable enough. Examples include antibiotic resistance crisis, also known as antimicrobial resistance (AMR).<sup>19</sup> Another key example is the failure to fund research into poverty-related and neglected diseases, such as HIV/AIDs, or tropical illnesses. While investment is urgently needed here, industry is not interested as there is little profit to be made on diseases that mostly affect poor and marginalised communities who cannot pay high prices for medicines.

IMI is, in theory, meant to address this. Yet, it is unclear how this was envisioned to take place, as, despite the public recognition that pharmaceutical companies act according to their economic interests, they were still tasked with writing the agenda for IMI. As we will see, the result was that major critical market failures have been left unaddressed.

Given the economic interests of the corporate players, it must surely have come as no surprise that the result of allowing industry to set the research agenda might result in the most potentially profitable areas receiving the most research funding under the IMI. And this is precisely what a review of IMI’s outcomes shows has happened.

## b) Public subsidies for industry’s pre-existing R&I strategies

A core justification for IMI’s existence is the idea that the research done under its auspices would not have happened otherwise (the criterion of ‘additionality’). To reinforce this justification, the IMI website includes “success stories from projects”,<sup>20</sup> filled with testimonies from Big Pharma and other project participants which attest to how projects would have been more difficult or slower without IMI. For example, pharma giant GSK describes one project as “definitely not” possible without IMI.<sup>21</sup> The testimonies are anecdotal rather than quantitative, however, and very much come across as PR material.

One reason that large pharmaceutical companies might be so keen to try to get this message across, is in order to obscure a more candid and less PR-friendly message that EFPIA had previously made: “Large pharma will also benefit ... from the discoveries made in projects that are worth many times the value of each individual company’s contribution. In some cases, this offers tremendous cost savings, as the IMI projects replicate work that individual companies would have had to do anyway.”<sup>22</sup>

This admission by EFPIA is of monumental importance when assessing the validity of the objectives and justifications for the IMI.

That is because EFPIA’s early admission that IMI projects replicate work individual companies would have had to do anyway seriously undermines one of the major justifications for the public-private partnership. The implication that the Big Pharma companies involved would in any case have “spent” their “in-kind” contributions on equivalent research, makes IMI look more like a clever way for pharma to get public sector buy-in, and obtain financing and free academic work (and by extension, less critical assessments) for their own goals.

And this impression is more than reinforced when we look at the breakdown of IMI’s funding priorities and project topics, which leave many neglected and low-profit areas out.

**“Large pharma will also benefit ... from the discoveries made in projects that are worth many times the value of each individual company’s contribution. In some cases, this offers tremendous cost savings, as the IMI projects replicate work that individual companies would have had to do anyway.”**

## 2. IMI's research priorities: addressing priority health needs?

### a) How does IMI live up to the WHO list of priority research areas?

The World Health Organisation (WHO) Report on Priority Medicines for Europe and the World 2013<sup>23</sup> highlights diseases of public health importance, for which pharmaceutical treatments either do not exist or are inadequate and lists 25 areas which should be prioritised for future research. The report was intended to help set a research and development agenda based on public-health-based goals and had been commissioned by the European Commission for the Horizon 2020 research programme, which included the IMI. Despite this, as *Der Spiegel* reported in 2015, only a few of the WHO list's 25 focus areas can be found among IMI's research projects, while major and urgent research topics such as malaria, heart disease, and arthrosis, for example, are missing.<sup>24</sup>

This problem was anticipated by the WHO itself, which noted in its 2013 report that “Pharmaceutical industry-driven agendas for the development of new therapeutics (such as the Innovative Medicines Initiative, IMI) have not yet addressed R&D efforts [for neglected tropical diseases]”.<sup>25</sup> And civil society groups furthermore noted that poverty-related and neglected diseases remain “marginal in the current research agenda” for IMI.<sup>26</sup>

Despite this criticism, in 2020 this picture does not appear to have changed greatly.

The “pharmaceutical gaps” identified by the WHO were intended to guide the IMI in the direction of developing priorities that are based on public-health needs. Predictably, however, with industry steering the research agenda, the IMI has ended up prioritising the disease areas at the more profitable end of the WHO's list. [Figure 1](#) shows this to quite a remarkable extent, comparing the WHO's 25 priority research areas with the glaring gaps in the IMI's projects.

**With industry steering the research agenda, the IMI has ended up prioritising the disease areas at the more profitable end of the WHO's list**

# Figure 1: How does IMI live up to the WHO list of priority research areas?

0 IMI projects
  0/1 IMI project
  2-5 IMI projects
  6-15 IMI projects
  16+ IMI projects

WHO List of Priority Medicines Research Areas for Europe (2013)	No. of IMI projects	Notes re. search of IMI's Project Factsheets <sup>27</sup>
Rare Diseases	<b>Unclear</b>	Searching "Rare diseases" brings 19 project results, but many of these relate to Ebola, and it is not clear in what way they have been categorised. (See <a href="#">Part 1, 2b</a> for more on Ebola.)
Ischaemic Heart Disease	<b>0</b>	0 projects found under search term 'Ischaemic Heart Disease', though there are 3 projects listed under the disease area 'cardiovascular diseases'.
Tobacco Use	<b>0</b>	No search results for 'tobacco'.
Alcohol Use Disorders and Alcoholic Liver Disease	<b>0</b>	0 results for 'alcohol'; though there are 2 liver disease projects, one is explicitly about non-alcoholic fatty liver disease (LITMUS) and the other about drug-induced injuries to liver et al (SAFE_T).
Hearing Loss	<b>0</b>	0 results from searching 'hearing' and 'hearing loss'.
Postpartum Haemorrhage	<b>0</b>	No search results.
Neonatal Conditions	<b>0</b>	No search results for 'neonatal'.
Low Back Pain	<b>0</b>	No results for back pain. There are 2 projects in disease area 'Pain': IMI-PainCare re acute/chronic pain, NGN-PET re pain treatments.
Malaria	<b>0/1</b>	1 project result for 'malaria', WEB-RADR, which is not directly about malaria, but about a mobile app for reporting adverse drug reactions.
HIV/AIDS	<b>0/1</b>	No search results in the IMI project factsheet database under any version of the search terms. <sup>28</sup> There are 5 projects in 'autoimmune diseases' disease area; <sup>29</sup> 3 relate to Rheumatoid Arthritis, but none relate to HIV/AIDS. However, a reference to a project with results that indirectly pertain to HIV/AIDS was found elsewhere in an IMI report. <sup>30</sup>
Diarrhoea	<b>0/1</b>	Only 1 project with a result for 'diarrhoea', and this is only referring to diarrhoea as a symptom of Clostridium difficile infection (CDI) in one of the Antimicrobial Resistance projects COMBACTE-CDI.
Acute Stroke	<b>0/1</b>	1 project result from searching 'stroke', SUMMIT, which actually focuses on diabetes complications, but has results relevant to stroke.
Neglected Tropical Diseases	<b>Unclear 0-4</b>	19 of the 20 neglected tropical diseases on the WHO's current list produced 0 results. 'Dengue and Chikungunya' is the remaining category. 'Dengue' produces 10 results, but most of these relate primarily to Ebola (another kind of "viral haemorrhagic fever"), and when the 10 project factsheet pages were searched for 'dengue', only 4 – VHFMoDRAD, VSV-EBOVAC, EBOMAN, EbolaMoDRAD – came up with a result (though not necessarily as a focus of the project – several as part of an explanation about the disease group). Chikungunya produced 1 search result, the project ZAPI, about zoonoses, infectious diseases transmitted to humans by animals; Chikungunya is named in the project description as an example of a zoonosis but it is not one of the three viruses that the project is focusing on. <sup>31</sup>
Osteoarthritis	<b>1</b>	APPROACH project.
Chronic Obstructive Pulmonary Disease (COPD)	<b>1</b>	PRO-active project, specifically about COPD. An asthma project, U-BIOPRED, is also listed, but asthma is not a COPD, <sup>32</sup> and the reference to it in the project factsheet relates to future research questions (post project).
Tuberculosis	<b>2</b>	PreDiCT-TB and RAPP-ID. [NB the TB Alliance recently joined IMI re Antimicrobial Resistant Tuberculosis, and 2018 calls included a new Antimicrobial Resistance Accelerator Program, featuring a Tuberculosis Drug Development Network.] <sup>33</sup>
Obesity	<b>3</b>	3 projects, EMIF, IM2PACT, and DIRECT relate to obesity, among other things).
Depression	<b>3</b>	3 projects relating to depression. There are 6 projects under disease area 'psychiatric diseases', 1 re depression and schizophrenia (NEWMEDS), 1 re schizophrenia, Alzheimer's disease, and major depressive disorder (PRISM). The others focus on stem cells, autism, central nervous system disorders, preclinical data. In addition, searching also produces RADAR-CNS re "new ways of monitoring major depressive disorder, epilepsy, and multiple sclerosis using wearable devices and smartphone technology". <sup>34</sup>
Pneumonia	<b>3</b>	3 projects that relate pneumonia, an Antimicrobial Resistance related one (COMBACTE-NET), plus RESCEU and RAPP-ID.
Pandemic Influenza	<b>4</b>	Influenza has 4 results (though 'pandemic influenza' has 0).
Antimicrobial Drug Resistance	<b>9</b>	9 projects under disease area 'Antimicrobial Resistance'. 2 case studies on antimicrobial resistance in <a href="#">Part 1, 4c</a> highlight that where industry drives the projects, the results risk favouring industry's proposed solutions at the expense of alternatives that may better meet public interest goals.
Cancer	<b>10</b>	10 projects in disease area 'Cancer'.
Diabetes	<b>12</b>	12 projects in disease area 'Diabetes & metabolic disorders'.
Alzheimer Disease and other Dementias	<b>17</b>	17 in disease area 'Alzheimer disease'. NB 20 projects are listed under the category 'neurodegenerative diseases'.

What becomes clear from [Figure 1](#) is that poverty-related and neglected diseases overall have far fewer IMI projects dedicated to them than conditions such as Alzheimer's and diabetes, where Big Pharma is already investing heavily in R&I.

Seven WHO-identified priority areas have zero IMI projects, including neonatal conditions and postpartum haemorrhage. Four more priority areas have only one ambiguously-linked IMI project, including HIV/AIDS, malaria, and diarrhoea. A further three priorities areas have just one or two IMI-related projects, including tuberculosis.

Meanwhile three auto-immune projects relate to Rheumatoid Arthritis – which is not on the WHO priority list – whilst, incredibly, none relate directly to HIV/AIDs.

A further 17 projects relate to Alzheimer's disease, 12 projects to diabetes, and 10 projects to cancer. Without question there is a very real need for research into these areas. Areas such as cancer and Alzheimer's affect the lives of many citizens and attention to them is greatly warranted. Yet this raises the question of the added value of public funding from the EU, as these are areas where the industry is already investing heavily.

The pharmaceutical industry's own analysis<sup>35</sup> shows cancer is by far the biggest focus of private R&I by therapeutic area, representing more than a third of their pharmaceutical research.<sup>36</sup> In fact in 2016, the top ten therapeutic areas for private R&I by number of research projects, were cancer, then neurology – which includes research into Alzheimer's<sup>37</sup> – at number two, with diabetes also in the top ten.<sup>38</sup> In terms of the top ten diseases by number of active drugs, in 2018 the top five were all cancer treatments, number six was diabetes, number eight Alzheimer's, and ten was rheumatoid arthritis (seven and nine were also cancer).<sup>39</sup>

Clearly these disease areas are not suffering from a market failure, as the global pharmaceutical industry is investing heavily in them already, which is not surprising given the large market potential for new treatments. Yet they are where most IMI projects are oriented. This is a widespread problem, as noted in a recent report by the economist Mariana Mazzucato, who was a special advisor to the previous EU Commissioner for Research and Innovation Carlos Moedas. The report, co-written with several public health NGOs, noted that R&I priorities are not determined by public health needs and that “disease areas that are not potential ‘growth markets’ are largely ignored” and that “between 2000 and 2011, only 37 of 850 (4%) of newly approved products were for neglected diseases that affect middle and low-income countries”.<sup>40</sup>

One of IMI's primary objectives was to address diseases where there is a “lack of market incentive”,<sup>41</sup> ie where the lack of profit motive stymies private investment in R&I by pharmaceutical companies. Yet HIV/AIDS is all but ignored, and 19 of the 20 neglected tropical diseases identified by the WHO priority list have no related IMI projects.

We asked the IMI office directly why so many of these crucial priority areas are left out. In their reply they highlighted that IMI's remit is to improve “European citizens' health and well-being”, and therefore they did not focus on HIV/AIDS or poverty-related and neglected diseases.<sup>42</sup>

However, this argument about “European” priorities does not stand up to scrutiny. The gaps in IMI's priorities do not entirely correspond to a distinction between Europe and the rest of the world. For example, a WHO Europe report concluded that in 2013 there were 80 per cent more new HIV cases in Europe compared to 2004.<sup>43</sup>

Recently, *Politico EU*'s series on HIV highlighted that in 2019, "new diagnoses are exploding in Eastern Europe and Russia", and while the rates of new diagnoses are falling in many EU countries, they have "doubled since 2008 in Bulgaria, Cyprus, and Lithuania".<sup>44</sup> In fact IMI2's strategic research agenda itself notes the "increase in the incidence of neglected and poverty related diseases (such as HIV and tuberculosis (TB))" in Europe. And while unlike HIV, TB is not absent from IMI, the programme has historically invested very little in the disease (though there have been some recent improvements owing to the link between TB and anti-microbial resistance).<sup>45</sup> Even within 'European' priorities, we still see a neglect of unprofitable areas.

And yet even if we were to accept IMI's claim that it focuses on European health priorities, there is nothing in its legal base that mandates that it should do so. The Council Regulation that sets up IMI<sup>46</sup> once mentions the needs of "European citizens", but also states that IMI should address societal challenges as described in the health pillar Horizon 2020, which is not restricted to Europe and includes poverty-related and neglected diseases.

It must be emphasised that neglected diseases with limited market potential are strongly reliant on public funding, without which there is little hope for prevention, new treatments, or cures for them. It is the responsibility of public institutions such as the European Commission to ensure they receive sufficient priority in public R&I budgets, in particular by ensuring a more inclusive priority-setting process that is not dominated by commercial interests.

Failure to do this is a failure to defend the public interest, which undermines two of the political justifications for the IMI, which are to increase European competitiveness and focus investment into priority research areas as determined by the WHO, by investing into market failures, ie neglected public-health oriented areas where there is limited market incentive.

In response to our query about why so many priority research areas have been neglected, IMI noted that they seek to avoid "unnecessary duplication" and ensure "complementarity" with other parts of the EU's research programme, meaning the Horizon 2020 work programmes and the European and Developing Countries Clinical Trials Programme (EDCTP). However, it is not clear by what process or decision-making procedure duplications and complementarities are identified. While representatives from the European Commission sit in both governing bodies and do input on overlaps,<sup>47</sup> this falls short of the technical coordination required to concretely evaluate risks of duplication or opportunities for complementarity.

And as EDCTP focuses on clinical trials, and IMI2 on the drug development process, it would appear there are opportunities for IMI2 to fill some of the many pharmaceutical gaps in research into poverty-related and neglected diseases in the EU<sup>48</sup> provided it is reformed to ensure an inclusive and needs-driven priority-setting process.

## b) IMI's late Ebola investments

A case that highlights IMI's broken research incentives is its belated response to the Ebola crisis. As we have already seen, with a research agenda overly dominated by industry priorities, poverty-related and neglected diseases such as Ebola and malaria have not been prioritised. As a result, when a pandemic emerges such as the Ebola crisis in 2014, the research and development simply has not been done in time to respond effectively; in the case of Ebola IMI was playing catch-up, and did not succeed in producing a usable vaccine in a timely fashion.

Ebola is an emerging infectious disease which is clearly poverty-related,<sup>49</sup> and was neglected by private sector R&I for years. Triggered by the deadly 2014 outbreak in West Africa, in recent years IMI has belatedly focused significant resources on Ebola.

However, like other neglected diseases, Ebola was not included in the original Strategic Research Agenda of IMI.<sup>50</sup> This reflected a general lack of private sector investment in Ebola in the years prior to the 2014 outbreak. The lack of investment was due to several factors, for example that outbreaks only occurred sporadically, in remote areas, and affected limited numbers of patients. However, the critical factor was that Ebola – a disease affecting poor countries with smaller health budgets – was not seen as a profitable market opportunity by pharmaceutical companies. Corporations' interest in investing in Ebola R&I, after all, would depend on its commercial attractiveness. In 2016 experts noted that “a vaccine would probably exist today if Ebola affected a large number of people in high-income countries, making research and development financially attractive to drug companies”.<sup>51</sup> And so at the time of the outbreak there were no vaccines or medicines for Ebola that had been proven effective for humans.<sup>52</sup>

The WHO's former Director-General Margaret Chan has “criticized the pharmaceutical industry's lack of investment in investigational treatments for [Ebola], saying many companies had likely determined the return on any investment for an Ebola treatment was not worth the development cost”.<sup>53</sup> Some efforts had been made by governments to stimulate pharma companies to invest in neglected diseases, but they have not been very successful, because even generous incentives “are not enough when prospective gains from commercialization are poor”.<sup>54</sup>

This reflects a wider lack of investment in non-profitable neglected diseases<sup>55</sup> which as we have seen is widely described as a ‘market failure’,<sup>56</sup> or ‘non-profitable’.<sup>57</sup> Indeed, the problem is so serious that some scientists have noted bluntly that in our current model: “the only hope for serious investment in reducing the incidence and impact of such diseases is via spread to developed countries”.<sup>58</sup>

As one public health expert noted, “it is extremely unfortunate that it took a devastating [Ebola] outbreak to bring neglected tropical diseases to the forefront of public attention”.<sup>59</sup> Indeed the 2014 Ebola crisis in West Africa triggered a humanitarian response from the EU. As it became clear that urgently needed treatments and vaccines were lacking, and IMI was in a unique position to engage industry to move forward on this quickly,<sup>60</sup> the European Commission asked it to focus on Ebola as a matter of urgency.<sup>61</sup>

A key example is IMI project VSV-EBOVAC which provided nearly €5 million funding for one of the most promising Ebola vaccine candidates at the time.<sup>62</sup> The vaccine candidate was initially developed through public funding at a Canadian government laboratory, and showed potential effectiveness as early as 2003.

As is common, the research laboratory licensed the candidate to a company, NewLinkGenetics, for roughly US\$205,000. The vaccine was not developed further and by the time of the 2014 Ebola epidemic it was still unknown whether the vaccine was safe for use in humans. NewLink Genetics sub-licensed the vaccine to Merck for \$50 million plus royalties, gaining substantial profits despite its lack of investment in the vaccine.<sup>63</sup> Merck took development further and by March 2015, one year after the outbreak started, clinical trials began.<sup>64</sup> The IMI project on the vaccine also commenced at that time. However, by this time, the peak of new cases and deaths in the Ebola epidemic had already passed.<sup>65</sup>

In 2018, with two new Ebola outbreaks in Congo in 2018 at risk of spiralling out of control, the IMI vaccine candidates were still not ready for use. Despite successful phase three clinical trials from the 2014-2016 outbreak with Merck's Ebola vaccine, the company had not yet obtained regulatory approval when the 2018 outbreaks began. The lack of regulatory approval during the most recent outbreak in Eastern Congo<sup>66</sup> resulted in heavy restrictions on the use of the vaccine<sup>67</sup> which seriously hampered immunization efforts.<sup>68</sup>

So public funding went into early development of this vaccine, showing promising results. However, these then languished in departments of the private pharma companies who were not sufficiently motivated by profit to develop them further.

While the IMI project is welcome, it was a belated response that came about due to a crisis. Until that crisis hit, IMI did not enable or stimulate the development of Ebola vaccines as it did not appear in any original IMI research agenda. This development is indicative of how IMI follows industry priorities.

IMI provided funding for Ebola vaccines only when commercial interest by private companies picked up due to a large outbreak. Had IMI been guided by public health priorities and addressing barriers to R&I in neglected areas, as its mandate includes, the course would have been very different.

In addition, MEPs – echoing many civil society groups<sup>69</sup> – have lamented that results of IMI Ebola projects are not required to be published, and that there are “no rules about how affordable or accessible any medicines would have to be,” and called for “open access to results from any trials related to Ebola” and for any successful vaccines or diagnostics developed to be truly affordable.<sup>70</sup> The EU currently does not attach conditions to its public biomedical R&I funding which could help to ensure the accessibility and affordability of medical products resulting from public investment, including in IMI.

Again, while the humanitarian response from the EU was welcomed, it illustrates a real problem when it comes to dealing with epidemics: the pharmaceutical research and trials must already be “far along the development pipeline if they are to have an impact in the near term”.<sup>71</sup> The above example illustrates that when public funding is driven by industry interests we will be unprepared for ‘ticking time bombs’, ie diseases which are of huge public health interest but little commercial interest.<sup>72</sup> The lesson is that public funding should be needs-driven and guided by public health priorities not commercial interests.<sup>73</sup> Only then will vaccines be ready and available when we need them.<sup>74</sup>

It does not seem that this lesson has been learnt within IMI. There is still very little investment in the EU in malaria R&I for example, despite its endemic nature and ongoing outbreaks,<sup>75</sup> and the urgent need for new tools as rising levels of parasitic resistance to malaria drugs risks making the disease untreatable.

## Box 2: New coronavirus outbreak and IMI response: very little, very late, again?

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A new epidemic broke out in January 2020 while we were writing this report. Coronavirus disease – named COVID-19<sup>76</sup> and confirmed as pandemic by WHO<sup>77</sup> – is currently creating a global public health crisis.

At the time of writing, no definitive treatment against COVID-19 exists, although several compounds, including both novel and older medicines, are being investigated to treat the disease in the short term. In the medium term, there are a variety of efforts to develop a vaccine, eg led by the US government and the Coalition for Epidemic Preparedness Innovations (CEPI) – an international initiative supported by the EU and other public and philanthropic funders.<sup>78</sup> While most technologies under development have relied on biotechnology companies and universities, several multinational vaccine manufacturers have also declared their willingness to contribute their technologies to vaccine development efforts. As we were told by MSF, “with the containment of the novel corona virus increasingly unlikely, and the rising possibility of it becoming a fifth endemic coronavirus or a seasonal pathogen causing pneumonia, these ventures could become lucrative.”<sup>79</sup>

It is important to note that meeting minutes from the IMI Governing Board in March 2018<sup>80</sup> show that when the Commission proposed making “biopreparedness”, ie preparedness for epidemics, a “regulatory topic” for IMI, industry rejected the idea. And while IMI does have a limited interaction with CEPI, it does not invest any money in this initiative, and according to the minutes, “no immediate co-investment is expected”.<sup>81</sup>

Nevertheless, as part of the European Commission’s wider response<sup>82</sup> to the current coronavirus outbreak, in March 2020 IMI launched a fast-track €45 million call for proposals for the development of therapeutics and diagnostics to tackle coronavirus infections.<sup>83</sup> While this might have the potential to accelerate the development of treatment and diagnostic tools, IMI’s move is again a belated response to the public health emergency caused by the novel coronavirus outbreak, as we previously saw with the Ebola outbreak. Moreover, with no conditions attached to the IMI funding<sup>84</sup>, it is not clear whether any successful treatment or diagnostics developed as a result of the IMI projects will be affordable or accessible for those who need them.

### 3. IMI's impact: equal benefits to society?

#### a) Missing accountability mechanisms

The European Commission is obliged to commission evaluations of its policies and programmes, including research.<sup>85</sup> IMI has had both interim and final evaluations, and IMI2's interim evaluation was published in 2017. One of the most astonishing things about the IMI2 interim evaluation is that it exposes that for almost ten years, in which €2.6 billion of public money was committed, IMI1 and IMI2 operated without any real, planned way of measuring societal impact.

IMI's impacts were not measurable because “a monitoring system based on Key Performance Indicators (KPIs) remained absent”. Astonishingly, KPIs remained absent “despite recommendations in the two previous interim evaluation of IMI1”. This meant that IMI's reporting was “not aligned” with the “goals and success criteria that were used in the argumentation to set up a joint undertaking”. In other words, the Big Pharma-led initiative was not even trying to monitor if it was living up to all the promises it made to secure the cushy partnership in the first place.<sup>86</sup>

The report notes that at the time of writing (2017), the IMI's Governing Board and Executive Office were developing a new set of Key Performance Indicators.<sup>87</sup> Even taking this into account, that means that for nearly ten years the Commission – supposedly representing the public interest, in balance with the private – did not correct this.

Meeting minutes from the IMI Governing Board in March 2018 show that when the Commission proposed making “biopreparedness”, ie preparedness for epidemics, a regulatory theme for IMI, industry rejected the idea

### Box 3: Open access – unless Big Pharma companies decide otherwise

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Whilst Horizon 2020 rules mean publications – such as journal articles originating from its projects – should be open access, this can be opted-out of, including to protect Big Pharma’s intellectual property rights. Although open access to research data ought to be applied ‘by default’ through the Open Research Data Pilot since 2017, IMI project consortia have a very broad array of justifications that can be used to opt-out at any time. These justifications, explains IMI, include “for intellectual property rights (IPR) concerns”.<sup>88</sup> Thus opting-out of open data access is not just applicable for rare exceptions, but can (and is expected to) be used to serve the industry’s commercial interest in IP.

IMI’s new Key Performance Indicators (or KPIs) include the – arguably unambitious – target of 50 per cent for the “Share of IMI projects whose resources/outputs are made accessible beyond the consortia partners (with or without fee), such as major databases, bio-banks, in silico tools, training materials, clinical trial networks, guidance etc” (KPI6).<sup>89</sup> However, the first results show this target is not even close to having been met, with the 2018 KPI indicating a paltry 19.23 per cent of projects with open access.<sup>90</sup>

Moreover, project proposals are not penalised in any way if they plan to opt out rather than share their data. The case of GSK and the Mario Negri Institute (see [Part 1, 4c, i](#)) suggests that, given the unequal power relationships within project consortia – whereby Big Pharma companies (and all their legal resources and IP lawyers) can dominate over smaller research institutions, SMEs or academic institutions – if these big industry players want out, there may not be much that other participants can do.

Information on IMI projects that have opted out of open data access (or which did not opt-in, prior to 2017) has not, it seems, been made publicly available. Directorate-General for Research and Innovation (DG RTD) told us they do not have access to this information and that we must approach the individual PPPs.<sup>91</sup> That the Commission is not monitoring open access derogations, a key public interest condition, is a failing in accountability.<sup>92</sup>

## b) Evaluations show lack of impact for patients and society

The IMI2 interim evaluation describes the lack of a “satisfying” monitoring system of impacts to be a “major weakness” of both IMI1 and IMI2.<sup>93</sup>

And this concern was well-justified, as the evaluations found that despite the billions in funding so far, IMI is not having much of a demonstrable impact. The final evaluation of IMI1 (2008-2016) concluded that “no socio-economic benefits from IMI JU activities could be identified”. Damningly, nor did it find any examples of it “bringing new, safer and more effective therapies or products to patients” or shortening development time: two of the objectives that justified the €1 billion of public money. It also concluded that research topics “closer to the public interest than those identified by the industry” may be better identified under the wider research programme, and “at a lower cost for the public budget”. Despite this, an even greater sum of EU public money was dedicated to IMI2.<sup>94</sup>

The first IMI underwent an impact assessment, which considered the socio-economic impacts of nine IMI1 projects completed in 2016.<sup>95</sup> Despite the IMI’s press release boasting, “Major new report reveals socio-economic impact of Innovative Medicines Initiative projects”,<sup>96</sup> this report actually found that there was “no evidence yet of noticeable socio-economic impacts on the health system (such as improved access to new treatments, improved work productivity or more effective use of healthcare budgets or reduced costs) or health benefits for patients”. It also concluded that “the potential or actual socio-economic impacts of projects had rarely been at the forefront of the minds of those involved in the projects”. It recommended that socio-economic impact should be considered much earlier in IMI, before decisions are made on which projects to fund.<sup>97</sup>

Lest these findings be deemed premature, the IMI2 interim evaluation in 2017 made similarly damning conclusions, finding that to date, “there were no examples of IMI bringing new, safer and more effective therapies or products to patients”, nor “of the time to develop such new applications being shortened”, and that in this respect the “added value of IMI2 JU for patients or society in general was hard to demonstrate”.<sup>98</sup> The cherry on the top: it also concluded that there are “no guarantees” that IMI funded projects will lead to the development of new drugs. It also recommended that the IMI’s intellectual property policy be reviewed to “guarantee that more results from IMI2 JU projects may be translated into applications at the benefit of the society”.<sup>99</sup>

These conclusions indicate that IMI has failed to meet the goals that justified it, including overcoming market failure, and improving the development and availability of public health-oriented medicines. Yet despite this, the evaluations share a tendency towards top-line messaging that is generally a positive endorsement and encouragement for continuation, whilst the meat of the reports actually contain very serious findings about lack of societal impact or evidence of meeting its goals. The IMI2 interim evaluation concludes, despite finding no evidence of real impact, that “the reasons to create a PPP to strengthen the European pharma industry were valid and the goals were justified”. However, in its main text it admits that it is unclear if “the current organisation of IMI2 JU, with EFPIA as the leader and coordinator of projects for the industry, was able to adequately tackle new challenges”.<sup>100</sup>

### c) No concrete evidence on economic benefits

Setting aside the question of whether the outcomes of IMI have a public interest value, we even have reason to question whether IMI has met its core goal of increasing the competitiveness of EU industry.

Two of IMI's core goals are to increase the European pharmaceutical industry's competitiveness, and to increase pharma's research investment in Europe. However, academic analysis has shown that the rationale of falling R&I investment in Europe is "not supported by data that the IMI itself relies on to make its argument". While the IMI's 2008 Strategic Research Agenda refers to the "relative under-investment" in European biomedical research, in fact around this time, as academics point out: "European pharmaceutical R&D spending rose from €17.8 billion in 2000 to €21.7 billion in 2005, compared with a rise from €23.1 billion to €25.3 billion in the USA in the same years".<sup>101</sup>

And even if R&I spending were in decline as IMI claimed, the interim evaluation of IMI2 noted that in fact there "were no quantitative data available that indicated whether the big pharmaceutical companies were increasing their research investments in Europe, that would indicate that Europe had become a more attractive location for biopharmaceutical research". This was in part because the "lack of an accountable performance measurement system meant it was still not clear whether IMI2 was 'refuelling' the pharmaceutical industry in Europe". Indeed, this is not unique to IMI: the Commission currently has no "ex-ante definition of leverage" for public-private partnerships, however there are plans for "developing a methodology for quantifying it for European Partnerships".<sup>102</sup> While this is a positive step, the fact that no such concrete methodologies currently exist mean that claims of leverage from IMI are impossible to quantify.

The interim evaluation of IMI2 also noted that the fact that 30 per cent of the total in-kind contribution comes from activities outside the EU (and Horizon 2020 associated countries), hampers the IMI's stated goal of increasing the European pharmaceutical sector's competitiveness. The evaluation noted that, "in fact the lever created to increase investments in European pharmaceutical industry and boost European competitiveness is weakened by 30%". The EU's emphasis on building European pharma's capacity to compete on the global stage also pays scant attention to the fact that "competitors are increasingly trans-national companies, whose global integration is further helped by policies for 'competitiveness'".<sup>103</sup> And despite EFPIA's claim "to promote 'European competitiveness', one third of its 39 full company members are US-based multinationals, which press for similar institutional and policy changes on the other side of the Atlantic."<sup>104</sup>

It can be argued that global collaboration in biomedical R&I is in the public interest, as it facilitates the sharing of knowledge and data. However, given the stated goal of IMI to enhance EU companies' competitiveness, there are questions about the coherence of this approach.

It is also questionable to argue, as the interim evaluation does, that the "IMI may have contributed to resilience of the European pharmaceutical industry" through the economic crisis, as the number of clinical trials "remained stable across Europe following the crisis in 2008".<sup>105</sup> Given the many different factors and variables which affect clinical trial numbers, such a claim cannot be substantiated. And if this is the extent of evidence offered – along with anecdotal claims that the "IMI2 JU was envied elsewhere in the world" – to justify the spending of €2.6 billion of public money to increase pharma competitiveness, then the IMI's political justification must be called into doubt.

#### d) A bias towards big partners and corporations

The European Commission has described small and medium-sized enterprises (SMEs) as “the backbone of Europe’s economy” and different initiatives and mechanisms are in place to support SMEs in the EU.<sup>106</sup> Despite this rhetoric, however, the interests of large corporations appear to have been favoured over those of SMEs in IMI.

As a result the participation of SMEs in IMI has dropped sharply. Reasons appear to include the way Big Pharma dominates the research agenda, and is able to prevail in negotiations over the resulting intellectual property. Indeed the final evaluation of the first phase of the IMI (2008-2016) found that the participation of SMEs in IMI JU was represented by 15.96 per cent of the EU-funded participations (ie non-EFPIA). The interim evaluation of IMI2<sup>107</sup> (2014-2016) found that SME participation dropped by almost 30 per cent compared to 2007-2013, down to just 11.78 per cent. The share of the IMI’s EU-funding going to SMEs decreased by 13.25 per cent to 10.33 per cent. In comparison to other Horizon 2020 initiatives, IMI2 had 15 per cent lower SME participation and 25 per cent lower funding.<sup>108</sup>

Given that SMEs participating in IMI are beneficiaries of both EU public funds and of in-kind resources from the large multinational pharmaceutical company members of EFPIA, why are they turning away from the IMI? This is an important question given that SME participation is an IMI goal: as the IMI2 interim evaluation notes, it is considered “a key element for the success of this multidisciplinary approach of innovation” and “SMEs are seen as essential cog-wheels that drive competitiveness of the European health industry.”<sup>109</sup>

Both the IMI final evaluation<sup>110</sup> and the IMI2 interim evaluation<sup>111</sup> reveal numerous explanations for the low participation of SMEs. Both found that that SMEs were “hampered by the complexity of IP negotiations” (IMI) and that that SMEs “often lack human and financial resources and expertise” to properly engage in consortium IP negotiations with Big Pharma companies (IMI2). The IMI2 interim evaluation said that SMEs found the topic descriptions in IMI2 calls to be too narrow, prescriptive, and “defined top down by the pharmaceutical companies” in a way which meant, “SMEs were obliged to follow the lead of big pharma, while SMEs on the contrary often need more flexibility”.

What’s more, it turns out that a core goal of IMI, to do “pre-competitive research”, is systematically disadvantaging SMEs. The focus on what Big Pharma considers “pre-competitive” – where companies collaborate openly without limits such as IP – is in fact often “core business for an SME”. For example, SMEs often patent “research tools” such as biomarkers, and while Big Pharma have an interest in being able to access these for free, “the developers of the tools... will have very different interests”.<sup>112</sup>

Such SMEs are often funded by venture capital firms which expect high rates of return based on the SMEs selling their exclusive rights or being bought up by Big Pharma.<sup>113</sup> SMEs entering into a consortium need to be able to negotiate to retain these rights. If they are unable to, the incentive for Big Pharma companies to pay to license their research findings or buy the firm is removed.

Given this, SMEs understandably don't want to give away their background IP. However, the evaluation notes that in IMI that there is "no room to negotiate on exclusive rights", as "big pharma wanted to have access to all results generated from IMI projects". It concludes in stark terms that the rules around IP agreements in IMI are a "significant deficiency" that "weaken or destroy the ability [of SMEs] to raise private funding" and constitute "a 'major disincentive' to SME participation".<sup>114</sup>

It is not hard to see then why SMEs are reluctant to participate. This also shows how Big Pharma is in an incredibly advantageous position, not only setting the research agenda, but putting SMEs in a position whereby if they want EU public funding through IMI, they must accept a situation where Big Pharma can profit from the results of their research without buying it.

These concerns were first raised a decade ago. In 2010 the League of European Research Universities (LERU) wrote to the IMI Board to complain that the IP rules were disadvantageous to academic or SME participation, and that the "EC and EFPIA should not expect their 'partners' to accept rules, by which they basically give away all their IP for free". They accused EFPIA lawyers of rigidly assuming that both academic institutions and SMEs would "simply accept such unfavourable terms without even the pretence of negotiation", demonstrating the lack of equal partnership between industry and academic/research institutions.<sup>115</sup> The 2015 investigation by *Der Spiegel*, which brought attention to LERU's earlier complaints, reported that biotech SMEs were also unhappy, without the time to "review the complex IMI contracts", and concluded that IMI's IP rules were biased towards large pharmaceutical companies.<sup>116</sup>

Four months after the *Der Spiegel* piece, a journal article – seemingly a PR move in response, in order to deflect criticism – was published which sought to quell such concerns.<sup>117</sup> The article, based on "qualitative" case studies produced under contract for the IMI, claimed that "the initial fear that SMEs' business model would be jeopardized" by making their background IP "freely available" to the "larger part of SMEs' target customers (ie the large pharmaceutical companies) who are present in IMI consortia" has "disappeared and should no longer impede SMEs applying to participate in IMI projects". Instead, it argued, despite the fact that "no major profits can be made by exploiting foreground IP developments during the project", SMEs should welcome the "opportunity to create technical standards and to occupy a preferred position in the market".<sup>118</sup> However, the 30 per cent drop in SME participation recorded in the 2017 evaluation suggest biopharmaceutical SME's remain unconvinced by these IMI-funded reassurances.

Following extensive criticism of IMI1's IP rules and how they disadvantaged SMEs and academic institutions in favour of Big Pharma's interests, the IP regulation in IMI2 is an improvement. It "has been more fully aligned with the one of Horizon 2020 with only a few derogations", according to the IMI2 interim evaluation. However, as evidenced above, the IMI2 IP rules still require IMI project consortium partners to hash out the specifics of the IP agreement that they will be bound by. The inequality of power and resources between for example a non-profit research foundation, academic institution, or SME, and multi-billion euro pharmaceutical transnationals with large and well-resourced legal departments, unfortunately mean that the results are by no means guaranteed to reflect a balance of interests, or safeguard the public interest in broad access to research results.<sup>119</sup>

The interim evaluation of IMI2 therefore recommended that the IP policy should be further reformed to allow “negotiations on exclusive rights”, to support SME engagement.<sup>120</sup> The recommendation was included as a follow up point in the IMI’s Action Plan to address the evaluation. However, Governing Board minutes show that the Board decided not to act on this recommendation on the basis that “the action cannot be addressed in the context of the IMI2 framework”. Despite no action being taken, the Board agreed that the indicator for the recommendation should be marked green, ie completed, as it was to be “considered for a potential future initiative”.<sup>121</sup> But as this is not necessarily a concrete commitment to address the issue, the green indicator is questionable at best, and at worst could increase the possibility that the issue will not be addressed in the next programme.

Alarming, the minutes also reveal that EFPIA is using its position on the IMI Governing Board to lobby for rolling back even these inadequate reforms. During discussion on the future IMI, they stated that an “ideal future” IMI “would comprise positive features of IMI1 such as [a] relatively flexible IP regime and financial rules”. As we have seen, a major criticism of the first IMI was that it allowed too many derogations from the standard IP rules of the framework programme, which allowed Big Pharma companies to take advantage of smaller companies and other participants. In response, IMI2’s IP rules were brought more closely into line with Horizon 2020 to allow fewer derogations (though they still disadvantage SMEs). Yet EFPIA is using its governance role to lobby for a return to policies that even more strongly disadvantage SMEs and universities.<sup>122</sup>

## Box 4: A rich country club?

The IMI2’s interim evaluation notes that applicants to and participants in IMI projects from the newer member states or EU-13 countries are under-represented. And in terms of the beneficiaries<sup>123</sup> of the EU contribution to the budget – which is distributed among non-EFPIA members of project consortia – it is notable that of the successful proposals made to IMI1, 91.5 per cent were from researchers based in the richer EU-15 countries, and only 1.8 per cent from EU-13 countries. Further, the IMI public funding going to applicants from EU-13 countries dropped from 1.3 per cent in IMI1 to 0.5 per cent in IMI2, whilst the amount going to EU-15 countries increased from 93.9 per cent in IMI1 to 95 per cent in IMI2.<sup>124</sup> Given that this is a well-recognised problem which requires efforts to remedy across the wider Horizon2020 framework,<sup>125</sup> the success rate of EU-15 applicants was also nearly more than double that of EU-13 applicants.<sup>126</sup> As to the individual entities that receive most of the EU funds, this information is not readily available, whilst the IMI project pages do provide a breakdown of IMI funding per project.

## 4. Under the spotlight: IMI projects with questionable public interest

In addition to the IMI's lack of engagement with many neglected diseases the WHO listed as priority areas for research, there are also several types of IMI projects which are hard to justify as being in the public interest, including those that allow industry to lobby regulators on issues like the evidence standards for new medicines, or how to assess the risks of pharmaceutical products in the environment. Other examples in this section relate to important public health projects on anti-microbial resistance that were undermined by industry dominance, and to conflicts of interest in patient training.

### a) IMI projects give industry opportunities to directly lobby regulators

Big corporations have a vested commercial interest in dismantling regulations that companies perceive as an obstacle for their business. Public regulations that intend to protect the environment, workers' rights, or public health, may create additional costs to business. As a result, businesses are well-resourced with teams of lobbyists, in order to push a deregulation agenda.<sup>127</sup> Scandals such as the 2017 revelations that the pesticides industry was editing the EU's Food Safety Authority's risk assessment on the chemical glyphosate,<sup>128</sup> have taught us that great caution is needed when the industry comes into direct contact with regulators. While strict independence of regulators and strong conflict of interest rules should be basic requirements, IMI is pushing in exactly the opposite direction.

Indeed, roughly €1 billion of public funding has been spent to date on IMI projects that support industry's policy agenda, including projects on how to assess the safety risks of new medicines and the environmental impacts of pharma products.<sup>129</sup>

IMI acknowledges that its projects are intended to have “direct or indirect impacts” on regulatory processes.<sup>130</sup> In the early days of IMI, EFPIA identified regulation on safety issues and risk assessments as one of the ‘pre-competitive’ bottlenecks to be addressed. IMI confirms that a “number of tools and processes developed by projects have been or are being reviewed by regulatory authorities such as the EMA [European Medicines Agency] and FDA [US Food and Drug Administration]”. Moreover, a senior official at Bay Pharma noted that some of their in-kind funding was in the form of “regulatory experts”; meaning from the outset they are allowed to lobby regulators on crucial issues like safety that serve their commercial interests while counting it as their ‘contribution’ to IMI.<sup>131</sup> These projects include highly sensitive regulatory areas such as developing tools for predicting and monitoring safety and methods for risk-benefit assessment.<sup>132</sup>

As noted above, scandals have shown that this kind of direct access to regulators is not advisable. Measures should be in place to ensure an appropriate distance or firewall between a profit-motivated business sector and those tasked with regulating it in the public interest. The European Medicines Agency itself notes that, “In general terms, EMA will not engage in regulatory science activities with pharmaceutical companies”, recognizing that “Joint activities of regulators and pharmaceutical industry are very sensitive and have the potential to create a negative perception with the general public”.<sup>133</sup>

Yet they did. Witness the AstraZeneca rep who said of the IMI's ADAPT-SMART project led by the EMA (in which industry “learned how to interact” with regulators) that, “Without IMI, it would have been more challenging”, referring to post-licensing evidence generation, after authorising a product that raised serious safety issues for patients (See Part 1, 4a, i below).<sup>134</sup>

Despite recognizing the risks, IMI is held up as a “neutral platform where industry engagement with regulators can take place.”<sup>135</sup> However, a closer examination shows imbalance in favour of the private sector that undermines the ‘neutral platform’ justification and risks giving industry free rein to lobby regulators.

*i) Case 1: IMI pushing controversial proposals to lower evidence standards for new medicines*

Several other IMI projects are supposed to get medicines to market faster. While it can be argued that this is in the interests of patients, public health groups warn this can have implications for the rigour of clinical safety tests.

ADAPT-SMART was an IMI project working on the accelerated approval of medicines through ‘adaptive pathways’. The term ‘adaptive pathways’ describes a process for lowering the initial level of evidence required for approving new medicines, ie changing the pathways by which medicines reach patients. The EMA describes it as having the potential to speed up access to medicines for patients. In this process, a medicine can receive early approval for a small group of patients, without submitting all the necessary scientific evidence. It can then receive wider approval when more evidence is gathered.

A similar project, GETREAL, is about incorporating ‘real-world evidence’ earlier into the drug development process.<sup>136</sup> ‘Real world evidence’ means that, rather than conducting randomized clinical trials on new medicines, where data is gathered in a controlled environment, data can be captured in the real world (eg through wearable devices or health apps). Proving the reliability of ‘real world evidence’ is critical to the adaptive pathways model, which depends on the idea that reliable data can be gathered after new medicines have entered the market.

Pharma companies have a strong motivation to pursue this approach. Randomised clinical trials, the “current gold standard for judging medicines”, are costly to pharma companies, both to implement and because they lose some of the time during which they can sell their medicine while it is still patented, the so-called ‘cash cow’ phase in a commercial product life cycle. If the risks of medicines could be assessed ‘in real time’, ie after they enter the market, this would be a valuable cost-cutter for companies.<sup>137</sup>

Yet while this new approach to risk assessment has the potential to bring medicines to patients faster, there is considerable debate about whether it is really safe and reliable.

**While adaptive pathways could bring medicines to patients faster, it is unlikely that the public interest is best served by putting industry in the driving seat to develop them.**

Some scientists have expressed concerns about adaptive pathways, noting that “Early market approval is sometimes associated with a higher rate of post-marketing safety warnings”.<sup>138</sup> In other words, some medicines that are approved before all the facts are in have been shown to have safety issues down the line. They also point out that ‘real-world evidence’ is essentially the same as “observational evidence”, where data is gathered by ‘observing’ what happens in the real world’, rather than in a controlled scientific setting. They caution that there is “enormous body of evidence calling into question the reliability of observational data to test hypotheses”.<sup>139</sup> Adding further reason for caution, they warn it is much more difficult to recall a drug once it has already entered the market, even if it is shown to be less effective than the existing drugs in the market or even harmful. This has potential implications for patient safety and national health budgets, if countries cannot withdraw expensive drugs that are shown to be no better than old drugs.

The EMA, who is working with IMI on adaptive pathways, conducted a pilot project on the approach. It drew in part on surveys gathered via the ADAPT-SMART project<sup>140</sup> and had the aim of testing the viability of plans put forward by companies to collect “real world data” on the risks and benefits of their medicines. However, the pilot’s final report published in 2016 showed the persistent unreliability of attempts to use real world data to gather information on the efficacy and safety of new medicines.<sup>141</sup>

IMI is held up by pharma as a ‘neutral’ platform where interaction with regulators can happen free from conflicts of interest. But this claim does not stand up to scrutiny. Take the ADAPT-SMART project, which is touted as a “Sustainable, Multi-stakeholder Approach from Research to Treatment-outcomes”, yet the breakdown of participants suggests the dominance of commercial partners: two research institutes, one SME, two patient groups,<sup>142</sup> and a total of twenty Big Pharma companies (almost all the big names in the pharmaceutical sector: Abbvie, Amgen, Astrazeneca, Bayer Pharma, Boeringer, GSK, Janssen, Eli Lilly, Merck, Novartis, Pfizer, Hoffman-Laroche, Sanofi, Servier) engaging with regulators.<sup>143</sup>

When we also look at the public-private balance in terms of who is leading the project, again we see that despite the publicity, it is tilted to industry. The project’s website states that each of its “work packages” are led by one “private” representative (from an EFPIA company) and one “public” representative, giving the appearance of a balance between private interests and public actors tasked with defending the public interest. However, this turns out to be very misleading. One of the “public” representatives is Lygature, self-described as an “independent third party”<sup>144</sup> which exists to “drive” the implementation of public-private partnerships. While it is technically a ‘non-profit’, it is also certainly not ‘public’ in the sense that it has no democratic mandate to defend the public interest.

Despite this, Lygature represents the ‘public’ side in two out of three work packages in ADAPT-SMART. One of its work packages is responsible for “designing” the methods for early market approval. In this package, only Lygature and EFPIA member Servier lead,<sup>145</sup> meaning there is no public actor in a leadership role in this highly sensitive work stream on “designing” proposals for how regulators can assess the risks of new medicines with less evidence.

In fact, with regard to the lack of public actors in a leadership role, neither the European Commission nor the IMI office are actively engaged in projects. The IMI office describes itself as having a “financial monitoring role” only in projects. Importantly, this means it plays no active role in mediating between participants. In other words, IMI does not act as a mediator between the industry and regulators in for example projects that address the safety standards for evaluating new medicines. This seriously undermines EFPIA’s presentation of IMI as a “neutral broker” bringing together “the regulated and the regulators”.<sup>146</sup>

Meanwhile, despite concerns about the reliability and safety of moving away from controlled clinical trials toward “real world evidence”, it looks like IMI is pushing forward. The draft Strategic Research Agenda for the successor to IMI, written entirely by industry, proposes “leveraging real world data” along the “healthcare continuum”.<sup>147</sup>

This reflects industry’s determination to move full-steam ahead, with one Astra Zeneca rep stating that they would soon like to see real world data “used much more aggressively than it is today”.<sup>148</sup> So while adaptive pathways could bring medicines to patients faster, it is unlikely that the public interest is best served by putting industry in the driving seat to develop them.

## *ii) Case 2: Pharma decides which pharmaceuticals are dangerous for the environment*

Another IMI project, this time related to the environment, also raises concerns about the public interest value of putting industry in the driving seat on sensitive regulatory issues.

The project Intelligent Assessment of Pharmaceuticals in the Environment (iPiE) aimed to “develop sound scientific methodology for prediction and screening of environmental hazards and risks of pharmaceuticals”.<sup>149</sup> Existing EU guidelines require environmental risk assessment for all new marketing authorisation applications for human medicinal products.<sup>150</sup>

However the guidelines don’t apply retroactively and therefore do not apply to pharmaceuticals authorised prior to 2006. This is a major issue because many pharmaceuticals for human use – such as hormones and antibiotics – detected in the environment were authorised before that date. iPiE sought to determine which of these legacy pharmaceuticals should be assessed first for targeted environmental risk assessment and/or environmental monitoring.

It is therefore highly problematic that the project’s participants are – once again – dominated by Big Pharma, with 13 industry participants, more than the combined total of all other participants, which include the German Environment Agency, one private consultancy, seven research institutes, and three SMEs.<sup>151</sup>

Public health or environmental NGOs are absent, despite the fact that several organisations exist who work closely on this sensitive issue, such as the European Environmental Bureau,<sup>152</sup> and Health Care Without Harm Europe<sup>153</sup> (HCWH), which works for environmentally responsible healthcare.

The inclusion of such organisations might have drawn attention to deficiencies in the public interest value of this project. Indeed HCWH had criticised iPIE due to issues with the focus of the project, as well as with governance and transparency. They questioned the reliability of a project in which industry itself (for whom withdrawal of products or enhanced safety measures can have costly implications) is in charge of deciding which legacy pharmaceuticals should be prioritised. They suggested a more public-interest driven approach would be for the European Commission to introduce a 'catch-up procedure' as it did with veterinary medicinal products, meaning that all pharmaceuticals that could pose a risk to the environment would be assessed, including those authorised prior to the guidelines coming into force (in 2006), and for the data to be made publicly available.<sup>154</sup>

HCWH also raised concerns about the lack of transparency around the project. There was for example no clear indication on how the money has been spent and there has been no progress report to date, at least nothing publicly available (which is symptomatic of a general lack of access to information about ongoing IMI projects).<sup>155</sup>

In terms of the content and focus of the project, the organisation expressed regret that the project looked at the environmental impact of pharmaceuticals, but didn't seek to assess the risk of antimicrobial resistance development in the environment, despite the fact that "the discharge of antibiotics and antimicrobial compounds from human and veterinary medicine into the environment is a driver for the development of resistant bacteria". This issue is described by UN Environment as "one of the most worrying health threats today".<sup>156</sup>

As noted at the outset, roughly €1 billion of public EU funding has been spent that gives industries with a vested financial interest in limiting regulations direct access to regulators on topics like on the safety of medicines for people and the environment. Is this really an appropriate use of public funding? The case studies on antimicrobial resistance noted below (see [Part 1, 4c](#)) highlight that where industry drives the projects, the results tend to favour industry's proposed solutions, which often involve less regulation and more public money flowing to industry, at the expense of alternatives that may better meet public interest goals, but are not as appealing for commercial interests.

## b) IMI project gives industry direct opportunity to lobby patients

Patient organisations are groups set up and run by patients to give them a critical voice in policy debates around public health. However, IMI funds projects which involve pharmaceutical companies training such patient representatives, which is of questionable public interest value as this can skew the groups towards acting as lobbying vehicles rather than patient empowerment.

For example controversial IMI project EUPATI<sup>157</sup> was criticised as being a lobbying school in which pharmaceutical companies could teach patients how to lobby for faster approval of medications.<sup>158</sup> This is in the interest of the companies, who want their products to get onto the market as fast as possible, but a concern for many public health groups, who fear the result may mean rushing through clinical safety tests or weakening of vital regulatory requirements, potentially to the detriment of patients' health.

The framing of EUPATI around “therapeutic innovations” has also been criticized, because it leaves out “proven effective therapies” and focuses only on “new” treatments.<sup>159</sup> The focus on new medicines is also problematic because, as has long been raised by public health groups, there is mounting evidence that most new medicines, in particular in areas like cancer, often bring little added therapeutic value.<sup>160</sup> While bringing new, expensive products to market is undoubtedly of added value to pharma companies, who can charge more while these products are still under patent, it is not always of value to patients or healthcare systems.

**Where industry drives the projects, the results tend to favour industry's proposed solutions, which often involve less regulation and more public money flowing to industry, at the expense of alternatives that may better meet public interest goals, but are not as appealing for commercial interests**

Several experts who joined the scientific advisory board of EUPATI released a statement citing strong concerns that industrial involvement meant there was a high risk that the project would not meet its aims and that robust conflict of interest rules needed to be in place. They opted to remain on the board in the hopes that they could serve to balance the interests in some way, while also expressing concern that industry participants and others could use their participation to legitimatise the project. Further to this, at least one of those members, an academic from the University of Hamburg who specializes in evidence-based patient information, resigned in protest at the lack of plurality. They noted that courses for patient representatives should provide an opportunity to encourage critical thinking, including about the pharmaceuticals industry, yet added: “But I doubt that works when those leading the courses come from the firms themselves”.<sup>161</sup> EUPATI has now become independent of the IMI and has been endorsed by IMI, the Commission, and EFPIA as an initiative which is “well-designed to meet the needs of patients and patient advocates”.<sup>162</sup>

There is significant potential for conflict of interest in unmediated relationships between patients and the pharma companies who have a vested commercial interest in maintaining the current system for drug development. A recent report from the *British Medical Journal (BMJ)* looking at pharma funding of patient organisations in the UK raised similar concerns. It found that pharma investment in patients' organisations was increasing, and that companies were most interested in funding “engagement with outside audiences”. This creates the risk that industry players are using patient groups as “third parties” that could “influence the public's and policy makers' perceptions, consistent with other industry marketing practices” and hence leverage “industry influence in areas like drug development and approvals, health technology assessment”.<sup>163</sup>

It also found the medical conditions funded by such schemes “reflected the industry’s commercial priorities” and that the “biggest donors in these condition areas have recently launched several high-priced drugs”.<sup>164</sup> In light of this, the economic rationale for IMI’s patient engagement platforms’ narrow focus on accelerating access to ‘new therapies’ may become clearer.

This is not an argument against the EU funding patient organisations. Patients’ voices are vital in the discussions, yet they lack the resources alone to organise. It is sometimes argued that industry can therefore step in to fill the funding gap, because this is somehow preferable to public funding.<sup>165</sup> But this is not convincing. The *BMJ* noted the important role of public grants, pointing out that the lack of public funding was contributing to the unsustainability of patient organisations,<sup>166</sup> as industry was only interested in funding PR and communications, and not the essential operational costs that keep organisations running.

The EU should support patient groups. However, through IMI it is doing so in a way that allows pharma companies – who have a well-documented track record of intensive lobbying and PR to defend their profit-maximisation, often at the expense of patients’ access to affordable and urgently needed medicines<sup>167</sup> – to be the ones teaching patients.

Public funds should go to support independent patient organisations and increase patients’ capacity to advocate for their interests in health-related policy making. But it should ensure patients are exposed to a diversity of perspectives, analysis, and solutions to systemic issues such as accessibility and availability of medicines, for example. The value of independent medical education is widely recognized, and the need for impartial health information is even greater for patient groups.

### c) Pharma dominates agenda setting and sidelines public partners in Anti-Microbial Resistance projects

Anti-microbial resistance (AMR) is one of the clearest areas of major public health interest and an urgent societal challenge. The World Health Organisation (WHO) defines AMR as “the ability of a microorganism (like bacteria, viruses, and some parasites) to stop an antimicrobial [treatment] (such as antibiotics, antivirals, and antimalarials) from working against it.”<sup>168</sup> The WHO identified AMR as one of the top ten global health threats of 2019.<sup>169</sup>

In particular, AMR is threatening a post-antibiotic era, and is “already making many standard treatments ineffective, with far-reaching and life-threatening consequences for humans, animals, and the environment”.<sup>170</sup> AMR is a critical priority for public R&I funding, with a strong case for public interest goals to ensure responsible access to antibiotics. AMR rightly receives significant attention from IMI, being one of the few examples where the project addresses actual ‘market failures’, and is also mentioned specifically in the IMI legislation.<sup>171</sup> As shown in [Figure 1](#), IMI has nine AMR projects currently listed. On the face of it this may appear to be a win for public interest goals. But on closer inspection it becomes clear that once again IMI’s corporate-friendly set up means that the public interest takes a backseat.

The two case studies below demonstrate how the very structure of IMI, ie delegating huge decision-making power to industry at both governance and project level, and an apparently absentee Commission, resulted in partners pulling out over severe ethical concerns being ignored and project outcomes whose public interest value is at best questionable.

In the first case, a Big Pharma project partner attempted to dictate an agreement to the other participants that would severely restrict access to data on clinical trials for project participants and the public. One non-profit research partner considered this an unacceptable ethical breach that went against the interests of patients, and left the project.

In the second case, a public partner raised concerns about possible conflicts of interest in the decision-making process behind a set of AMR recommendations for world leaders that arguably amounted to little more than industry lobbying for further financial incentives at the expense of other reforms. The partner eventually pulled out due to the lack of transparency around the handling of dissent.

*i) Case 1: Lack of open access for AMR project causes non-profit to pull out*

The example of COMBACTE raises concerns about the Commission's apparently passive approach to resolving a conflict between a pharma firm, and a research institute which had serious ethical concerns about said firm's control over the project.

In 2013 a new IMI anti-microbial resistance (AMR) project called COMBACTE, which receives more than €100 millions of EU public funding,<sup>172</sup> caused controversy. The project was aimed at coming up with new ways of designing and implementing efficient clinical trials for novel antibiotics. A non-profit independent medical research foundation, the Mario Negri Institute, left the project over ethical objections to the approach of pharma giant GSK. The 90-odd page project agreement drafted by GSK meant that other participants like Mario Negri, would “have had to ask GSK's permission to access the data from our own trial and that GSK reserved the right to block publication of our analysis of that data at any time after the study was completed”.<sup>173</sup>

The rules and conditions laid down by GSK effectively meant the study would not be collaborative, but controlled by GSK. For the Mario Negri Institute – which has been held up as a best practice example of a public health model for pharmaceutical research<sup>174</sup> – this was an ethical breach too far: “secrecy on clinical data implies undue exploitation of the rights of physicians and patients involved in the studies”, they said, especially since in order to protect the “interest of the patients, an independent review must be conducted by clinical researchers”. They rightly note that this breach is “even more inappropriate when publicly funded”.<sup>175</sup>

Mario Negri tried to negotiate with GSK, asking that clinical researchers who contributed subsets of data be allowed to look at the overall raw data before publication, but GSK's lawyers refused, insisting GSK “alone could decide who would ever see the raw data and for what purpose”, and that no one would have the right to publish anything about the outcomes of the study “without the company's written consent”.<sup>176</sup>

Mario Negri again proposed compromises, such as a two year embargo before publishing (to accommodate the company's arguments about needing secrecy during the regulatory approval process), but GSK remained inflexible.<sup>177</sup>

The Mario Negri Institute then sought help in finding a solution, explaining the situation in a teleconference with an official involved in the IMI.<sup>178</sup> They were told that it was not possible to interfere in the relationship between industry and the other participants in a consortium, since the participants had together defined the conditions by which that consortium would operate.<sup>179</sup> They were also told that, whilst the Commission or IMI Programme Office might have a view as to what conditions they consider fair (such as sharing of data and freedom of publication), it is nonetheless up to the consortium participants to decide otherwise.

Given that the Commission is expected to make sure that the public interest is protected in the writing of the rules that govern IMI consortia, it seems deeply problematic that these rules allow a consortium (or more often the dominant partners in it) to effectively deviate from conditions for a project that would best serve the public interest.

Facing the option of remaining in the project without access to the data, Mario Negri decided to withdraw in order to maintain consistency with its institutional policy, a decision they described as “painful” for a non-profit organisation that needs grants in order to survive. While they had originally been keen for the opportunity to – as they initially believed – cooperate with the industry on equal terms, thanks to the public funds they would receive, it soon became clear that it was not an equal partnership, which did not give the same type of rights and duties to both parties.<sup>180</sup>

They are at pains to point out that they are not a “difficult organisation”: Mario Negri has been a participant in other IMI (1 and 2) projects, with at least one still ongoing.<sup>181</sup> And in these projects, which were experimental rather than involving clinical trials, such problems were not encountered. However, the result of this imbalance of power meant that they were being asked to accept a study design they considered “unethical”.<sup>182</sup>

**Mario Negri called for reforms to the IMI’s framework, which they described as allowing industry to keep “interpreting public-private partnerships as ‘public duties and obligations’ and ‘private privileges and advantages’”**

At the time, Mario Negri called for reforms to the IMI’s framework, which they described as allowing industry to keep “interpreting public-private partnerships as ‘public duties and obligations’ and ‘private privileges and advantages’”.<sup>183</sup> Yet six years later, it is still possible for consortiums – and therefore often their most powerful members, the EFPIA companies – to write up project agreements however they like, including opting-out of all open access to research data conditions. And since these details are not made public, citizens have no way of knowing what conditions are agreed, whether some partners have been able to impose them on others, or just how far they deviate from public interest conditions.

Transparency and access were not the only issues with this project either. GSK also pressed major methodological choices – such as the comparator drug, ie the drug used as a comparison to the drug being trialled – onto the other participants. Mario Negri noted that they were presented with an already-prepared protocol, without any possibility of challenging the choice of comparator, which they considered very questionable. Other partners that chose to stay in the project also expressed concerns about this, for example Herman Goossens from the University of Antwerp (who viewed the data access restrictions as an inevitable cost of working with Big Pharma), noted that GSK’s comparator drug “would not have been my first choice”.<sup>184</sup> One reason the comparator was questioned, *Der Spiegel* reported, was that GSK’s drug was designed to combat a strain of the resistant MRSA bacteria that is rarely seen in Europe, though a major problem in the US, where a new antibiotic could be lucrative for GSK.<sup>185</sup>

## Box 5: Big Pharma can drop out of projects at will

Not only can Big Pharma companies exercise undue influence over the projects' conditions or communication, which has resulted in research institutions or academic groups leaving IMI, they are also allowed to back out of their project commitments without any penalties. In fact, EFPIA companies can pull out of projects, taking all their 'in-kind' resources, such as laboratories and staff, and thus abandon their commitments without any way of being penalised. According to the IMI rules they face no repercussions. The IMI2 interim evaluation confirms this problem, noting that "there is no system in place to guarantee that the industrial commitments in the project will be maintained". The premature withdrawal of EFPIA partners is described as "a major risk to successful project execution" with serious implications for both a project's content and budget.<sup>186</sup> And regarding the reasons EFPIA companies might drop out, the evaluation points to "[d]ecreasing interest or commitment from EFPIA companies and frequent changes in strategy". Once again, the IMI's set up works in industry's interest over the public's.

### *ii) Case 2: No space for dissent from Big Pharma policy objectives*

COMBACTE is not the only IMI project where participants have left after coming into conflict with Big Pharma. Though the IMI does not seem to list former members of project consortia on its project webpages, let alone their reasons for leaving (as was the case with COMBACTE), another AMR project – this time in IMI2 – called DRIVE-AB gained notoriety in 2017 when a project partner withdrew "due to problems of conflict of interest of the industry actors involved" and their "dominance" in developing the project's policy recommendations.<sup>187</sup>

ReAct, an independent network dedicated to the problem of antibiotic resistance and affiliated with Uppsala University, was part of DRIVE-AB. The project's stated goal was to "transform the way policymakers stimulate antibiotic innovation and to ensure that these new antibiotics are used sustainably and are available equitably", including the task of "developing and costing new economic models to promote the desired antibiotic innovation".<sup>188</sup> In other words, it did not conduct research into new antibiotics, but considered how to best encourage and enable that research to happen.

This is a highly important public policy debate, and solutions are far from agreed. On the one hand, the pharmaceutical sector proposes that more public money should be spent on 'incentives' to industry. On the other, many public health NGOs promote the model of 'delinkage' to encourage new antibiotics. This means ending the model of recouping the costs of R&I through the creation of monopolies (through patents) that allow companies to charge high prices. These, they suggest, should be replaced by rewards such as "innovation prizes" when milestones in the development of new antibiotics are achieved.

In its statement of withdrawal, ReAct noted that it had believed the project might come up with “truly transformative innovation models” that would ensure equitable access to new antibiotics.<sup>189</sup> However, it points out, “unresolved problems of conflict of interest in shaping policy recommendations” and a “lack of clearly established processes to guide decision-making”, led to serious concerns about transparency around dissent in the project. The final straw came when a commentary was submitted to a prestigious academic journal on behalf of the DRIVE-AB Steering Committee, addressed to G20 leaders. The article gave advice on how to incentivize antibacterial R&I, and placed a heavy emphasis on Market Entry Rewards for the industry (ie policy intervention that guarantees future revenue by providing a financially valuable prize to a manufacturer when their qualifying drug enters the market),<sup>190</sup> in advance of a G20 Summit shortly to take place in Hamburg.<sup>191</sup> ReAct highlighted that it included “recommendations that were not agreed upon nor supported by the full group”, a fact which the article’s authors did not make clear. ReAct withdrew from the project, noting that it could not “stand behind a process where recommendations ignoring key disagreements in the group are presented with the aim to be perceived as multistakeholder recommendations”.<sup>192</sup>

In its response to ReAct’s departure, DRIVE-AB issued a statement lamenting the loss of an “important voice within the project to represent civil society”, and referring to the challenges of “weighing” the input of all participants, and presenting solutions “in a timeframe that is relevant for policy makers”. It also acknowledged that “some improvements could have been made” including introducing a “more formal process” to foster consensus earlier in the project, and promised that minority views would be made “especially visible” in DRIVE-AB’s final report.<sup>193</sup> And when the final report was published in January 2018,<sup>194</sup> it did indeed better reflect that consensus was lacking on some of its core recommendations.

However, as ReAct noted, only a subset of the people who were heavily involved in deliberations during the project ultimately put their name on the final report<sup>195</sup> – suggesting that dissent and dissatisfaction with the process and industry domination continued.

Moreover, the main problem – the content of the recommendations the report provided – did not change. ReAct commented that merely stating that “Conflicts of interest were managed through full transparency of potential stakeholder biases”<sup>196</sup> in the report does not alter the rather stark fact that “its recommendations propose moving significant public funding towards the industry and organizations of some of its leading co-authors”, and that there is world of “difference between recruiting input from key stakeholders versus having those stakeholders author recommendations that favor their own interests”.<sup>197</sup> In particular, ReAct raised serious questions about the policy recommendations in the report, in particular that it promotes the concept of “partial delinkage” (see delinkage discussed above), meaning it still relies on the sales of antibiotics as a revenue stream for the company on top of Market Entry Rewards (one of the report’s main recommendations). They argue that by not fully delinking antibiotics from profit incentives, the proposal is “incompatible with global conservation and stewardship goals of new antibiotics”; and that it removes the issue of price – and therefore of affordable access – from how it defines delinkage. They point out that this is contrary to the definition adopted by the UN General Assembly which separates the costs of R&I from both sales volume and price. DRIVE-AB instead refers to delinkage as “making innovation more attractive for the developer” and “encouraging antibiotic stewardship”. They also argue that the proposal diverges from the project’s own original vision statement by removing the goal of ‘global access’ and instead talks about ‘equitable availability’ of novel antibiotics.

Yet availability is not the same as access, as a “product can be registered and available in a country, but still not be accessible for patients due to eg high prices”. They further criticize that the report’s policy recommendations focus disproportionately on Market Entry Rewards, a pull incentive which, whilst they may be one component amongst many needed to change the antibiotics R&I model, are “not a panacea”, and too much focus on them “risks diverting urgently need broader investments for early stage R&I, for improvement of global access to antibiotics and preventive measures.”<sup>198</sup>

Once again, IMI’s procedures allowed the setting up of a project which was an unequal partnership between Big Pharma – in this case EFPIA companies Astellas, AstraZeneca, MSD, Pfizer, GSK, Roche, and Sanofi-Aventis<sup>199</sup> – and the rest of the project’s partners. This project – which was two-thirds funded with EU public money<sup>200</sup> – was effectively co-opted by Big Pharma to lobby world leaders for innovation models that served their commercial interest. The model promoted involved diverting public funding to pay for “incentives” at the expense of other solutions to issues of access and affordability, an approach that public health groups are increasingly warning against.<sup>201</sup> Moreover this lobbying was presented in such a way as to give the impression that its recommendations were broadly supported by diverse actors, when they were not. As Helle Aagaard, Policy Advisor at ReAct Europe, concluded, “we cannot continue to rely on actors such as the pharmaceutical industry with such strong financial self-interests to provide the solutions to these problems”.<sup>202</sup>

A further reminder of the problem of putting industry in a dominant position with regards to solving antimicrobial resistance is reflected in a debunked 1999 position paper by EFPIA on the ‘Containment of Antibacterial Resistance’ that actually questioned whether antibacterial use (including antibiotics) contributed to resistance: “The often implied assumption, that resistance is caused by antibacterial use, and hence antibacterial use must be reduced, is based on a fundamental misconception about the nature of the biological phenomena involved.”<sup>203</sup> Shockingly, this was written just five years before EFPIA under the auspices of InnoMed, drafted the 2004 strategic research agenda (SRA) which became the basis for IMI’s 2008 SRA.

EFPIA’s since-debunked claim that over-use of anti-bacterials was not causing AMR – and hence that their use should not be reduced (which would mean fewer antibiotics sales for them) – is a stark reminder that an industry’s foremost priority is to maximize sales and profit, rather than to consider the impact on society.<sup>204</sup> So it should come as no surprise that the companies steering DRIVE-AB, proposed incentives and Market Entry Rewards as solutions, essentially prioritizing greater financial rewards for the industry in addition to profits from drug sales. This may not have been an issue if IMI was a truly balanced multi-stakeholder partnership. But as we have seen, and as will be further explored in [Part 2, 2](#) on IMI’s governance, the reality is that industry has immense control at all levels.

The DRIVE-AB project exemplifies the problems with IMI. Because industry can set the priorities, in this case they could choose to put a topic on the IMI agenda that was of strategic interest for them (how to incentivize AMR research), and then dominate the projects to push proposals that benefited them financially (ie more subsidies to industry), at the cost of proposals with a wider societal benefit.

#### d) IMI: improving access to medicines or entrenching a system with skyrocketing medicines' prices?

##### *i) Accelerating approval without guaranteeing access: gene therapies for cancer*

IMI describes its mission as to “accelerate patient access” to medicines.<sup>205</sup> In practice however the IMI’s focus is on getting medicines approved faster (“acceleration”), rather than, say making medicines cheaper to access. Acceleration, for example through adaptive pathways (see [Part 1, 4a, i](#)), is a strategic interest for the pharma industry, yet one that carries a lot of risks for patients and citizens. This focus on acceleration comes at the expense of a focus on reducing high prices for medicine, which would increase access but go against Big Pharma’s core interests.

It is notable, then, that IMI’s framing of the access issue simply does not address the high prices for medicines set by Big Pharma, an issue which has long been a crisis for low- and middle-income countries, and is increasingly a serious concern also for high-income countries including in Europe. The European Cancer League notes that “high prices and the burden they lay on European healthcare budgets are the primary obstacle for patients’ access to innovative cancer treatments”.<sup>206</sup> In one stark example, discussed in more detail below, Novartis’ new “high value blood cancer treatment” costs between €320,000 and €350,000.<sup>207</sup>

IMI works on several disease areas where access to medicines is of critical concern, and EFPIA is keen to tout IMI’s leadership on access issues.<sup>208</sup> However, academic analysis shows that IMI’s first research agenda, which was written by the pharma lobby, argued that access issues are the result of “governments’ unwillingness to pay high prices for new drugs”, rather than questioning whether those high prices are justified.<sup>209</sup> This approach is inherently wrong as high prices are often set simply because monopolies given to the industry allow them to do so, and commonly do not reflect the real costs of developing medicines. This comes at a very high cost to national health budgets which often cannot afford to pay for high priced medicines for all those who need them.

The European Parliament and the European Council have repeatedly called for new approaches to ensure affordability of health products, noting that the EU R&I programme has a key role to play.<sup>210</sup> Several international fora have also asserted the need to attach conditions to public research funding so that they become guided by principles of accessibility and affordability, and urged “delinking” financing of R&I from the price of medicines.<sup>211</sup> Numerous public health groups have also put forward proposals urging the EU to attach public interest conditions to its biomedical R&I funding.<sup>212</sup> However, despite the considerable public investments being made by European taxpayers, the EU currently does not attach safeguards or conditions to public funding of biomedical R&I to ensure the accessibility, availability, and affordability of medical products that result from such investment, including in IMI.

Unsurprisingly then, IMI's 'solutions', rather than addressing high prices through affordability provisions, focus on "acceleration", meaning regulatory reforms that benefit pharma. IMI also focuses on improving "efficiency" in the drug development process, with the idea being that this reduces costs, and, in theory, price. However, this argument conveniently ignores the fact that it remains entirely at the discretion of the patent holders, ie the pharma companies, whether efficiency gains that save them money will actually translate into lower prices for health systems and patients. As we will see below, this is certainly not guaranteed.

Cancer therapy is among the areas receiving the most attention in IMI, and one growing area of interest for IMI is CAR-T, a type of innovative personalised gene therapy that engineers patients' own T cells to fight cancer.<sup>213</sup> Yet CAR-T therapies are highly controversial in terms of access to medicines. For example, one of the first approved CAR-T therapies Kymriah is marketed by EFPIA member Novartis; Kymriah is prohibitively expensive, costing between €320,000 and €350,000 for one intravenous treatment. Public health groups have opposed the patent license to Novartis.<sup>214</sup> They argued that Novartis' patent is illegitimate because CAR-T has "not been invented by Novartis but was essentially developed through university research and public funding".<sup>215</sup> The European Cancer League also questions<sup>216</sup> industry claims that high R&I development costs were the reason behind the high price tag, noting the significant public funding behind the development of CAR-T.<sup>217</sup> They warn that this therapy will put intense pressure on national health budgets if the price is not dropped.

IMI is driven by pharma companies with a commercial interest in maximising profits and with a strategic interest in resisting reforms that delink the high price of medicines from the costs of R&I and attach access conditions to public funding. It is therefore unlikely that IMI-funded work would contribute to improving access to CAR-T for patients. In contrast, in Switzerland<sup>218</sup> (Novartis' home), as well as in Italy and Spain, leading university hospitals are teaming up to develop their own, non-commercial cancer cell therapies, and they hope to offer the treatment at a fraction of the current commercial price. These examples of public options for making life-saving drugs indicate that there may be better models of how to spend public funding to support patient access.

### *ii) Cutting production costs without ensuring drug supply: the case of HIV drug flucytosine*

One IMI project highlights IMI's failure on access issues in particularly stark terms, as investigation reveals that IMI's hype around helping to make a HIV treatment more affordable does not stand up to scrutiny.

CHEM21 is a project focusing on making "the drug development process more environmentally-friendly", which it claims will "help the pharmaceutical industry to cut costs, resulting in cheaper medicines for patients".<sup>219</sup> It includes the development of a "new, more efficient way" of producing a drug known as flucytosine, used to treat a common and often deadly fungal form of meningitis in people with HIV/AIDS (making it also one of the only IMI projects to relate to HIV/AIDS, see [Figure 1](#)). IMI claims that it is "expected to decrease drastically costs of production, and so make the medicine more affordable for the many people with HIV / AIDS who live in low income countries".<sup>220</sup>

Such a claim depends however on the assumption that the high price of flucytosine results from the high costs of production. Yet the story of access to flucytosine is more complicated.

Flucytosine is a 60 year old medicine, and was once used for cancer treatment but it is also a critical medicine for the treatment of cryptococcal meningitis, one of the main causes of death of people with HIV.<sup>221</sup> An estimated 181,000 AIDS deaths each year are due to cryptococcal meningitis, and medical NGO MSF states that combining flucytosine with other drugs “could cut cryptococcal meningitis death rates from 70 per cent in low-income countries to less than half”.<sup>222</sup>

Flucytosine is on the World Health Organization’s 2019 List of Essential Medicines, which lists the safest and most effective medicines needed in a health system.<sup>223</sup> However, it is not available in most of Asia and Africa. In sub-Saharan Africa where flucytosine is largely absent, the death rate is much as 70 per cent, a figure comparable to Ebola. So “where the need is greatest, flucytosine remains entirely out of reach”.<sup>224</sup> A 2013 Lancet article on access to cryptococcal meningitis treatments noted that “the main barriers to access to flucytosine include absence of drug registration and generic drug manufacturing in low-income and middle-income countries”.<sup>225</sup> The registration of medicines is “the process by which a national regulatory authority approves the use of a medicine in a country, having considered evidence of the [m]edicine’s safety, quality and efficacy. It is thus primarily concerned with protecting public health”.<sup>226</sup> But the cost of a medical product registration might make pharma companies reluctant to register their product in a country where there are insufficient market opportunities for making profits.

MSF has been campaigning for registration of affordable flucytosine for several years. They argue similarly that “pharmaceutical corporations have not registered the treatment in high-burden countries that are not able to pay the exorbitant prices charged by US corporations”.<sup>227</sup> Indeed, while the medicine has been for sale on the global market for over 60 years, the price has significantly gone up in recent years. While a decade ago the product was for sale in the US for \$6 per day, in mid-2018, the product was for sale in the US at a price of \$2000 per day.<sup>228</sup>

While a generic version of flucytosine has been approved, controversial pharmaceutical company Mylan<sup>229</sup> obtained the license in 2016 and, according to MSF, “promptly doubled the price”.<sup>230</sup> The generic price of flucytosine is approximately US\$120 for a week-long course, and while significantly lower than the previous on-patent price, MSF points out that this is still “unaffordable and unavailable to most people in need” and has urged the company to “prioritize its registration more broadly in low- and middle-income countries”.<sup>231</sup>

The issue of affordability of flucytosine is not a matter of high production cost: the production of flucytosine is very similar to that of the HIV medicine emtricitabine. MSF notes that, because this drug is an intermediate product in the synthesis of another antiviral drug “which is used worldwide”, it “should not require a considerable investment on the part of generic... manufacturers to produce [the product]”.<sup>232</sup> The high cost is in reality a matter of price gouging and profit maximization in a context of lacking competitive pressure to keep prices down.

Cutting production costs of a medicine to reduce its price – what the IMI’s CHEM21 project is trying to achieve – could be a valuable endeavour, as is scaling back pharmaceutical waste. Yet necessary safeguards are also needed to ensure that these lower production costs are reflected in a drop in the price of the end product. Otherwise publicly-funded efficiency gains that reduce production costs will only benefit the company owning the rights with larger profit margins. The IMI project does not spell out how efficiency gains in production cost will translate into lower prices for patients and healthcare systems.<sup>233</sup>

Moreover, moving from innovation in drug production to access is not necessarily straightforward. Once a new process has been discovered, it must then be brought to scale and applied in the manufacturing of the drug before any cost-saving benefits can be realised.

The key participants in the CHEM21 project were Durham University, which originally developed<sup>234</sup> and patented<sup>235</sup> the new process, and EFPIA member Sanofi. Sanofi contracted out French group MEPI (Maison Européenne des Procédés Innovants) to design a scaled-up plant to produce the drug, which was successfully achieved by early 2017.<sup>236</sup>

Pierre Meulien, the Executive Director of IMI, said: “This is an excellent example of how through IMI, universities and pharmaceutical companies can work together to deliver a promising discovery that addresses an unmet medical need, and then rapidly progress it to a larger scale.”<sup>237</sup>

Except the “rapid progress” seems to have slowed to a halt after the project ended. Neither Sanofi nor any company seem to have started manufacturing flucytosine with this new method. According to sources familiar with the project, Sanofi is now controlling the intellectual property (IP) for the upscaled manufacturing process and is likely to have entered into an IP transfer agreement with Durham for the original process. Sanofi did not respond to our repeated questions to clarify this, and Durham refused to comment on this point, citing confidentiality issues.

Durham University told us that they “own some of the IP arising out of the project”, which they “have patented but not yet licensed”. We were also told that they are “active in looking for ways to ensure this technology is used” for both commercial and social responsibility purposes (for example in low and middle income countries).<sup>238</sup>

Two years later, a Sanofi factsheet merely notes that a technology transfer “would be proposed”<sup>239</sup> to the South African company Inicio/ Pelchem, which specialises in fluor-based compounds thanks to abundant local resources (Fluor gas is a precursor to flucytosine in this process). Yet we could not find any evidence that discussions between these two companies even started (neither of the two companies replied to our questions).

For Durham, this is part of longer term project on the use of application of fluorine gas in industry, and is touted as one of their “successful knowledge transfer partnerships with industry”.<sup>240</sup> Universities make a significant amount of their income from the transfer or sale of licenses to industry to commercialise the results of their research. Public health NGOs advocate for universities to implement “socially responsible licensing” to ensure that such knowledge transfers come with conditions to ensure access to the results, especially for low-income countries. Durham however does not appear to have a policy of using socially equitable licensing, nor the European Commission requires or encourages the use of it or other forms of public-interest driven licensing as a condition for IMI (or any other EU biomedical R&I) projects.

The CHEM21 project page notes that the patented process, with its efficiency gains and potential cost-savings, can also be applied to capecitabine, an off-patent cancer drug which Sanofi does sell, and emtricitabine, the commonly used HIV treatment, Atripla.<sup>241</sup> This raises the question whether this publicly-funded project advertised as rescuing the poor will really result in a reliable supply of affordable flucytosine, or instead provide Sanofi with a competitive advantage in the production of two of its existing medicines?

**Necessary safeguards are also needed to ensure that these lower production costs are reflected in a drop in the price of the end product. Otherwise publicly-funded efficiency gains that reduce production costs will only benefit the company owning the rights with larger profit margins.**

Meanwhile, as Sanofi takes its time, people with HIV continue to die in Africa for not having access to flucytosine. International global health organisations like UNITAID are attempting to help by buying the drug from generic manufacturers.<sup>242</sup> MSF’s campaign to push Mylan – which currently owns the license for flucytosine’s generic production – to register flucytosine in African countries seems to have delivered some results. According to MSF<sup>243</sup>, Mylan has moved the manufacturing site to India to reduce flucytosine production costs and finally filed to register the medicine in South Africa in December 2019 and with WHO Pre-Qualification (PQ).<sup>244</sup> It took time, but thanks to public pressure things seem to be finally moving in the right direction. Although it remains to be seen whether Mylan will register flucytosine in lower-income African countries.

But the new production method developed by CHEM21 with EU funding has so far not played any role in these developments. Increasing patient access to affordable flucytosine was a commendable goal. Yet IMI appears not to have sufficiently grasped the factors that hindered patient access to affordable flucytosine. Pfizer, another EFPIA member provided a related antifungal medicine for free to developing countries for many years,<sup>245</sup> following public pressure. This suggests that companies can be encouraged to prioritise patient access where it is most needed.

It is therefore all the more regretful that IMI has not leveraged its investment in research in flucytosine to drive down prices and ensure availability, by attaching affordability and availability conditions and/or by ensuring the investment brings price competition in the market. Meanwhile, IMI's CHEM21 project – advertised as rescuing the poor – has not yet resulted in a supply of affordable drugs for people living with HIV/AIDS in low-income countries.

### e) Big decisions over health data behind IMI's closed doors

One of the most concerning ways that IMI enables corporate interests – rather than serving public interest goals – is in giving industry the chance to write the future rules on how our health data is governed. This opportunity for industry to shape the regulatory environment could create a privacy, safety, and ethical minefield.

The pharmaceutical sector is increasingly looking into the potential offered by Big Data and Artificial Intelligence (AI) via the digitization of health records, a veritable 'data goldmine'.<sup>246</sup> This holds out potential promise of advances such as personalised medicine, but also comes with major privacy concerns.<sup>247</sup> Meanwhile complex issues such as ownership and control of health data, not to mention the risks of using 'real world' data over traditional randomized clinical trials, need serious public scrutiny and debate, without commercial interests setting the agenda. Yet IMI's governing members are keen to shape the regulatory environment for health data, and are bringing more tech-related private sector participants into the successor to IMI to do so.

Indeed the early proposals for IMI's successor partnership (IMI2 runs till 2020 and will most probably be replaced by 'Innovative Health Initiative') suggests that pharma lobby EFPIA should team up with big data, medical technology, and biotech companies.<sup>248</sup> This is a general trend in the industry: for example one EFPIA company, Roche, recently made a US\$2 billion purchase of Flatiron Health, a company that collects oncology data.<sup>249</sup> Meanwhile pharma companies across the board are hiring high level staff with experience in the digital and tech sectors.<sup>250</sup>

Undoubtedly this kind of integration could bring benefits for patients, and these potential benefits are being touted both by industry and the European Commission at every step.<sup>251</sup> It is also potentially highly lucrative, a veritable "gold mine"<sup>252</sup> with projections of a global digital health sector valued at US\$6 trillion within the next few years.<sup>253</sup>

The opportunities for patients and industry in large part revolve around the collection of and access to patient and population data, for example to 'machine learning', or AI to deliver precise diagnosis, personalised treatments, better care, and other benefits".<sup>254</sup> But such opportunities also come with privacy, ethics, and security risks for patients and citizens.<sup>255</sup>

The public is already very familiar with the risks of data harvesting by the tech sector, for example the misuse of personal information collected by Facebook by the political consultancy Cambridge Analytica, both for Donald Trump's 2016 election campaign and the UK's Brexit referendum.<sup>256</sup> Currently, public policy debates beyond health are focused on how to respond to such scandals, ie by regulating the tech sector and protect citizens' data, for example through GDPR, the EU's recent general data protection regulation.<sup>257</sup>

Such concerns translated to the health sector are not groundless: there are already examples of the digital health sector abusing patient data. A British hospital trust found itself in trouble in 2017 for “passing on personal information of around 1.6 million patients to artificial-intelligence firm Google DeepMind”.<sup>258</sup> Meanwhile ProPublica in the US reported in 2018 that breathing machines for people with sleep apnea were “secretly sending usage data to health insurers” who used this information to justify reducing how much they paid out.<sup>259</sup> And *The New York Times* reported in 2018 on a healthcare start-up that sold data collected from its digital thermometers. The purchaser, a multinational manufacturer, used the information to target advertising of their products, like disinfecting wipes, at zip codes with increased thermometer use.<sup>260</sup>

Tailored healthcare means releasing health data into the global data ‘supply chains’ that underpin this new economic imperative,<sup>261</sup> and so properly addressing the risks of misuse of data will be critical to realising the full potential of personalized medicine. Hence regulations like GDPR that manage access to data to prevent citizens’ data from being commercially exploited are positive steps in protecting citizen’s interests.

However, GDPR appears to be a target of criticism by those driving the digital health agenda. Some countries such as Israel are taking a less cautious approach to data protection to facilitate more commercial exploitation,<sup>262</sup> and despite the risks of this approach, this move appears to be triggering pressure inside the EU to revisit our data protection rules. In October 2018 EFPIA hosted an event criticizing the impact of GDPR on health research<sup>263</sup> and did so in partnership with an organization called the Future Privacy Forum, whose top corporate donors include Amazon, Apple, Facebook, Google, and Microsoft; all companies with an interest in limiting stringent data privacy rules.

At the IMI Forum in June 2019 the introductory presentation by the former Head of the Italian Medicines Agency argued that GDPR could make the EU “non-competitive” and that access to health data for companies is “impossible with the limits” of GDPR.<sup>264</sup> Such pushback could be concerning when we recall that measures like GDPR are a response to the uncovering of repeated scandals regarding misuses of data for commercial and political motives.

Such exclusive and non-transparent forums driven by commercial interest are not appropriate platforms for defining the direction of future regulations. IMI, a partnership that excludes scientists and academia as well as civil society organisations from its key governance mechanisms (see [Part 2, 2](#)) should under no circumstance be entrusted with implementing this new agenda.

But rather than opening up, the successor to IMI threatens to entrench its approach. The industry has already drafted a proposal for a strategic research agenda for the next partnership (see Box 6), and worryingly, it proposes to put the critical issue of developing data access rules within IMI’s remit. The minutes of the IMI Governing Board – which includes both the European Commission and EFPIA – show an agreement “that regulatory issues with digital therapeutics should be addressed” within IMI.<sup>265</sup> If the proposed successor partnership ramps up industry dominance, this risks putting the rules for access to data into the hands of industry that have vested interests in the commercial use of technology and patient information.

There's also the question of added value for EU funding. The roadmap for IMI's successor argues that there is "limited collaboration" between industries in the digital health space, and hence this means public money should be spent facilitating such collaboration.<sup>266</sup> Yet this assumption is not borne out. Companies in digital and health sectors have a major commercial incentive to invest in the digital health transformation,<sup>267</sup> and pharma executives are publicly stating that "there is no choice but to do partnerships", and that we "are going to see more deals".<sup>268</sup> Given this, and keeping in mind that IMI is meant to be directed "areas of unmet medical need",<sup>269</sup> the case for additional public EU money is hard to justify.

**If the proposed successor partnership ramps up industry dominance, this risks putting the rules for access to data into the hands of industry that have vested interests in the commercial use of technology and patient information**

## Box 6: EFPIA still shaping the next EU health partnership

The next EU framework programme for Research and Innovation (Horizon Europe) will kick off in 2021. It will more than likely include a successor to IMI, and will probably be called the "Innovative Health Initiative". The IMI office has claimed that officially IMI and its Governing Board, made up of EFPIA members and European Commission officials, have no role in preparing the next IMI.<sup>270</sup> However, freedom of information requests show that the IMI office was involved in convening meetings to come up with narrative and objectives for the new partnership.<sup>271</sup> They also reveal that once again Big Pharma is in the driving seat, setting the agenda and using its position on the IMI Governing Board to lobby against reforms of the new partnership.

Governing Board minutes from as late as June 2018 show that considerable discussions have taken place between Board members EFPIA and Commission on the future of IMI:

- March 2018 minutes show EFPIA using its position on the Governing Board to lobby against efforts to reform IMI's IP regime and to make in-kind funding from industry more accountable.<sup>272</sup>

*(Continued overleaf)*

- June 2018 minutes show that EFPIA lobbied against “mandatory cash requirements” from industry and wanted to discuss issues of “governance and transparency”, and that they proposed to work “together” with the Commission (rather than “in parallel”) on the next partnership,<sup>273</sup> basically using the Board to stay close to the process. The minutes also show EFPIA also seemed to take the lead in seeking out new partners (from industry).<sup>274</sup>

Out of these discussions a working group was set up in 2018. Between October and December 2018, at least six meetings were held between Commission directorates and EFPIA and EFPIA’s chosen partners.<sup>275</sup> Topics under discussion included “criteria for the next partnership”, “funding and governance models” and “expected contributions” from partners.<sup>276</sup>

Continuing into 2019 EFPIA has played a leading role in planning the next stage of IMI: EFPIA and industry partners have drafted the next Strategic Research Agenda<sup>277</sup> for the next partnership.<sup>278</sup> In a bizarre move, EFPIA also launched a so-called “public consultation” on this draft agenda.<sup>279</sup> This is perhaps an attempt to give a veneer of inclusiveness to the process, but only serves to highlight the entrenched industry domination which the European Commission is facilitating by not ensuring a genuinely inclusive agenda-setting process overseen by public actors and with all stakeholders engaged on equal footing.

Serious conflict of interest issues are evident here, including EFPIA using its position on the Governing Board to lobby decision-makers on the next partnership. And it is entirely unclear how the IMI’s Governing Board can play no role in the future partnership – as the IMI office claims – when EFPIA, half of Board, are clearly instrumental in drafting the agenda and bringing in partners. Not to mention that the Director General of EFPIA, Nathalie Moll, sits on the IMI Board, and it is highly unlikely decisions on how to shape the next partnership are taken in EFPIA without her awareness. Perhaps of most concern, is that industry has taken control of the public input into the agenda for this future EU initiative. This is a massive step in the wrong direction, when reform is needed towards inclusive multi-stakeholder agenda-setting, and it raises the concern that the European Commission once again is ceding control over billions in EU public funding to industry.

## How and why was the public interest sidelined?

Serious questions are raised by the examples set out in Part 1 about the ability of IMI to meet public interest goals, including its own stated aims. The market failures that form the justification for IMI are not being addressed. Funding meant for areas of research neglected by the private sector is not reaching them; at best there is no clear added value for European competitiveness, and at worst European SMEs who take part run the risk of being exploited by the biggest and most powerful players in the industry.

In terms of accountability, with over the €2.6 billion of public money already committed to IMI and IMI2, we must ask how a partnership which was set up under a public research and innovation programme is failing to ensure that the public interest is defended? To answer this, the following section assesses IMI's goals, governance, and agenda-setting processes, as well as its the accountability mechanisms. Our analysis show heavy industry dominance both in the governance structures and the agenda-setting mechanisms, while lack of transparency remains a serious issue for IMI's governance and industry's financial contribution to IMI's budget.

### **1. Incoherent public and private goals on a collision course**

The first question to address is the coherence of IMI's goals. From the start, IMI's overarching priorities and objectives – to improve “the efficiency and effectiveness of the drug development process”<sup>280</sup> – were established under the direction of trade association and corporate lobby group the European Federation of Pharmaceutical Industries and Associations (EFPIA). And sure enough, as academic analysis has shown, EFPIA has duly steered the IMI's agenda, from its original position papers back in 2004 through to the Strategic Research Agenda adopted by the IMI in 2008.<sup>281</sup>

As noted in Part 1 (see [Box 1](#)), letting industry set the agenda was the stated intention of IMI. But at the same time, the partnerships were also intended, even if indirectly, to address key societal challenges in the public health sphere. Indeed, the Commission talks of IMI being “particularly well suited to answering both EU public health and economic needs”.<sup>282</sup>

However, the absence of a coherent analysis of how this should work is stark. Even the interim evaluation of IMI2 has questioned the coherence of this set-up, noting that the different “goals and modes of operations of industry and the public partner appeared to interfere with the efficiency of the decision making process”, as the Commission’s Governing Board members “must report on socio-economic benefits of IMI2 JU [Joint Undertaking] to the European Parliament ... while the [Governing Board] members from EFPIA represent interests of global pharmaceutical companies, which are focused on growth, net profit and bringing benefits to their shareholders”.<sup>283</sup>

For defenders of IMI, the link between ‘market wealth’ and ‘public health’ is more or less taken for granted, ie the assumption that pursuing industrial competitiveness through funding industry priorities will translate naturally into better public health outcomes for society. The heart of the issue therefore is that the political justification for IMI rests on the assumption that a public-private partnership whose research agenda is steered by companies with vested interest in profit-maximisation can somehow simultaneously achieve the very different aims of increasing industry competitiveness and addressing public-health needs. It ignores the fact that all too often these aims are contradictory.

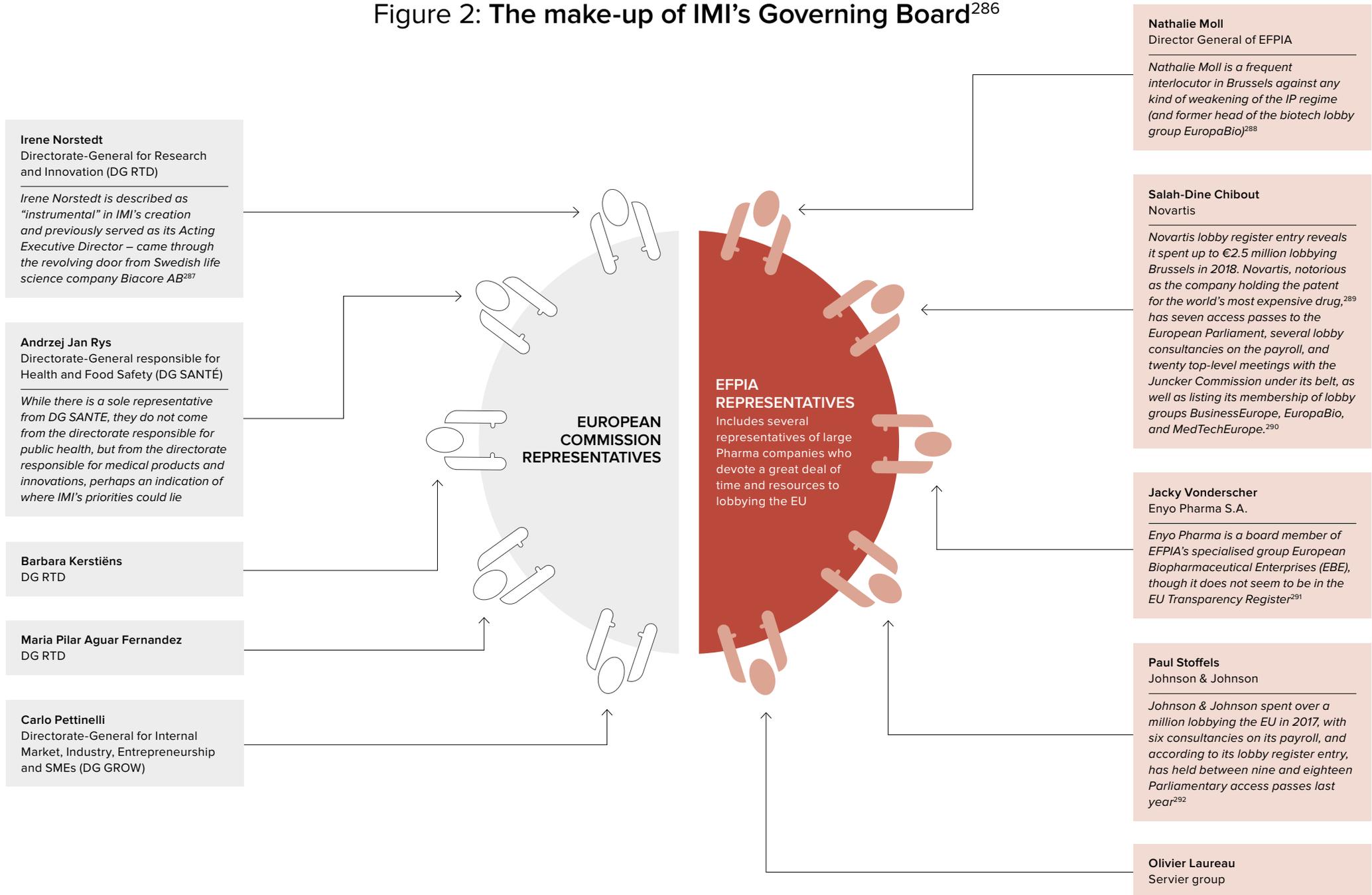
Indeed, is it any wonder that the actual outcomes of such a set up are that the research priorities focus on areas with potentially large markets and high profits, given that the framing of IMI “largely ignores disease prevention or public health, except where they favour development of new diagnostic products, thereby aligning societal benefits with a particular techno-fix”?<sup>284</sup> And not only are techno-fixes prioritized over other possible solutions, but policy recommendations that emerge to deal with issues like access and affordability of medicines, favour, quite unsurprisingly, the carrot over the stick for industry. If incoherent goals threaten to undermine the societal impact of IMI, the next key question is whether appropriate governance structures are in place to defend the public interest?

## **2. Private interests dominate IMI governance structures**

### **a) Imbalance of private over public in IMI’s Governing Board**

The IMI – as a partnership between the European Commission and EFPIA – has a Governing Board composed of five Commission representatives and five EFPIA representatives (the chair is held alternately). As the IMI’s highest decision-making body, it must take decisions by a majority of at least 75 per cent of all votes.<sup>285</sup>

Figure 2: The make-up of IMI's Governing Board<sup>286</sup>



## Box 7: Big Pharma’s lobbying aims at odds with public research interests

Novartis is a member of BusinessEurope, Brussels’ most influential business lobby group, whose partner companies also includes EFPIA members Bayer, Johnson & Johnson, MSD and Pfizer.<sup>293</sup> BusinessEurope has lobbied to “increase the proportion of industry evaluators” in Horizon 2020 projects, and lobbied against open access by default for research data in public-private partnerships. It has also warned about involvement of citizens in R&I agenda setting, stating that it must “avoid situations of decision-making processes being delayed or initiatives being minority driven”.<sup>294</sup> And that public-private partnerships in research should only get ‘in-kind’ contributions from companies, as trying to raise “up-front cash funding from companies” discourages their participation (see [Part 2, 5](#) on in-kind funding).<sup>295</sup>

**It is highly questionable how the public interest is served by the Commission responding to official evaluations by seeking to deflect criticism through a communications campaign.**

It must be asked whether it is in the public interest to give major agenda-setting powers to entities whose lobby activities demonstrate an intense commercial interest in shaping funding and regulatory agendas in the EU.<sup>296</sup> For instance, the last Chair of the Governing Board, Jean-Christophe Tellier, is the Chief Executive of Belgian pharmaceutical company UCB which spent up to €300,000 lobbying EU in 2018.<sup>297</sup> Tellier is also a member of US Big Pharma lobby group Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA recently lobbied the US Government to pressure the European Commission not to tamper with its intellectual property rules or system of pharmaceutical incentives and rewards,<sup>298</sup> a system that is currently under scrutiny over whether it is skewed in favour of the industry’s commercial interests at the expense of access to affordable medicines.<sup>299</sup>

### b) Is the European Commission defending the public interest in IMI?

At the very least, the half of the Governing Board composed of European Commission officials, representing the public interest (and purse), should in theory be equipped to balance the private interests. Particularly given that the Commission believes its role in defending the public interest is sufficiently strong in its PPPs not to require any direct citizen involvement, as evidenced by comments from a Commission official that “the Commission represents the citizens”.<sup>300</sup> We asked the Governing Board directly how it defined and defended the public interest and monitored the societal impact of the partnership.

Its response noted that “the Commission holds 50 per cent of the voting rights in the JU Governing Board”, its positions are determined “collegially” and “no decision can be adopted there if the Commission does not agree”.<sup>301</sup> Yet the evaluation of IMI2 found issues with the alignment of public and private agendas in the Governing Board,<sup>302</sup> noting that the different goals of the Commission and pharma industry “may complicate negotiations” and “interfere with quality of the decision making process”. Further, the minutes of the Governing Board meetings are not made public. And as was noted above, there is the issue of some officials coming through the revolving door from industry. It is reasonable to expect, in a partnership where private companies have already been delegated a great deal of power to set the agenda, that at a minimum the Commission officials tasked with balancing these private interests must be un-affiliated with industry.

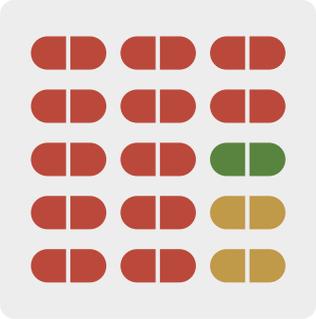
With regard to how the European Commission defines the public interest or societal impact in such partnerships, the Governing Board response points to the IMI’s legal base, and to a broad range of EU policies and priorities.<sup>303</sup> One issue with such a broad definition of the public interest is that it is not clear how a clash between any of these policy objectives would be handled, for example between competitiveness and sustainability goals. Furthermore, alignment with EU objectives does not rule out the possibility of establishing public interest criteria within partnerships to ensure that societal impact is consistently prioritized. Yet the Commission’s response is silent on this question.<sup>304</sup>

The Board response also notes that “the societal impact of the IMI2 JU is being monitored through a set of dedicated key performance indicators (KPIs)”. Yet, as noted in [Part 1, 3a](#), these KPIs were only developed recently, after ten years without indicators, and the first results of the KPIs show poor results in addressing WHO Priority Medicines and ensuring open access.

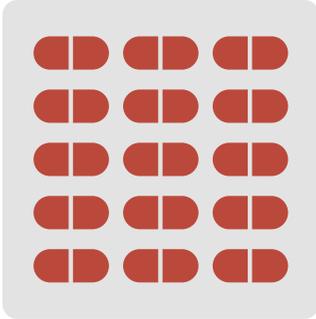
## Box 8: The Commission deflects criticism of IMI

Documents obtained under freedom of information laws reveal activities by the Commission that question its commitment to primarily defending the public interest. The documents show that the European Commission’s DG RTD was so displeased by the negative findings in the IMI1 final and IMI 2 interim evaluations – complaining that “deficiencies” meant the reports “do not clearly demonstrate the achievements of IMI” – that it suggested to the IMI2 Programme Office that they together prepare “a short fact sheet quantifying the main achievements of IMI, to be released in parallel with the evaluation reports” and “clearly demonstrating the value of IMI”.<sup>305</sup> The ‘short factsheet’ ended up as a 21 page brochure entitled ‘Carrying the torch for medical innovation’. Following the Commission’s advice of ‘quantifying’ its achievements, this brochure claims that the “added value” of IMI is “demonstrated” by the high number of scientific publications and citations its projects produce.<sup>306</sup> How exactly this demonstrates added value is not explained; papers and citations are not an indicator of societal impact or improving public health. It is highly questionable how the public interest is served by the Commission responding to official evaluations by seeking to deflect criticism through a communications campaign.

Figure 3: A closer look at the composition of the seven Strategic Governing Groups (SGGs) shows the massive imbalance in real agenda-setting power



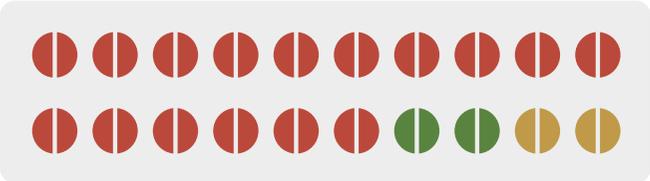
DIABETES / METABOLIC DISORDERS



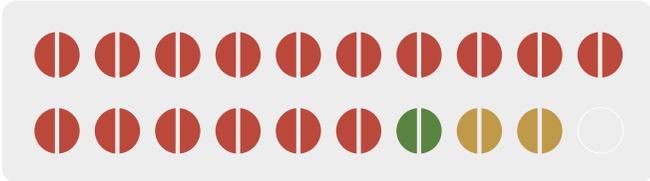
INFECTIONS CONTROL

- EFPIA representatives
- European Commission representatives
- Scientific Committee representatives

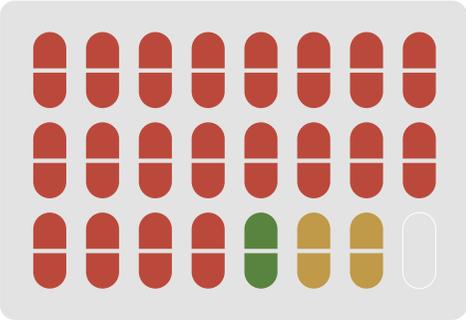
IMMUNOLOGY



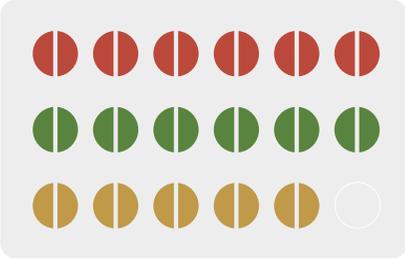
TRANSLATIONAL SAFETY



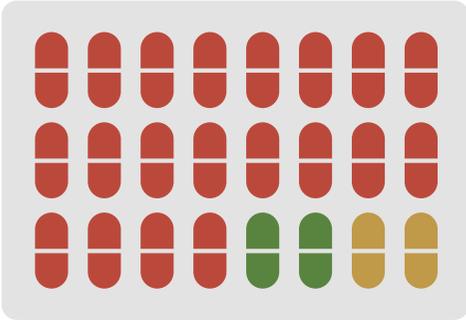
NEURODEGENERATION



DIGITAL HEALTH & PATIENT-CENTRIC EVIDENCE



ONCOLOGY



## Box 9: Commission staff struggle to access ongoing IMI project information

One very practical criterion for ensuring the Commission is able to hold IMI to account is its ability to access information about IMI and its projects. However, as late as 2018 meeting minutes (accessed under a freedom of information request)<sup>307</sup> show that DG RTD flagged the problem of European Commission services still not being able to access research results from the Joint Undertakings, raising the question of what was going on for the entire decade before this. They noted the “importance and necessity for policy units in the Commission to have full, unrestricted online access to detailed... project data and deliverables, including project mid-term and final reports and respective assessments by project officers, for the purpose of developing, implementing and monitoring Union policies or programmes”. According to the minutes, the JU representative indicated that Commission staff “were always welcome to ask JU programme/project officers about activities”. However this only further highlights the hands off approach from the European Commission, as formal accountability mechanisms were not already in place. This is finally being addressed, and “direct access to project information and results for the Commission services” was listed as one of the main findings of the “Lessons Learned” on Joint Undertakings in Horizon 2020.<sup>308</sup> It remains to be seen how this will be implemented in practice.

## 3. Big Pharma dominates in IMI’s agenda-setting processes

The Commission’s response to our question on the IMI governance and accountability mechanisms notes that the strategic research agenda “was developed by the (EFPIA) in cooperation with the Commission and is fully aligned with both the EU’s health research priorities... and the World Health Organisation’s Priority Medicines for Europe and the World report”.<sup>309</sup> This confirms that the Commission does indeed allow the industry to write the agenda – and IMI itself explains that EFPIA was “entrusted with the preparation of the SRA”.<sup>310</sup> However, our analysis shows that research agenda and the actual projects funded under IMI are not sufficiently aligned with the WHO list and the overall funding is focused on areas of high profitability for the pharmaceutical industry (see [Figure 1](#)).

Indeed the IMI2 interim evaluation itself strongly criticises the agenda-setting process as “not transparent and too much top-down industry driven and dominated by EFPIA partners with insufficient inclusion of other significant stakeholders”.<sup>311</sup>

**Advisory groups have no significant influence on IMI agenda-setting unless they are heavily dominated by industry representatives, as is the case with the Strategic Governing Groups.**

In its response, the European Commission also points to the fact that “advisory bodies that have been established in accordance with the IMI2 JU Council Regulation”. This is true, several advisory bodies exist, and in theory this could mean that the agenda has sufficient external expert input to ensure a balance of interests. However, the evaluation noted that despite the fact that feedback on the Strategic Research Agenda, work programmes, and call topics was received from the advisory groups, “it was not clear to most stakeholders how such feedback was taken into account or why certain decisions were made.”<sup>312</sup> As we will see below, these advisory groups have no significant influence on IMI agenda-setting unless they are heavily dominated by industry representatives, as is the case with the Strategic Governing Groups.

#### a) Industry dominates IMI Strategic Research Agenda, work programmes, calls, and topics...

In the only advisory group that does have a concrete role in the agenda, again we see the industry holds much of the control. The IMI’s call topics are developed by the seven Strategic Governing Groups (SGGs).<sup>313</sup> These groups are responsible for developing the IMI’s call topics<sup>314</sup> and are by far the most influential advisory groups. Our research shows that these groups are heavily dominated by EFPIA companies, and are therefore in fact a serious source of concern regarding the protection of the public interest in IMI (see [Figure 3](#)).

The IMI2 interim evaluation noted that they were “very active and had a very significant impact on the decisions of the [Governing Board], the call topic selection and determining the research priorities”. In comparison, the two advisory groups – the Scientific Committee and a States Representatives Group<sup>315</sup> – had “no significant influence on the activities of the IMI2 JU”.<sup>316</sup>

The Strategic Governing Groups are, according to IMI, comprised of representatives of pharma companies, the Commission, and the Scientific Committee. Yet while the Governing Board is ostensibly a 50:50 public-private split, represented by the Commission and EFPIA respectively, the private heavily outweighs the public in the SGGs. Big pharma companies outnumber European Commission or Scientific Committee members in the SGGs in some cases by as much as 20 companies to one.

The IMI2 interim evaluation noted that the industry considers their over-sized role in setting the call topics to be justified since “the pharma companies allocated half of the budgets to the proposed projects”.<sup>317</sup> Yet as noted above, the evaluators concluded the process was far too industry-driven. Furthermore, the operations of the SGGs lack transparency. Governing Board minutes from April 2019 show that there is still no “clear and consistent way for the SGGs to report to the [Governing Board] on their activities” and that “increased transparency” is needed on their activities.<sup>318</sup>

The disparity evident above raises questions about the balance of power: it seems at every level of priority-setting – from the Strategic Research Agenda to the work programmes, calls and topics, industry is the dominant pen-holder.

## b) ...An imbalance that the IMI's Scientific Committee does little to correct

The Commission also cites the role of the Scientific Committee as a key element in ensuring the priorities of IMI are set in the public interest. However, IMI's evaluations, as well as sitting members of this committee, have questioned the relevance of their input. Our own interviews with two members suggest that their input, especially on public health priorities, is not taken on board.

The Scientific Committee is tasked with providing the Governing Board with “high-level recommendations” on the scientific priorities to be included in the Strategic Research Agenda and in the Annual Work Plans.<sup>319</sup> Its composition, according to its rules of procedure, “shall reflect a balanced representation of worldwide recognised experts from academia, industry and regulatory bodies”.<sup>320</sup> So, despite industry already representing half of IMI's Governing Board, and dominating its Strategic Governing Groups, it is also expected to be represented on the Scientific Committee.<sup>321</sup> And indeed two (of its eleven full time) members have worked for EFPIA member Novartis.<sup>322</sup>

Yet it appears that industry is not satisfied and hopes to have an even greater say in the Scientific Committee. Governing Board minutes show that in June 2018, “EFPIA voiced concerns over the lack of industry experience among the 37 shortlisted candidates” for the Scientific Committee, and “requested to review the shortlist”.<sup>323</sup> This Committee should serve as an independent counterweight to the influence of partners having a commercial interest. Industry partners ‘reviewing’ or controlling the selection of members would seriously undermine the independence of the Committee.

The IMI2 interim evaluation reports that the Scientific Committee considered there to be “insufficient communication and not enough interactions” with the Governing Board, and that the Board “should be more open for their feedback and input and open dialogue, which was limited”.<sup>324</sup> According to one IMI Scientific Committee member we spoke with, since then there have been some improvements in this direction, and a more active role for the Committee.<sup>325</sup> And the Action Plan drafted as a follow up to the interim evaluation included a point on “improved involvement of, and communication between” the Board and the advisory groups. However, it is the industry-dominated Strategic Governing Groups who control the drafting of IMI's calls and topics. Bearing this in mind, it is alarming that Governing Board minutes show that still in June 2018 the Scientific Committee “pleaded for increased and early interaction with [these] topic writers”.<sup>326</sup>

One improvement is that the IMI website now includes on the Scientific Committee page three publications which set out its positions and makes their recommendations to the Governing Board (the first dated January 2018). One paper from 2019 discusses getting “the balance right between public and commercial interests in the IMI”. It cautions that “whilst the potential for commercial benefit is accepted as a prerequisite for funding, precisely because of this... the public health benefit needs to be at least as obvious” in IMI.

On the issue of IMI's added value, it also notes that “it needs to be clear why public funding is required” or to show why the research would not be carried out anyway by a company without IMI backing.<sup>327</sup> This is a very significant observation: it implies that, from the perspective of the Scientific Committee, after ten years and billions in public funds spent, public health benefits and added value are still not apparent in IMI.<sup>328</sup>

So, while there is greater transparency and activity around the Scientific Committee, has this translated into actual influence on the agenda? Unfortunately, despite a more ‘active’ role for the Scientific Committee, it seems its opinions and feedback can still be ignored.

According to one IMI Scientific Committee member we spoke to, although the committee Chair presented its position papers to the Governing Board, the Board has not responded officially – nor do they have an obligation to respond. They commented further that if the Scientific Committee suggests a research project deemed to be useful to society, but no pharma company is willing to put up the matching in-kind project financing, then it simply won’t happen. This is another sign that though the EU is putting up half the cash, the very design of IMI means that ultimately Big Pharma companies get the final say over where the money goes.

Another relatively recent member of the IMI Scientific Committee we spoke to described their experience of commenting on topics with the aim of pushing them in a more public health direction. They found it was not quite clear how, or if, these comments had been used. For example, in their actual experience so far they found that Scientific Committee feedback on early stage presentations for projects was not taken into account. The member expressed that they were in “a little bit in doubt of what influence we have as a Scientific Committee”.<sup>329</sup>

**If the Scientific Committee suggests a research project deemed to be useful to society, but no pharma company is willing to put up the matching in-kind project financing, then it simply won’t happen.**

And in terms of what that means for which projects get funded in IMI, the Committee member suggested that, while some of the research topics being funded make sense and have relevance for many parts of the world, there are other priority areas that are already very well-funded and attract a very large interest from industry, such as diabetes, raising the question of why such areas are a priority for IMI. Unfortunately these concerns are not merely abstract: as we have seen in [Figure 1](#), an analysis of the IMI’s balance of projects does show that overall funding is focused on areas of high profitability for the pharmaceutical industry.

### c) Civil society missing in action

There does not appear to be any clear avenue or mechanism for civil society organisations to engage in the agenda-setting or governance of the IMI. The Commission cites the annual IMI Stakeholder Forum as an example of how IMI is shaped in the public interest, as the forum “is open to all public and private stakeholders”.<sup>330</sup> However civil society organisations are notably absent from any description of relevant stakeholders, and indeed at no point does the response from IMI’s Governing Board reference civil society organisations such as public health-focused NGOs.<sup>331</sup>

The IMI2 interim evaluation also did not include any civil society groups (other than patients’ representative groups, including the European Patients Forum, which is largely funded by Big Pharma)<sup>332</sup> in its ‘List of stakeholders interviewed’. And although the full evaluation material includes public consultation results, which include critical responses from NGOs calling for civil society to be more involved in IMI and its decision-making processes,<sup>333</sup> the evaluation itself does not include any mention of ‘civil society’.<sup>334</sup>

This omission is also symptomatic of the overall exclusionary nature of IMI, as many other stakeholders interviewed for the evaluation considered there to be “insufficient inclusion of other significant stakeholders in the European biopharma ecosystem, including the academic, research and clinical centres, SMEs, regulators and patient groups”.<sup>335</sup>

The only actors in the civil society space deemed relevant are patients’ representatives. Understanding and addressing patients’ needs is one of the ultimate aims of health research; patients are therefore a vital voice, as long as their representative organisations are free from conflict of interest issues related to pharma funding (see [Part 1, 4b](#)). Yet there is also the need for a publicly funded health programme to engage with a broader range of civil society groups who focus on societal impact, eg public health NGOs concerned with issues such as the sustainability of healthcare systems, fair pricing, neglected diseases, access and availability etc. Especially given that the evaluations of IMI, along with our analysis here, show that it repeatedly falls short on its broad positive societal impacts. Furthermore the European Commission has committed to improving engagement with citizens and civil society organisations in its next research programme, and the successor to IMI should not be an exception to this commitment.<sup>336</sup>

**IMI’s decision-making process is far from transparent, with no minutes of Governing Board, Scientific Committee, States’ Representatives Group, or Strategic Governing Groups meetings made public.**

## 4. IMI decision-making a black box

Beyond the imbalance in agenda-setting power evidenced in the governance body and its advisory groups, there are several other aspects of the decision-making procedures of the IMI that lack transparency, from the strategic level to the development of calls for proposals, and decision-making within projects.

The IMI’s decision-making process is far from transparent, with no minutes of Governing Board, Scientific Committee, States’ Representatives Group, or Strategic Governing Groups meetings made public. Board decisions are published, but provide very little information about how or why decisions were reached. And whilst three recommendations made by the Scientific Committee have been published, the Committee’s rules for procedure on transparency state that its advice shall be published on the IMI website “unless the IMI2 JU Governing Board decides otherwise”, without any further reason given.<sup>337</sup>

Research calls, proposals, and project agreements are just as – if not more – opaque. Calls for proposals are of course public, published on the EU’s Funding & Tenders Portal. However, the project proposals submitted are not public, nor are any materials relating to the substantive issues considered – or ranking given – in the evaluation process. The IMI does publish annual lists of experts that it has selected to evaluate project proposals – but it does not give their organisational affiliation.<sup>338</sup> It should be noted that this is the same across the Horizon 2020 programme, however given the unique set up of the public-private partnerships, it merits questioning. The public has the right to access crucial information such as how Governing Board decisions are made, and how research areas or projects to receive EU public funding are chosen.

However, again as with other Horizon 2020 projects, the IMI does publish the reports of independent observers who sit in on evaluators' meetings to confirm correct procedures and guidelines were followed. While a small sample shows a generally positive appraisal, some criticisms were reported, and in at least one case the IMI's response highlights the lack of transparency in handling concerns. In an observer's report from the end of 2018, it was noted that "some experts felt that the process of getting buy-in from several big pharma partners can result in calls that are too prescriptive in some respects and too general in others" and that it was "unclear as to how specific call topic texts were arrived at".<sup>339</sup>

Yet the IMI's response did not address the concern that Big Pharma had too strong an influence over the definition of calls, instead only focusing on how it could better display an "figure explaining the development of the topics",<sup>340</sup> – once again opting for a PR-type response to criticism it receives.

Similarly, an observer's report from the end of 2017 notes that some experts found the "content of the Consensus Evaluation Reports risked to be altered by the review of the lawyers", and that their "scientific role was weakened" by not being "allowed to make recommendations in the consensus report but only describe shortcomings".<sup>341</sup> The IMI publishes responses to these observers' reports, but does not appear to meaningfully address the causes of the issues raised. In this case IMI merely stated that it is not the legal check's intention "to interfere with the scientific meaning", and that Horizon 2020 rules mean it is not possible to provide recommendations in the Evaluation Summary Report.<sup>342</sup>

Finally, partner's agreements are not made public, including the winning project consortium's Grant Agreement (which governs the relationship between the project and IMI, eg duration, budget, eligible costs, rules for reporting on project deliverables, intellectual property (IP) rights, dissemination, and roles and responsibilities of the different partners) and its Consortium Agreement (which governs the relationship between the project partners, on issues such as project governance, liability, IP, etc).<sup>343</sup> Only templates and models are made available on the IMI website, which means that there is no transparency around the specifics of IP and other rights and access conditions, which are agreed between the EFPIA companies and the other partners (academic and research institutions, SMEs, etc) in any given project. This is despite the vital importance of these issues for determining societal impact (ie whether or not there is open access to research data, or a non-exclusive IP policy that prioritises public access to the resulting drugs or treatments developed). Project interim evaluations also do not appear to be published.

As we have seen, transparency remains a serious issue for IMI's governance and decision-making processes on many levels – from the publication of the minutes of the Governing Board meetings, to disclosing the criteria for selection of the proposals or the provisions of the grant agreements – with much information still only obtainable through freedom of information requests.

## 5. Accountability: a litany of problems with industry in-kind funding

IMI2 (2014-2024) has a total budget of €3.276 billion, with €1.638 billion (half the budget) coming from the Health, Demographic Change and Wellbeing Societal Challenge of Horizon 2020.<sup>344</sup>

Out of the total budget, €1.425 billion is committed to the programme by EFPIA companies – largely ‘in-kind’ ie contributions of lab time, researchers etc rather than cash – and the rest (up to €213 million) can be committed by “other life science industries or organisations that decide to contribute to IMI2 as members or Associated Partners in individual projects”.<sup>345</sup> This means IMI grew by 50 per cent since its first stage, as IMI1 (2008-2013) had a total budget of €2 billion (€1 billion from the Health theme of the 7<sup>th</sup> EU Framework Programme for Research (FP7) that ran from 2007 to 2013, and €1 billion from EFPIA companies).

EFPIA companies’ contribution to the IMI budget is primarily ‘in-kind’, for example “by donating their researchers’ time or providing access to research facilities or resources”.<sup>346</sup> Yet the lack of transparency around EFPIA’s in-kind contributions, makes it hard to be confident about whether the committed ‘in-kind’ budget was actually ‘spent’: the IMI2 interim evaluation emphasized the lack of transparency over how the in-kind contributions were calculated.

In particular, EFPIA companies’ secrecy around timesheets continues to impede IMI’s accountability. Timesheets record the time spent by EFPIA staff directly working on IMI projects, in order to be quantified into a financial equivalent.

Their in-kind contributions audit is done via a private company of the firm’s choice, which sends a ‘certification’ of its in-kind contributions to the IMI Programme Office.<sup>347</sup> However if the IMI Programme Office has reason for concern and requests to see the companies’ time sheets, many Big Pharma firms become recalcitrant. As the interim evaluation notes: “often EFPIA companies are not willing to make time sheets available for auditing the in-kind contributions, claiming that it violated their confidentiality” on “engagement in other non-IMI projects and could lead to unpermitted disclosure of information”, an issue that was flagged in IMI1 and remains unresolved. This is based on “several interviews with IMI2 JU staff” who also noted that “it is not clear, however, whether or not this would indeed implicate a risk of competitive loss for those companies, as timesheets may involve project names without revealing the targets and part of the audit may be kept strictly confidential”.<sup>348</sup> The IMI1 final evaluation similarly notes that the “actual implications of disclosing time sheets are questionable”. The evaluation also noted that in-kind contributions of the pharma companies “cannot be correlated to the overall company R&D budgets”.<sup>349</sup>

All of this throws into question the validity of the ‘in-kind’ model, and the accountability of EFPIA’s contributions.

Moreover, somewhat stunningly, EFPIA members can count their work / staff time spent in the IMI’s Strategic Governing Groups as part of EFPIA’s ‘in-kind’ contribution to IMI. Given that we learned in [Part 2, 3a](#) that these groups are controlled by industry, this essentially means they benefit twice: they spend time writing IMI’s agenda to suit their own interests, and can then claim that time as a “contribution” to the programme.

## Box 10: Transparency and accountability problems with in-kind funding

Governing Board minutes reveal other ongoing problems with in-kind funding, and the consequences these have on IMI's work and impact. The minutes reveal that in 2019 at least one IMI call was at risk of being delayed due to a "gap" in in-kind "industry commitments". The Board did not seem to have a great deal of agency to address the problem. This power seemed to rest with pharma executives, as the minutes state that EFPIA would "urge the heads of R&D [for the pharma companies] to shed light on the value of the in-kind contribution initially slated for Call 18 that can realistically be committed".<sup>350</sup> To avoid disruption, the Governing Board agreed to go ahead with the calls in question, despite uncertainty around what the companies would actually commit.<sup>351</sup>

Some of these concerns are not new, and in-kind contributions are already under the spotlight. The IMI describes its "internal control and audit activities" as striving to "achieve a balanced approach based on risk management" that does not "overburden project participants".<sup>352</sup> But as the interim evaluation notes, both the European Parliament and the IMI2 States Representatives Group have been pushing for increased "transparency of the calculation rules and composition of in-kind contributions by pharma companies". Indeed in 2015 the European Parliament's budgetary control committee demanded, "Detailed information on the in-kind contributions of EFPIA [members], especially on the type of the in-kind contributions and their respective value".<sup>353</sup>

As a result of these concerns, the legislation for the next Framework Programme, Horizon Europe proposes that a majority of contributions from partners should be in cash instead of in-kind contributions.<sup>354</sup> Meanwhile a reflection exercise carried out by the Commission concluded that a key lesson for Horizon Europe was that, "Financial and in-kind contributions from Members other than the Union should be ex-ante agreed," and, "[c]omprehensive, clear and transparent methodologies for their reporting and certification should be ex-ante defined".<sup>355</sup>

In response to moves that would favour cash over in-kind contributions from private partners, EFPIA appears to be exploiting its privileged position on the IMI Governing Board to lobby not just against reform of in-kind funding but to amplify it. For example in a March 2018 Board meeting EFPIA pushed for a more flexible interpretation of in-kind funding in the future IMI, claiming that the current interpretations are in fact "too narrow".<sup>356</sup> In June 2018, as EFPIA suggested that they and the European Commission "work together, rather than in parallel" on the future IMI; they questioned the need for cash contributions.<sup>357</sup>

While it is unsurprising that an industry group is lobbying for rule changes that benefit their members financially, the public interest is hardly served by IMI facilitating such direct lobbying.

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# Conclusions

We set out to see what exactly IMI has been doing since 2007 to address societal health challenges, since it justifies its existence by claiming to address unmet medical needs while at the same time enhancing competitiveness for EU industry.

We first looked at IMI's priorities and impact. We found that **IMI was failing to invest in areas where public funding is urgently needed, such as HIV/AIDS and poverty-related and neglected tropical diseases, yet investing heavily in high profit areas where the industry is already putting considerable resources.** Public health topics where public funding is most needed have been side-lined. Moreover the **IMI invests in extremely dubious priorities that let industry write the rules on important safety standards for human and environmental health.** In particular, many projects seemingly allow industry to use the IMI to lobby regulators on crucial questions of the safety standards of new medicines, with little involvement from public actors like the Commission. Worryingly, we also found that the next partnership plans to double down on these kinds of projects, including developing rules for how industry can exploit citizens' health data.

We also found that **IMI is not contributing to making medicines more accessible, but rather is entrenching a system that is sending medicine prices skyrocketing and straining national health budgets.** IMI claims to “accelerate patient access” to medicines appear more as a cover for diverting public funding to industry goals of deregulation rather than a genuine commitment to make medicines more affordable. In one stark example, IMI claimed to contribute to making a life-saving HIV drug more affordable, yet our investigation revealed that nothing has actually been done to date to make the drug more accessible to those who need it.

**Even where IMI is investing in areas with a public health interest, such as in the fight against antibiotic resistance, we found partners who raised alarms about industry dominance and corresponding concerns about transparency, ethics, and conflicts of interest,** and who felt forced to pull out of projects because of this. Perhaps most worryingly, when such conflicts arose, it seems neither the Commission nor the IMI office have been either equipped or motivated to intervene.

At the same time we've seen **no evidence of leverage, or enhanced competitiveness; rather, SMEs have fled the programme thanks to exploitative behaviour by large pharmaceutical companies.**

These conclusions indicate that IMI has failed to meet the goals that justified it, including overcoming market failure and improving the development and availability of public health-oriented medicines.

To understand why IMI was investing in areas that did not seem to align with the interests of citizens, we examined how IMI is set up. We found **industry influence prevailed in the IMI's governance mechanisms.** While the Governing Board is ostensibly 50-50 split between public officials and the private sector, the Commission takes a hands-off approach to agenda-setting. **The groups who are responsible for writing IMI's agenda are shockingly weighted toward industry,** sometimes by as much as a factor of 20-1.

Our analysis has shown that, rather than IMI providing a 'neutral' platform to bring industry into contact with regulators, the reality is industry dominates the programme in order to pursue their own private interests. The claim that IMI provides a neutral space crumbles on even a cursory inspection and appears to be merely a way of giving the appearance of public oversight.

Meanwhile the IMI's advisory groups such as the Scientific Committee, who might want to input on public health topics beyond those of interest for commercial partners, have no formal influence over the agenda. Indeed, members have commented that if a topic is not interesting to industry, it will not get funded. **Civil society groups such as public health NGOs are absent from all agenda-setting mechanisms.** And while patient organisations are present, question marks remain over the conflicts of interest arising from their ongoing dependence on industry funding.

**Despite recent reforms, transparency remains a serious issue for IMI's governance,** with much information still only to be obtained through freedom of information requests.<sup>358</sup> In terms of accountability, **IMI operated for over ten years with no concrete indicators in place to measure its impact.**

There remains **no standard method for reporting or calculating 'in-kind' funding from industry** – ie the staff time, facilities etc – that EFPIA companies can claim as a significant part of their contribution to IMI. Moreover, what industry 'contributes' to the programme also often looks like it directly benefits them at the expense of citizens' interests. They are allowed to count their engagement in the IMI's Strategic Governing Groups as contributions, even though this allows them to direct public money towards their own interests. And they are allowed to count staff time in projects where they have free rein to lobby regulators and policy makers.

Furthermore, investigation shows that the lack of adequate monitoring of this funding has real costs, with delays and gaps in funding, putting projects at risk.

Most disturbingly, freedom of information documents reveal that **EFPIA is using its privileged position on the IMI Board to lobby for its own interests, for example against EU plans to reform in-kind funding and intellectual property rules in the successor to IMI.**

Overall, a worrying picture emerges of an institutional set up that creates "public duties and obligations" and "private privileges and advantages" as described by Mario Negri Institute. **A partnership in name only, that is in fact driven by private interests, with few real checks on their choice of priorities, and few mechanisms to ensure the public receives any real return on its investment.**

All in all, **this analysis of IMI raises stark questions about why exactly the European Commission is funding this initiative.**

And this is not a small matter: **in total roughly €1 billion of public funding has been spent to date on projects that could be used by industry as tools to push a deregulation agenda through the lowering of safety standards.** While controversies like the glyphosate scandal have taught us that great caution is needed when the industry comes into direct contact with regulators, IMI is leading us exactly the opposite direction.

Perhaps just as disturbing is the fact that many of these observations are not new. Alarm has been raised about IMI's industry-dominated governance and agenda-setting processes for many years, through multiple evaluations. Yet rather than address the fundamental issues, we have seen **the European Commission fail to hold the partnership accountable, instead focusing on deflecting criticism through PR.** This suggests an ideological commitment to the IMI model that is working in opposition to citizens' interests.

This cavalcade of criticism has led to accusations that IMI serves as a public subsidy to the industry. In response, IMI and its defenders in industry and the EU have pointed to the fact that industry does not receive any funding from IMI. IMI admits it has focused on doing a lot of work to dispel this idea that IMI was sending taxpayers' money to pharma,<sup>359</sup> and that industry are "contributors" to the programme.

This response diverts attention from the real critique. Industry may not be the direct financial beneficiaries of the programme, but what IMI provides them is far more valuable. Our analysis has shown – and Big Pharma has admitted itself – that IMI pays in areas where the industry would invest anyway. Thus, **EU taxpayers might not be handling funds directly to Big Pharma, but they are certainly saving them cash.**

The value of being able to direct public funding towards their own commercial priorities and to lobby regulators without having to abide by normal conflict of interest and transparency rules, is arguably worth more than cash. What is entirely less clear is what the added value is for the public purse.

When lobbying happens inside IMI, is not called lobbying, it is called collaboration. What is at stake here is the progressive corporate capture of EU policy making. What's more, **as partnerships like IMI are held up as emblems of public-private cooperation, they will proliferate, along with this model of institutionalized corporate capture.**

Now we are in the midst of preparing the future form of the EU's public-private health partnership. The EU has proposed some modest reforms to the Joint Undertakings, in the face of many criticisms, for example to address the (massive) accountability gap in in-kind funding, improve the Commission's ability to access project documents (staggering that they currently cannot), and to (finally) quantify the concept of leverage.

And while these reforms are welcome, they only address issues of ex-post accountability. They do not address the root of the problem. **The heart of the issue is that the political justification for IMI rests on the assumption that a public-private partnership whose research agenda is steered by companies with vested interest in profit-maximisation can simultaneously achieve the very different aims of increasing industry competitiveness and addressing public-health needs. It ignores the fact that all too often these aims are contradictory.**

There is a lot at stake. The next partnership will bring in even more industries, and will also focus on how to write the rules for using Big Data in health. Is anyone ready to trust pharma companies and technology companies to sit together and write the rules on how they can exploit our data?

The signs are not good. Already we can see **it is business as usual on the governance front, with EFPIA in the driving seat to write the agenda and choose whoever they want to work within the next partnership; all industry partners of course.**

In her hearing at the European Parliament in October 2019, the Commissioner for Innovation, Research, Culture, Education and Youth, Mariya Gabriel, said that she only wants R&I partnerships that have an impact and help us address global challenges.<sup>360</sup>

Assessing IMI on this standard, what we find is that at best, its impact is lacking, and at worst, as our analysis suggests, it is dangerous and counter to the public interest when it comes to the health and wellbeing of citizens within and beyond Europe, and when it comes to a public return on investment for the billions of taxpayers' money spent.

But rather than acknowledging the failures of IMI the Commission remains ideologically wedded to the idea that diverting public money to industry priorities is a relevant and justified goal for EU research and innovation policies. Indeed, looking at the wider context – “Research & Destroy: the factories of the industrial bioeconomy threaten the climate and biodiversity”, the partner report to this one analyses how almost €1 billion of EU public funding is used by the industry in another R&I private-public partnership Bio-Based Industries to pursue their commercial interests – in which IMI sits, **civil society has been raising the alarm about plans to merge the “industrial competitiveness” with “global challenges” in Horizon Europe,**<sup>361</sup> the next research programme.

**This blurring of commercial objectives with public health, sustainability, and needs-driven goals is deeply worrying.** IMI is a prime example of why this is dangerous, showcasing how these goals often collide, and that in the absence of robust public oversight, the outcome of such a collision is the domination of commercial interests.

**This kind of ‘magical thinking’ that commercial and public goals naturally align only serves to provide a useful justification for those who still believe in trickle-down economy.**

What would a public interest driven model look like? Accountability is important, and reforms that put in place concrete and quantifiable ways to measure the societal impact of these massive partnerships is essential. But without addressing the capture of EU institutions by private interests, these will not fix anything. When it comes to health research, the voices of academics, researchers, patients, and civil society organisations are equally essential for setting the agenda for how public money should be spent. Reforms are needed at all levels, from the governing board, through the advisory bodies and down to the project level, to end industry domination and ensure a truly multi-stakeholder process.

Below are a set of concrete recommendations to guide the process for creating the next EU health public-private partnership, to be called “Innovative Health Initiative”.

## Towards a new health Public-Private Partnership in Horizon Europe

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EU R&I Partnerships, and IMI's successor "Innovative Health Initiative" in particular, might have potential to deliver positive societal impact if their objectives are coherent and guided by the needs of society, and if they are governed in the public interest. The following are recommendations to ensure a public interest-driven partnership. **If these criteria cannot be met by the future partnership, then EU taxpayer's money should not be invested to serve industry's commercial interests at the expense of public health and well-being.**

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# Recommendations

## 1. GOVERNANCE that ensures less industry dominance and more public ownership

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**1.1 Public interest criteria needs to be defined to guide the European Commission's governance of the programme.** The mandate of the European Commission should be strengthened by avoiding industry's direct access to regulators or 'revolving door' issues. Measures should be in place to ensure an appropriate firewall between a profit-motivated business sector and the Commission.

**1.2 Governance mechanisms should ensure a balance of relevant stakeholders in strategic decision-making:**

- Civil society organisations and public interest groups need to be equally represented in all governance mechanisms.
- Industry stakeholders – whether from one industry or several eg including medtech, digital, and big data sectors – should no longer make up 50 per cent of the Governing Board
- The European Commission representatives should be diversified: the Directorate-General responsible for Health and Food Safety (DG SANTÉ) should have representatives from public health units, not only eg biomedical innovation unit as it is the case now.

**1.3 To ensure full transparency, within 15 days of all Governing Board meetings full minutes should be published.**

## 2. AGENDA-SETTING that responds to a needs-driven research agenda

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**2.1 The agenda-setting process, including the Strategic Research Agenda, should be an open, transparent, and inclusive process,** engaging all stakeholders including civil society organisations.

**2.2 Advisory groups, especially the Strategic Governing Groups, should ensure the balance of stakeholders,** by including civil society and public interest organisations. Their input into the agenda-setting on public health priorities – particularly that of the Scientific Committee – should be improved, and the process should be transparent.

**2.3 The partnership should prioritise neglected areas listed in the WHO Priority Medicines List,** including HIV/AIDS and other poverty-related and neglected diseases, to help address the pharmaceuticals R&I gaps in these areas. The European Commission should adopt a Global Health Strategy to inform R&I priorities and ensure needs-driven health R&I policies.

**2.4 Projects should ensure a balance of participants:** industry partners (whether one industry or several) should not dominate the leadership of working groups. Civil society organisations should also be encouraged and supported to participate in projects.

**2.5 Regulatory projects should not be led by industry:** Civil society organisations, such as public health NGOs and digital rights groups, as well as independent academic experts, should be robustly engaged in overseeing projects addressing highly sensitive areas like “ethics, privacy and security”.

## 3. ACCOUNTABILITY to ensure impact for society

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**3.1 Societal impact** should be clearly defined in a transparent multi-stakeholder process, be linked to Sustainable Development Goals, and have robust monitoring via targeted indicators. To ensure beneficial public health impacts, the European Commission should:

- Attach equitable **access conditions** to EU biomedical R&I funding to ensure public return on public investment and affordable access to health technologies resulting from EU R&I funds.
- Ownership and management of publicly funded R&I results should be driven by public interest and explore various forms of **intellectual property management and licensing**, including equitable licensing.

**3.2 Open access** should be mandatory and free for research outputs, including research data and data and results of clinical trials, in order to increase the chances of life-saving breakthroughs.<sup>362</sup> Derogations should be restricted to limited and rare circumstances and should be transparently monitored and reported by the European Commission.

**3.3** The drafting of **grant agreements** should be considered a matter of public interest and have public oversight and public interest criteria attached.

**3.4** ‘In-kind’ contributions by industry partners, providing staff to lead projects, should be changed to **financial contributions**. Furthermore, clear methodologies for quantifying additionality, ‘in-kind’ contributions, leverage and competitiveness gains should be introduced, and information should be transparent and accessible.

# Endnotes

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- 255 BEUC paper, ibid.
- 256 Politico EU, Cambridge Analytica helped 'cheat' Brexit vote and US election, claims whistleblower: Giving evidence to MPs, Chris Wylie claimed the company's actions during the Brexit campaign were 'a breach of the law.', Mark Scott, 27 March 2018, <https://www.politico.eu/article/cambridge-analytica-chris-wylie-brexit-trump-britain-data-protection-privacy-facebook/>
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- 259 The Harvard Gazette, High tech is watching you, John Laidler, 4 March 2019m <https://news.harvard.edu/gazette/story/2019/03/harvard-professor-says-surveillance-capitalism-is-undermining-democracy/> - <https://www.propublica.org/article/you-snooze-you-lose-insurers-make-the-old-adage-literally-true>
- 260 The New York Times, This Thermometer Tells Your Temperature, Then Tells Firms Where to Advertise, Sapna Maheshwari, 23 October 2018, <https://www.nytimes.com/2018/10/23/business/media/fever-advertisements-medicine-clorox.html>
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- 262 A blog by an academic at the Israel-Asia centre at the Hebrew University Jerusalem, in support that for the Israeli approach, argues the GDPR is "putting EU firms at a competitive disadvantage compared with their competitors in North America and Asia.". See: The Times of Israel, A bit of Israeli chutzpah — a way forward for AI applications in Healthcare!, Rahul Dutta, 28 October 2018, <https://blogs.timesofisrael.com/a-bit-of-israeli-chutzpah-a-way-forward-for-ai-applications-in-healthcare/>
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- 264 IMI webpage, Setting the Stage Digital Medicine and the Brain, Luca Pani, IMI Stakeholder Forum, 12 June 2019, <https://www.imi.europa.eu/sites/default/files/Luca%20Pani%20presentation.pdf>
- 265 Board minutes show the EC itself emphasized "the need for swift implementation, particularly in light of the development of digital therapeutics projects and expertise in the US". [https://www.asktheeu.org/en/request/7018/response/23441/attach/17/10%20Ares%202019%20836034%20Minutes%2023rd%20IMI2%20GB%20meeting%20Red.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/17/10%20Ares%202019%20836034%20Minutes%2023rd%20IMI2%20GB%20meeting%20Red.pdf?cookie_passthrough=1)
- 266 European Commission webpage, Better Regulation, European Partnership for innovative health (Horizon Europe programme), [https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972474\\_en](https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972474_en)
- 267 All Policies for a Healthy Europe campaign around the EU elections 2019, sponsored by Microsoft and Johnson&Johnson and led by FIPRA (consulting company that provides services to industries in digital & tech, banking & financial services, chemicals, energy & environment, health, among others), heavily featured digital health in their Manifesto for the future of health in the EU. See here: All Policies for a Health Europe webpage, <https://healthyeurope.eu/manifesto>
- 268 Roche Chief Executive Severin Schwan said "there's no choice but to do partnerships", and Susan Garfield, a partner in EY's life sciences advisory practice said "You are going to see new deals". Reuters notes that "With Apple's latest iPhone update including a new feature allowing users to view their medical records, Amazon teaming with Berkshire Hathaway and JPMorgan Chase on a new healthcare company, and numerous start-ups flooding in, the partnering opportunities are plentiful." From: Reuters, Ben Hirschler, 1 March 2018, Big pharma, big data: why drugmakers want your health records, <https://www.reuters.com/article/us-pharmaceuticals-data/big-pharma-big-data-why-drugmakers-want-your-health-records-idUSKCN1GD4MM>

- 269 IMI webpage, <https://www.imi.europa.eu/about-imi/mission-objectives> It should also be pointed out that it would be disingenuous to argue that "areas of unmet need" can include areas that do have a high commercial interest but are technically "unmet" right now because they are new areas for industry. Unmet need applies to areas that have limited potential for investment from the industry.
- 270 Interview with Pierre Meulien, Executive Director of IMI, op cit.
- 271 It was agreed that the IMI Office would convene a meeting for a brainstorming session with the aim of producing three or four measurable objectives for a prospective successor partnership to the IMI2 JU under the Horizon Europe Framework Programme taking into account the experiences under Horizon 2020. The IMI Governing Board meeting minutes June 2018: [https://www.asktheeu.org/en/request/7018/response/23441/attach/12/7%20Ares%202018%205351661%20Minutes%2021st%20IMI2%20GB%20meeting%2026%20jun%202018%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/12/7%20Ares%202018%205351661%20Minutes%2021st%20IMI2%20GB%20meeting%2026%20jun%202018%20Redacted.pdf?cookie_passthrough=1)
- 272 IMI Governing Board meeting minutes, 20/03/2019 obtained under FOI, [https://www.asktheeu.org/en/request/7018/response/23441/attach/5/3%20Ares%202018%202520836%20Minutes%2019th%20IMI2%20GB%20meeting%2020%20mar%202018%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/5/3%20Ares%202018%202520836%20Minutes%2019th%20IMI2%20GB%20meeting%2020%20mar%202018%20Redacted.pdf?cookie_passthrough=1) EFPIA identified "Challenges" a "too narrow interpretation of what in-kind contributions can cover", and urged a return to the "flexible IP regime" of IMI1 (see Part 1, 3d on SMEs and IMI's IP rules).
- 273 Governing Board meeting minutes 26 June 2018, [https://www.asktheeu.org/en/request/7018/response/23441/attach/12/7%20Ares%202018%205351661%20Minutes%2021st%20IMI2%20GB%20meeting%2026%20jun%202018%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/12/7%20Ares%202018%205351661%20Minutes%2021st%20IMI2%20GB%20meeting%2026%20jun%202018%20Redacted.pdf?cookie_passthrough=1)
- 274 The IMI Governing Board June 2018 meeting minutes showed that EFPIA had approached MedTech Europe and COCIR, who they said "have manifested a strong interest in participating in a successor partnership to the IMI2 JU." The board agreed that "A meeting between the three entities will be held on 10 July." See: [https://www.asktheeu.org/en/request/7018/response/23441/attach/18/1%20C%20October%208%202018%20WG%20meeting%20Invitation%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/18/1%20C%20October%208%202018%20WG%20meeting%20Invitation%20Redacted.pdf?cookie_passthrough=1)
- 275 The working group expanded to include EBE (European Biopharmaceutical Enterprises) and EuropaBio.
- 276 See the working group documents: here: [https://www.asktheeu.org/en/request/7018/response/23441/attach/18/1%20C%20October%208%202018%20WG%20meeting%20Invitation%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/18/1%20C%20October%208%202018%20WG%20meeting%20Invitation%20Redacted.pdf?cookie_passthrough=1), here: [https://www.asktheeu.org/en/request/7018/response/23441/attach/2/13%20E%20October%2018%202018%20WG%20meeting%20Invitation%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/2/13%20E%20October%2018%202018%20WG%20meeting%20Invitation%20Redacted.pdf?cookie_passthrough=1), here: [https://www.asktheeu.org/en/request/7018/response/23441/attach/14/14%20I%20November%2021%202018%20meeting%20Invitation%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/14/14%20I%20November%2021%202018%20meeting%20Invitation%20Redacted.pdf?cookie_passthrough=1), and here: [https://www.asktheeu.org/en/request/7018/response/23441/attach/7/15%20K%20December%205%202018%20meeting%20Invitation%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/7/15%20K%20December%205%202018%20meeting%20Invitation%20Redacted.pdf?cookie_passthrough=1)
- 277 Officially this needs to be approved by the EU institutions in the legislative process for the next partnership. It is possible that the Commission will propose changes or additions, but there is a lack of transparency over how this has or will occur.
- 278 EFPIA webpage, Call to contribute to the strategic research agenda for a Public-Private Partnership for Health Innovation under Horizon Europe, <https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/ave-your-say-and-contribute-to-the-strategic-research-agenda-for-a-public-private-partnership-for-healthcare-innovation-under-horizon-europe/>
- 279 Ibid.
- 280 IMI, History, op cit.
- 281 Birch, Kean, Innovation, Regional Development and the Life Sciences: Beyond clusters, Routledge 2016.
- 282 IMI, 246 Million Euros for faster medicine development, May 2009, <https://healthcare-in-europe.com/en/news/246-million-euros-for-faster-medicine-development.html>
- 283 IMI2 Interim Evaluation, op cit.
- 284 Birch, Levidow & Papaioannou (2014), op cit.
- 285 IMI Governing Board Rules of Procedure, [https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/Governing-Board/IMI2\\_GovBoard\\_Rules.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/Governing-Board/IMI2_GovBoard_Rules.pdf)
- 286 All members based on the information on IMI's Governing Board webpage, <https://www.imi.europa.eu/about-imi/governance/governing-board> as of May 2019.
- 287 IMI webpage, About IMI / Governing Board, Irene Norstedt, CV, [https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/Governing-Board/IreneNorstedt\\_IMI%20Bio%20\(003\).pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/Governing-Board/IreneNorstedt_IMI%20Bio%20(003).pdf)
- 288 Corporate Europe Observatory, High Prices, poor access, op cit.
- 289 The Guardian, \$2.1m Novartis gene therapy to become world's most expensive drug, 25 May 2019, <https://www.theguardian.com/science/2019/may/25/21m-novartis-gene-therapy-to-become-worlds-most-expensive-drug>
- 290 Transparency Register, Novartis, <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=91269481588-28>, last modified on: 16 April 2019
- 291 Searching in the Transparency Register webpage does not show any results: <https://ec.europa.eu/transparencyregister/public/consultation/searchControllerPager.do?declaration=Enyo+Pharma&search=search>
- 292 Transparency Register, J&J, <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=75617941310-89>, last modified on: 18 February 2019 – 9 access passes listed as of 29/05/19, down from an earlier 18 (see Corporate Europe Observatory, High prices, poor access, op cit.)
- 293 BusinessEurope webpage, ASGroup - our partner companies, <https://www.busesseurope.eu/about-us/asgroup-our-partner-companies>; EFPIA webpage, Members, <https://www.efpia.eu/about-us/membership/>
- 294 BusinessEurope webpage, Views on the LAB-FAB-APP report, Oct 2017, [https://www.busesseurope.eu/sites/buseur/files/media/position\\_papers/iaco/2017-10-09\\_views\\_on\\_lamy\\_report\\_lab-fab-app.pdf](https://www.busesseurope.eu/sites/buseur/files/media/position_papers/iaco/2017-10-09_views_on_lamy_report_lab-fab-app.pdf)
- 295 BusinessEurope webpage, Speech for Breakfast meeting on Horizon 2020 hosted by MEP Christian Ehler, May 2012 <https://www.busesseurope.eu/sites/buseur/files/media/imported/2012-00614-E.pdf>
- 296 Corporate Europe Observatory, High Prices Poor Access, op cit.
- 297 Transparency Register, UCB, <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=294359117093-66> last modified on: 10 April 2019. UCB also received EU funding of close to €60,000 for a non-IMI Horizon 2020 project.
- 298 Corporate Europe Observatory, High Prices, poor access, op cit. p17.
- 299 Ibid.
- 300 A Commission response to a questionnaire on another EU PPP, the Fuel Cells and Hydrogen Joint Undertaking, states first that indeed the partnership is "a PPP structure where the commission represent the public interest", and further that, with respect to "Citizen involvement" there is "None" because "the commission represents the citizens". DG Research, Mission-oriented research and innovation: Inventory and characterisation of initiatives, January 2018, Fuel Cells and Hydrogen JTI, (report version obtained by Global Health Advocates) <http://www.ghadvocates.eu/wp-content/uploads/MOP1-Annex-1-20180131.docx>
- 301 295 The Commission response further states that "The Commission position on issues presented to the JU Governing Board for decision is determined collegially, in close consultation between the three Directorates-General represented directly in the JU Governing Board and with those not represented directly in the Governing Board.". See: DG RTD response to GHA request on 'Research into the societal impact and governance of the IMI2 JU', <http://www.ghadvocates.eu/wp-content/uploads/Reply-1.pdf>
- 302 The Governing Board (GB) was the IMI2 JU main decision making body, having overall responsibility for the strategic orientation and the operations of the Joint Undertaking. The GB comprised two members with different goals and modes of operations (EFPIA and the EC), which may interfere with quality of the decision making process. The EC GB members may be expected to demonstrate evidence of bringing benefits to society and patients as well as of bringing economic value added, while EFPIA represented the interests of global pharmaceutical companies, which are focused on growth, net profit and bringing benefits to their shareholders. These different goals may complicate negotiations while aligning interests. IMI2 Interim Evaluation, op cit.
- 303 "Horizon 2020 Framework and Specific Programmes, the Juncker Priorities, the EU digital transformation of health and care strategy, the EU One Health Action Plan against antimicrobial resistance, the Sustainable Development Goals, etc.". See: DG RTD response to GHA request on 'Research into the societal impact and governance of the IMI2 JU', op cit.
- 304 Ibid.
- 305 Document released to GHA, Experts Reports on the Final and Interim Evaluation of IMI JU redacted, <https://www.asktheeu.org/en/request/6682/response/22121/attach/html/10/Experts%20Reports%20on%20the%20Final%20and%20Interim%20Evaluation%20of%20IMI%20JU%20redacted%20Redacted.pdf.html>
- 306 IMI webpage, Carrying The Torch For Medical Innovation, EC/EFPIA, [https://www.imi.europa.eu/sites/default/files/uploads/documents/reference\\_documents/Brochure\\_ResultsImpact.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/reference_documents/Brochure_ResultsImpact.pdf)
- 307 Minutes of Coordinating Meeting between Article 187 JUs and Commission Services, 24 April 2018, [https://www.asktheeu.org/en/request/6711/response/22131/attach/6/Minutes%2024%2004%202018Coordination%20JUs%20EC%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/6711/response/22131/attach/6/Minutes%2024%2004%202018Coordination%20JUs%20EC%20Redacted.pdf?cookie_passthrough=1)
- 308 Operational Conclusions of the 6th Coordination Meeting between Article 187 JUs and Commission Services, 12 November 2018, obtained through GHA Freedom of Information requests, <https://www.asktheeu.org/en/request/6711/response/22131/attach/5/Minutes%2012%2011%202018Coordination%20JUs%20REDACTED%20Redacted.pdf>
- 309 DG RTD response to GHA request on 'Research into the societal impact and governance of the IMI2 JU', op cit.
- 310 "As founding member of IMI and source of half of our funding, EFPIA was entrusted with the preparation of the SRA. As part of this exercise, EFPIA held extensive discussion with the European Commission and drew on input from more than 80 organisations, including regulators, patients, and academia." From IMI webpage, Strategic Research Agenda, <https://www.imi.europa.eu/about-imi/strategic-research-agenda>
- 311 IMI2, Interim evaluation, op cit.
- 312 Ibid.
- 313 IMI webpage, Strategic Governing Groups, <https://www.imi.europa.eu/about-imi/governance/strategic-governing-groups>
- 314 IMI webpage, Governance, <https://www.imi.europa.eu/about-imi/governance> Their mandate includes advising the IMI Governing Board (which has the ultimate task of approval of call texts, etc) on "annual scientific priorities for inclusion into Annual work plans" and on topics, programmes, and "the type of call process that is most suitable". Decision of the IMI2 Governing Board approving the Charter of the IMI2 JU SGGs, Dec 2016, [https://www.imi.europa.eu/sites/default/files/uploads/documents/AboutIMI/Governance/strategicgoverninggroups/IMI2\\_GB\\_DEC\\_2016\\_21\\_Decision\\_on\\_new\\_SGGs\\_Charter\\_SIGNED\\_30SEP2016.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/AboutIMI/Governance/strategicgoverninggroups/IMI2_GB_DEC_2016_21_Decision_on_new_SGGs_Charter_SIGNED_30SEP2016.pdf)
- 315 The SRG comprises representatives from EU member states (and countries associated with EU research frameworks, such as Norway, Iceland and Turkey).
- 316 IMI2 interim evaluation, op cit.
- 317 Ibid.
- 318 The point on transparency applies to all the advisory groups. See: The IMI Governing Board meeting minutes from April 2019, [https://www.asktheeu.org/en/request/7018/response/23441/attach/11/18%20IMI2%20GB%20DEC%202019%2010%20Annex%20Minutes%2025th%20GB%20meeting%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/11/18%20IMI2%20GB%20DEC%202019%2010%20Annex%20Minutes%2025th%20GB%20meeting%20Redacted.pdf?cookie_passthrough=1)
- 319 As well as on the scientific achievements in the Annual Activity Reports.
- 320 There is one patient representative on the committee, who amongst other things, serves as the president of EUPATI Austria (see Part 1, 4b on EUPATI).
- 321 IMI Scientific Committee's Rules of Procedure, [https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/sc/IMI2\\_SC\\_RULES%20OF%20PROCEDURE.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/sc/IMI2_SC_RULES%20OF%20PROCEDURE.pdf). Another point to note about the composition of the IMI SC is the geographical breakdown of members. Of the SC's 11 full members, 8 are from EU-15, only 2 are from EU-13, and 1 from Norway. The two ad hoc members are also from EU-15 countries, so only 2 out of 13 members come from EU-13 countries.
- 322 One of whom also used to work for AstraZeneca and MSD. Another member is a

- co-founder and share-holder of diagnostics company PROTAGEN AG, which was just bought up by a bigger firm for €4 million, See: IMI webpage, members of the Scientific Committee, <https://www.imi.europa.eu/about-imi/governance/scientific-committee#scientific-committee-members>
- 323 The IMI Governing Board meeting minutes from 26 June 2018, [https://www.asktheeu.org/en/request/7018/response/23441/attach/12/7%20Ares%202018%2053516161%20Minutes%2021st%20IMI2%20GB%20meeting%2026%20jun%202018%20Redacted.pdf?cookie\\_passthrough=1](https://www.asktheeu.org/en/request/7018/response/23441/attach/12/7%20Ares%202018%2053516161%20Minutes%2021st%20IMI2%20GB%20meeting%2026%20jun%202018%20Redacted.pdf?cookie_passthrough=1)
- 324 The IMI2 interim evaluation itself concluded that "more structured feedback from the SC covering different technological sectors may prove very valuable for future developments and innovation in healthcare". See: IMI2 Interim Evaluation, op cit.
- 325 IMI webpage, Scientific Committee, <https://www.imi.europa.eu/about-imi/governance/scientific-committee>
- 326 Governing Board meeting minutes, 26 June 2018, op cit.
- 327 IMI webpage, Scientific Committee recommendations regarding public private partnership funding – what makes a topic ultimately suitable for this kind of funding model?, February 2019, [https://www.imi.europa.eu/sites/default/files/uploads/documents/AboutIMI/Governance/sc/SCrecommendations\\_PPPfunding.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/AboutIMI/Governance/sc/SCrecommendations_PPPfunding.pdf)
- 328 IMI webpage, Sustainability solutions are important criteria determining project quality and output in IMI, June 2018. [https://www.imi.europa.eu/sites/default/files/uploads/documents/AboutIMI/Governance/sc/SC\\_Sustainability\\_June2018.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/AboutIMI/Governance/sc/SC_Sustainability_June2018.pdf); The paper also recommends that a "workshop with experts, patient representatives and other stakeholders" could be held before each call topic to shape "the scope of the topic proposals to help enhance public health impact". In another of its positions, from June 2018, the Scientific Committee argues that the IMI needs strategies – or 'sustainability requirements' – to keep assets developed by IMI projects available beyond the timeline of their funding. Without these, "continued use and access to the results can be strongly compromised", thereby undermining the IMI's "concept of delivering output that permanently improves drug development in the EU".
- 329 Interviews with three members of the Scientific Committee, 2019
- 330 The IMI also holds an annual IMI Stakeholder Forum which brings together the "entire" health R&I community to provide the IMI with feedback, and is described as having "an official advisory function to IMI". The IMI website says that: "We strongly encourage all stakeholders in health and medicines R&I to join the IMI Stakeholder Forum: small and medium-sized enterprises (SMEs); patient representatives and regulators; representatives of the academic and research community, the pharmaceutical industry and other sectors in healthcare; as well as representatives of other public-private partnerships and research-funding organisations." Civil society is conspicuously absent from this list (though they are entitled to register). IMI webpage, IMI Stakeholder Forum, <https://www.imi.europa.eu/about-imi/governance/imi-stakeholder-forum>
- 331 DG RTD response to GHA question on 'Research into the societal impact and governance of the IMI2 JU', , op cit.
- 332 EPF, Annual Report 2018, [http://www.eu-patient.eu/globalassets/library/annualreports/2018\\_epf\\_annual-report-final-web.pdf](http://www.eu-patient.eu/globalassets/library/annualreports/2018_epf_annual-report-final-web.pdf)
- 333 Responses to Horizon 2020 interim evaluation consultation re. IMI, [https://www.asktheeu.org/en/request/responses\\_to\\_consultation\\_re\\_int#incoming-22260](https://www.asktheeu.org/en/request/responses_to_consultation_re_int#incoming-22260); Submission by Global Health Advocates, March 2017: <http://www.ghadvocates.eu/wp-content/uploads/IMI-PublicConsultationSubmission.pdf>
- 334 And the IMI2 Interim Evaluation refers to NGOs only in relation to the fact that there "was a very low contribution to the overall IMI2 initiative by the associated partners (other industries, foundations, charities and other NGOs)" which indicated that "the inability of the IMI2 JU to attract other industry sectors and associated partners in a meaningful way."
- 335 IMI2 Interim Evaluation, op cit.
- 336 European Commission Proposal for a Regulation of the European Parliament and of the Council establishing Horizon Europe – the Framework Programme for Research and Innovation, 7 June 2018, [https://eur-lex.europa.eu/resource.html?uri=cellar:b8518ec6-6a2f-11e8-9483-01aa75ed71a1.0001.03/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:b8518ec6-6a2f-11e8-9483-01aa75ed71a1.0001.03/DOC_1&format=PDF)
- 337 IMI webpage, Rules of procedure of the Scientific Committee of the Innovative Medicines Initiative 2 Joint Undertaking, [https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/sc/IMI2\\_SC\\_RULES%20OF%20PROCEDURE.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/sc/IMI2_SC_RULES%20OF%20PROCEDURE.pdf)
- 338 See, for example, 2018 H2020 Expert List - Health, [http://ec.europa.eu/research/participants/data/ref/h2020/experts\\_lists/challenges/health/h2020-expertslists-challenges-health-2018\\_en.xlsx](http://ec.europa.eu/research/participants/data/ref/h2020/experts_lists/challenges/health/h2020-expertslists-challenges-health-2018_en.xlsx)
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- 362 Compliance with EU data protection rules must be ensured, and strong data security mechanisms must be put in place. In addition, depending on the types of research data (personal/non-personal) different modalities of data sharing should be considered.



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GHA is a non-profit advocacy NGO dedicated to ensuring equitable access to healthcare in the EU and globally. GHA works toward an EU whose policies are shaped to achieve direct and tangible benefits for citizens and society, with a particular focus on EU research and innovation (R&I) and development policies.

CEO is a research and campaign group working to expose and challenge the disproportionate influence that corporations and their lobbyists exert over EU policy-making. CEO works in close alliance with public interest groups and social movements in and outside of Europe to develop alternatives to the dominance of corporate power.

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