



IN THE NAME OF INNOVATION

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

EXECUTIVE SUMMARY

This is a summary of the findings and conclusions of two extensive reports on research public-private partnerships in the EU, written by the NGOs Global Health Advocates and Corporate Europe Observatory:

- · More private than public: the ways Big Pharma dominates the Innovative Medicines Initiative
- · Research & destroy: the factories of the industrial bioeconomy threaten the climate and biodiversity

They investigate two public-private partnerships between the European Commission's Directorate-General (DG) Research & Innovation, and industry lobby groups: the Innovative Medicines Initiative Joint Undertaking (IMI) and the Bio-Based Industries Joint Undertaking (BBI). Together they paint a picture of an institutional set up for public-private partnerships that enshrines 'privileges and advantages' for the private sector and 'duties and obligations' for the public sector, with worrying implications for the sidelining of the public interest in a wide range of subjects: from neglecting pandemic preparedness, to fueling deforestation and climate change.

In the name of innovation in health research, the pharmaceutical industry represented by pharmaceutical trade association and lobby group EFPIA (European Federation of Pharmaceutical Industries and Associations), has steered a €2.6 billion public EU research budget for the period 2008-2020 through IMI, but has so far failed to meaningfully invest in research areas where public funding is urgently needed. These areas include long-term preparedness for epidemics (including caused by coronaviruses), HIV/ AIDS, and poverty-related and neglected tropical diseases. Instead the partnership mostly used the budget to fund projects in areas that were more commercially profitable for the pharmaceutical industry.

BBI is a public-private partnership between lobby groups representing the agribusiness, forestry, bio-technology, chemical, and fossil fuel industries on the one hand, and the European Commission's DG Research & Innovation, ostensibly to help build a "sustainable low-carbon economy". In this partnership, established in 2014 for a ten year period, the public sector contributed a €975 million budget, while the private sector mostly brought in-kind resources. Industry defined the overall research priorities and drafted every annual work plan. The main purpose of BBI is to build 'biorefineries', and develop new technologies, to process unlimited quantities of biomass extracted from forests and soils, threatening their role as carbon sinks, biodiversity, as well as the food supply.

For more than 15 years, industry lobby groups have managed to convince the European Commission to let the private sector decide how very large amounts of public research funding should be used via research and innovation public-private partnerships. IMI and BBI belong to the largest of these partnerships, the Joint Undertakings. There are seven Joint Undertakings funded between 2014 and 2020, with more than €7 billion paid by taxpayers.

IMI and BBI have funded a vast array of projects to develop products, technologies, and processes primarily for the benefit of the companies involved, while the consequences for public health, people, and the environment are hardly taken into account. The reports include numerous detailed examples, such as a cheaper manufacturing process for a key drug for helping people living with HIV in Africa that so far appears to have only helped Sanofi's profits, or the chemicals multinational Clariant receiving millions of euros to build a factory to turn enormous amounts of agricultural 'residues' into biofuel (despite the fact that these have other important uses in farming and are important to nurture soils).

At the very moment the COVID-19 pandemic is highlighting how short-term thinking, and the privatisation of public services and research, have damaged the resilience of our societies, we risk perpetuating the same problems: EU member states are negotiating the 2021-2027 EU budget, including for Horizon Europe, the EU's next research and innovation framework programme. €100 billion is at stake. The European Commission and industry are lobbying hard to get IMI, BBI and other partnerships renewed in Horizon Europe using a new but comparable form, 'institutionalised European Partnerships'. But public health and sustainability are fundamental issues that require a research and innovation policy delivering knowledge and results for all, not just profits for a few.

IMI and BBI are meant to boost industry's competitiveness and address societal challenges, but industry controls their priorities

The two main official justifications for creating IMI and BBI were firstly to improve the competitiveness of the industries at stake, and secondly to address particular societal challenges by funding research projects that for IMI would improve health and patient access to medicines, especially in areas of "unmet medical or social need", and for BBI, to "contribute to a more resource efficient and sustainable low-carbon economy". The idea was to steer industry's technological innovations in a way that serves societal needs.

Our findings however show that, as far as BBI and IMI are concerned, hardly any societal challenges are being credibly addressed, and the evidence for competitiveness gains beyond the company level is limited. The overwhelming majority of the projects we looked at, the very structure and mechanisms of these public-private partnerships, show that participating companies are controlling the partnerships' priorities and the use of public EU money for their own direct benefit. And this is not only the result of these companies sometimes abusing the partnership, but also a logical consequence of the way these partnerships were set up.

Public-private partnerships (PPPs) are often controversial, but their most frequent arrangement is that the public sector defines the mission, contracts the private sector to implement it, and is then the final owner of the product. But here, although BBI and IMI were created by EU regulations, each PPP's strategic research agenda and even the annual work plans are proposed by participating companies, who also end up owning the final products.

The same companies – in consortia with public universities and small and medium-sized enterprises (SMEs) – apply to EU calls for research proposals that they have largely written themselves, ending up in the privileged position to sometimes directly obtain the public funding on offer or, more often, get SMEs and public researchers to work on their favoured priorities and appropriate the outcome afterwards.

The lobby group representing industry in BBI, the Bio-Based Industries Consortium (BIC), spelled it out: "Since BIC members develop the Annual Work Plan, they have access to information early before the official publication of the call for proposals. This increases their chance of writing successful project proposals. 64% of BIC large enterprises, SMEs and SME clusters are represented in granted BBI projects (2014-2017)."

The pharmaceutical industry lobby admitted in 2011 that IMI could be used to fund projects the pharmaceutical industry would have commissioned anyway.

Industry is also supposed to contribute to the partnership. Largely in-kind, but also in cash. But as far as BBI is concerned, industry partners have only paid 3 percent of their expected financial contributions and 3.7 percent of their auditable in-kind contributions so far. Meanwhile, the European Commission has already paid 27 percent (€264.6 million) of its cash contribution to the partnership. In addition, in both partnerships, industry partners have opposed transparency on how to value their in-kind contributions (which mainly consist of their own research facilities and staff).

Why not outsource the costs of your private research and development to the taxpayer if you can?

Corporate priorities dominate: IMI and BBI funded projects helping industry lobby regulators; but IMI blocked funding research into epidemic preparedness

We also documented how several 'research' projects funded by these partnerships are in fact helping corporate lobbying and PR by elaborating industry-friendly regulatory proposals targeted at EU regulators, or funding PR activities to improve the reputation of products in the public. For example, we found IMI projects that helped industry lobby regulators on the safety evaluation of new pharmaceuticals, such as lowering evidence standards for new medicines through accelerated market approvals. Some BBI projects helped industry lobby EU decision-makers on the regulation of GMOs or bioplastics' recycling, and produced short webbased videos to promote bio-based products to the public without mentioning their possible risks (safety, negative environmental impact, etc).

This 'partnership' format delivers additional perks to private companies: when their lobbyists interact with high-level Commission officials within the regular meetings of the PPPs' Governing Boards, they **get very detailed insider briefings and intelligence** into what goes on inside the Commission, including on the future of these partnerships.

We were outraged to find evidence that the pharmaceutical industry lobby EFPIA not only did not consider funding biopreparedness (ie being ready for epidemics such as the one caused by the new coronavirus, COVID-19) as a "regulatory topic" for IMI (meaning IMI could have looked for research projects to fund on the matter1), but opposed it being included in IMI's work when the possibility was raised by the European Commission in 2017. Since the coronavirus SARS - a close cousin of the novel coronavirus - emerged in 2003, researchers have been urging to speed up the development of medical technologies to address viruses of this type. In fact, there was "a promising candidate to treat coronavirus already in 2016," but it didn't get Big Pharma's attention for further development.² It is only now, with a global pandemic raging and that emergency public funds are mobilised to address it, that industry is showing willingness to help develop vaccines and treatments. In a similar way, industry dawdled on Ebola; only when it became an epidemic in 2014 did IMI start funding relevant research projects. That case shows how belated interventions when an epidemic is already underway are much less useful than the type of biopreparedness that industry rejected.

Time to end corporate capture of EU research policy and funds

Public research funding is a precious, strategic investment in knowledge production for tomorrow, and at a time of overlapping crises – from COVID-19 to climate change – this is more important than ever. But is the public interest best served by the current way of doing 'research partnerships' with the private sector? The evidence described in the two reports indicates it is not.

What is at stake here is the corporate capture of EU policy making and budgets in key areas. The EU has proposed some modest reforms to the PPPs to address the (massive) accountability gap in in-kind funding, or improve the Commission's ability to access project documents (incredibly, until now it could not). But these do not address the root problem: a flawed political justification resting on the assumption that a public-private partnership whose research agenda is defined by commercial interests, and whose main purpose is 'de-risking' private finance in technological innovation, can simultaneously address societal needs in a meaningful way.

The magical thinking that commercial and public goals naturally align only serves to provide a convenient justification for the interests served by the EU's current research and innovation policy. This all comes at the expense of research genuinely serving the public interest, and public researchers' freedom to define and evaluate their work. It is clear for example that without independent, public climate researchers, we would still be debating the reality of human-made climate change. It is high time that the EU's research policy receives the political attention and debates it really deserves.

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¹ See IMI's description of what 'topics' are in the partnership https://www.imi.europa.eu/apply-funding/future-topics

² Diarmaid McDonald, 'Trump's attempt to buy a coronavirus vaccine shows why big pharma needs to change', The Guardian, 16 March 2020, https://www.theguardian.com/commentisfree/2020/mar/16/trump-coronavirus-vaccine-big-pharma-president-drugs-industry-profit

DETAILED FINDINGS

On the Innovative Medicines Initiative (IMI)

IMI is a public-private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA), the EU trade association and lobby group of the pharmaceutical industry.

Timeline: The first IMI partnership ran from 2008-2013 and was renewed as IMI2 to run from 2014-2020 (some projects go on until at least 2024, but calls for proposals shall be launched by the end of 2020 latest). The next EU research framework programme (Horizon Europe) 2021-2027 is more than likely to include a successor to IMI, "Innovative Health Initiative"

Budget: IMI1 had €2bn (€1bn EU public funding and €1bn from EFPIA companies); IMI2 had €3.276bn (€1.638bn EU funding, EFPIA is committed to contribute €1.425bn in-kind).

Stated Objective: To improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need.

These findings indicate that IMI has failed to meet the goals that justified it, including overcoming market failure and improving the development and availability of health technologies for unmet medical needs.

Diverting public funds for commercial interests

- IMI is failing to invest in areas where public funding is urgently needed, such as long-term preparedness for epidemics, HIV/AIDS, poverty-related and neglected tropical diseases, yet investing heavily in high profit areas where the pharmaceutical industry is already putting considerable resources.
- IMI invests in priorities that let industry influence the rules on important safety standards for human and environmental health. 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 European Commission or member states.
- IMI is not contributing to making medicines more accessible, but rather is entrenching a system that is making medicine prices skyrocket and, thus, straining national healthcare budgets. In one stark example, IMI claimed to contribute to making a life-saving HIV drug more affordable in Africa by funding the development of a cheaper manufacturing process. However, our investigation revealed that this process has not yet been used to manufacture the drug in question; while it can also be used to cut costs in the manufacturing of more profitable drugs for high-income countries (cf. flucytosine case study).
- Even where IMI is investing in areas with a public health interest, such as in the fight against antibiotic resistance, we found public 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 have seen no evidence of leverage, or enhanced competitiveness; rather, SMEs have fled the programme due to exploitative behaviour by large pharmaceutical companies.

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- Industry influence prevails in IMI's governance mechanisms, which helps explain why it invests in industry priorities over unmet social needs. 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.
- IMI's advisory groups such as the Scientific Committee, which might want to input on public health topics beyond those of interest for commercial partners, have no formal influence over the agenda. Indeed, some members of the Scientific Committee 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 interests arising from their ongoing dependence on industry funding.
- Despite recent reforms, **transparency remains a serious issue.** IMI operated for over ten years with no concrete indicators in place to measure its impact. In addition, 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. 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.

All in all, this analysis of IMI raises stark questions about why exactly the European Commission is funding this initiative with EU taxpayers' money.

Overall, a worrying picture emerges of an institutional set up that creates 'duties and obligations' for the public sector and only 'privileges and advantages' for the private sector. A partnership in name only, 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 with EU taxpayers' money. Controversies like the glyphosate scandal have taught us that great caution is needed when the industry comes into direct contact with regulators, but IMI leads us in exactly the opposite direction.
- Alarm has previously been raised about IMI's industrydominated governance and agenda-setting processes via multiple evaluations. Yet rather than address the fundamental issues, the Commission has failed to hold the partnership accountable, instead focusing on deflecting criticism through PR.
- The future form of the EU's public-private health partnership is currently being prepared. While the EU has proposed some modest reforms in the face of many criticisms, IMI's Governing Board minutes show that European Federation of Pharmaceutical Industries and Associations (EFPIA) is using its privileged position 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. It is also business as usual on the governance front, with EFPIA in the driving seat to choose whoever they want to work with in the next partnership, and to set the agenda for the research.
- The next partnership will bring in even more industries, and will also focus, for example, on Big Data in health. Should pharmaceutical and technology companies really be given EU research funding to sit together and write the rules on how they can use and profit from patient and medical data?

On the Bio-Based Industries Joint Undertaking (BBI)

BBI is a public-private partnership between the European Commission and Bio-Based Industries Consortium (BIC), an ad hoc lobby group gathering companies in the agribusiness, forestry, biotechnology, chemicals and energy industries.

Timeline: Created in 2014 and running until 2024 (last projects to fund identified in 2020). The launch of BBI's successor, 'Circular Bio-based Europe', is being evaluated by the European Commission.

Budget: €3.7bn, of which €975m comes from public EU funding and €2.7bn is meant to be contributed by industry partners both in-kind and in-cash.

Stated Objective: To contribute to a more resource efficient and sustainable low-carbon economy and to increase economic growth and employment, in particular in rural areas.

BBI ignores the destructive consequences of its projects on Europe's terrestrial carbon sinks, soils, and forests. Increasing biomass extraction without imposing reductions in the use of fossil fuels combines the worst of both worlds: eliminating existing carbon sinks while emitting even more CO₂.

Implementing an industrial 'Bioeconomy' strategy

- The Bio-based Industries Joint Undertaking (BBI) was created in 2014 following a lengthy corporate lobby campaign, particularly by the biotech, forestry, and chemical industries. This market creation and support package is given by the European Commission to these industries to implement the EU's 'bioeconomy' strategy. BBI was to receive €975 million from the EU's budget, representing 21.8 percent of all the money spent by the EU in the second "Societal Challenge" identified by the EU's 2014-2020 Research Framework Programme, Horizon 2020: "Food security, sustainable agriculture and forestry, marine, maritime and inland water research, and the bioeconomy".
- The general idea behind the industrial bioeconomy is to partially replace fossil fuels with 'biomass' (biological matter, mainly the output of agriculture and forestry) in industrial processes, under the premise that 'biological' equals 'circular' which in turn equals 'sustainable'. This however is not necessarily the case. Indeed, the production of biomass in Europe has been plateauing over the past 15 years, and most of the current production is only achieved through unsustainable farming and forestry practices. The additional demand triggered by this industrial 'bioeconomy' can only be met at the expense of food production and the integrity of the remaining functioning ecosystems in Europe and abroad. Despite the BBI's insistence that its projects do not compete with food production, 24% of the projects it funded are based on agricultural biomass, 60% more than what was originally planned.

Eliminating existing carbon sinks in Europe and abroad, while emitting even more CO2

- BBI ignores the destructive consequences of its projects on Europe's terrestrial carbon sinks, soils, and forests. Increasing biomass extraction without imposing reductions in the use of fossil fuels combines the worst of both worlds: eliminating existing carbon sinks while emitting even more CO₂. Only 10 percent of all BBI-funded project coordinators predicted that their initiatives would have a positive impact on biodiversity, and only 27 percent anticipated having a positive impact on the sustainable management of natural resources.
- EU-15 countries got the lion's share of the total BBI funding, with 87.8 per cent of the participants coming from these countries versus 8.8 per cent from the EU-13.
- Building a European industry that feeds on biomass without sufficient domestic supply means a considerably increased risk of resource grabs elsewhere, particularly in the Global South where most of the planet's biomass is found. Should the path toward European sustainability really be about neocolonial imports of wood, oil, and sugar from the tropics again at the expense of the climate, biodiversity, and livelihoods of the people living there?
- BBI has dedicated more than 70% of its budget to date to funding pre-commercial and commercial-scale industrial projects for the production of various biomass-based items such as plastics and fuels. This is questionable: should pre-commercial and commercial-scale factories really be eligible for EU research funding, meant to fund research that is too risky for the private sector, when these projects have already been tested at the demonstrator scale, when the technology-related risks are minimal, and when the amounts involved are so significant?
 BBI also supports projects that include regulatory, lobbying, and public relations work to sway EU regulators and public perception to favour bio-based industries' priorities and products. Why should any of this be supported with public research funding?
- Due to a lack of transparency, the results of the research projects funded by the BBI are difficult to evaluate. Companies systematically privatise results and data regarding their projects, and the evaluation indicators used are so narrow that they at least initially completely failed to take social and environmental impacts into account.

While the EU brings in the money, industry partners hardly bring their share

While all BBI projects were supposed to be funded by both public money and industry's in-kind and financial support, the latest figures available show that participating companies had only paid a small amount of what they had promised. Thus the European Commission has already paid 27 per cent (€264,6 million) of their pledged cash contributions, while industry partners have so far only paid 3 percent of theirs, along with just 3.7% percent of their auditable inkind contributions. These companies are also opposed to disclosing the data that would enable a proper evaluation of these in-kind contributions.

A flawed model likely to be renewed in Horizon Europe (EU 2021-2027 research funding programme)

The European Commission's DG Research & Innovation is well aware of these failures, but has so far only slightly reduced its overall funding to BBI and continues to support the creation of its successor.

While all this could point to cases of industry abusing the system, they are also **consistent with the way in which BBI was set up**: its overall research agenda as well as its annual work plan have been authored by industry. Given such a set-up, that participating companies would divert BBI's resources for their own pre-existing priorities, instead of meeting societal challenges, was to be expected.

Member states and the European Commission are currently negotiating the EU's 2021-2027 budget, in particular Horizon Europe, the next EU Framework Programme for Research and Innovation. Meanwhile the corporate lobby groups interested in the development of the industrial bioeconomy – led by EuropaBio, the European lobby group of the biotech industry – are lobbying for the BBI's successor 'Circular Biobased Europe' to be expanded with even more public money. Given the central role that member states expect the EU's Bioeconomy strategy to play in the upcoming European Green Deal, and the support for 'Circular Bio-based Europe' expressed by the European Commission in its recent Circular Economy Action Plan, it is unfortunately quite possible that the industrial bioeconomy lobby will prevail.

RECOMMENDATIONS

(Specific recommendations are detailed at the end of each report)

On IMI2 and BBI (until their closure)

For BBI

- Only transfer to projects the remaining public funds due to them by the BBI once industry partners have delivered their expected cash and auditable in-kind (IKOP) contributions.
- Introduce a requirement to all BBI funded projects to publicly report the origin, nature and volumes of the biomass they use when relevant, and evaluate the projects' social and environmental impacts (including the fate of downstream waste), in particular looking at their consequences on direct and indirect land use change, food prices, climate, biodiversity and inequalities.

For IMI

- Incorporate pro-public safeguards and strict conditions to
 the remaining public EU funding, such as mandatory open
 access to projects' results, accessibility and affordability
 clauses, and public interest-driven forms of intellectual
 property management and licensing for exploitation of
 end-result products. This must particularly apply to the
 ongoing IMI funded projects directly or indirectly related
 to the coronavirus infections, such as the Zoonotic
 Anticipation and Preparedness Initiative (ZAPI) project,
 but also the projects funded through the calls IMI launched
 after the pandemic broke out.
- Grant and consortium agreements should be considered a matter of public interest and made public.
- Information about quantifying industry's 'in-kind' contributions, their composition and respective value for the projects should be transparent and made accessible.

On IMI & BBI's possible successors in Horizon Europe

Letting the lobby groups involved in IMI and BBI drive these Joint Undertakings' strategic research agenda and annual work plans gave them the possibility to steer both PPPs' funding and priorities for their own benefit, not that of the public, and they did not refrain from using it.

Industry seems to be again in the driving seat for IMI & BBI's possible successors in Horizon Europe, likely to be called Innovative Health Initiative and Circular Bio Based Europe respectively, already drafting their strategic agendas and lobbying the Commission on their features (no mandatory cash contributions from industry, IP governance, partners...). This is again a big step in the wrong direction, while serious reforms are needed towards an open, transparent and inclusive multi-stakeholder agenda-setting. It raises the concern that the European Commission once again is giving industry control over billions in EU public funding.

If the European Commission refuses to re-consider this essential feature and take the lead in designing these partnerships' agendas, as well as fixing the numerous governance, transparency and accountability problems of their predecessors, we strongly advise against their creation.

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