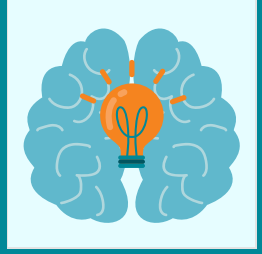
Building on Horizon Europe:

EFPIA'S recommendations for Framework Programme 10



DECEMBER 2024

Executive summary

In light of the upcoming negotiations on the next European Union (EU) Research and Innovation (R&I) Framework Programme (FP), the European Federation of Pharmaceutical Industries (EFPIA) is pleased to share nine recommendations which focus on maximising the impact of FP10. Implementing these recommendations would not only help maximise the investment in R&I but also help position the EU at the forefront of health R&I globally and prepare the EU to meet the upcoming healthcare challenges that will impact all Member States. The recommendations are clustered around three broad objectives, which address the need for funding along the continuum from drug discovery to healthcare delivery, the need for proactive inclusion of industry in all pillars of FP10, and the need for greater flexibility in the administration of R&I funding.

Improve continuity of funding for a globally competitive and impactful FP10, supporting research from discovery to delivery of healthcare products and services to increase Europe's global competitiveness in research and innovation by 2034 and beyond. With rising non-communicable diseases, an ageing population, and a shortage of healthcare workers, stable budgets are essential to advancing science and meeting healthcare system demands.

01 **Create funding instruments and resources for impact** by identifying and supporting high-priority projects, including late-stage biopreparedness and translational research.

02 **Increase and ringfence R&I budget to meet the needs of patients and health challenges, and fund large-scale projects.**

03 **Attract and involve the best world experts in EU projects** prioritising scientific excellence over geographical limits by enabling full participation of non-EU entities while distinguishing funding eligibility.

Strengthen industry participation across FP pillars from planning to execution to strengthen Europe's innovation capacity and meet Europe's long-term needs:

04 **Coordinate FP10 programming with industrial policies, under the steering of an EU Office of Life Sciences,** to accelerate R&D and benefit patients and society.

05 **Strengthen collaborative research and European competitiveness via an adequate budget in Pillar II, including public-private partnerships.**

06 **Tailor participation requirements to different stages of the R&I lifecycle to support translational and late-stage research,** particularly for large companies in Pillar III.

Embrace flexibility instead of one-size-fits-all and reduce administrative burdens to improve collaboration and maximise European investment. The Programme should be built on a trust-based system, unburdening companies with a detailed accounting:

07 **Adapt a Model Grant Agreement that also responds to industry operational reality,** with a specific status and simplified rules for participants not requesting EU funding, and allowing companies with multiple affiliates to manage processes centrally.

08 **Build public-private partnerships on in-kind contributions with fit-for-purpose reporting rules,** with reporting and certification of in-kind based on companies' usual practices, aligned with business operations and commercial accounting requirements.

09 **Intellectual property rules should enable the fast uptake, exploitation, and deployment of research results by industry,** avoiding far-reaching additional obligations.

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Introduction

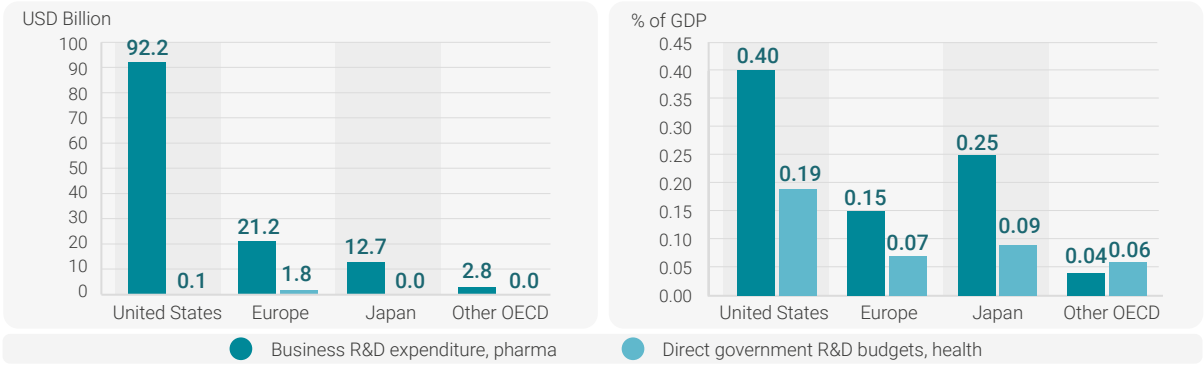
The ongoing poly-crisis—from COVID-19 to energy supply, geopolitical conflicts, and beyond—shows that quick changes in policy priorities often need to be made to adapt to the realities of the day. Therefore, the European Union's (EU) 7-year budgetary framework needs to be set up to support the EU's long-term strategic objectives while remaining flexible enough to adapt to change and fast enough to adapt to emergencies. This is particularly pertinent for the EU's Research and Innovation (R&I) Framework Programme (FP).

As the COVID-19 pandemic has demonstrated, health and life sciences are critical to addressing societal challenges and ensuring the well-being of citizens in Europe and around the globe. The research-based pharmaceutical sector, a key part of this ecosystem, is the most R&D-intensive sector in Europe[1]. In addition to driving medical progress by researching, developing, and bringing new medicines, this industry is a key asset of the European economy and represents almost 11% of EU exports. However, Europe lost its crown as the top innovation region in the world in 2000 and has now moved to third place on the podium as the originator of new molecules.

The 2024 Draghi report highlights both the importance of the pharmaceutical sector in Europe and the emerging EU competitiveness gap, which calls for a mobilisation of R&D efforts together with more supportive and coherent policies.[2]

Within this context, the next FP is a critical tool and an opportunity to support the EU's competitiveness, especially in health and life sciences. In the current FP, Horizon Europe, 10.3% is earmarked for Health R&I. This is slightly lower than what was allocated nearly two decades ago under FP7 (11.7%)[3]. Current OECD figures indicate that the EU invests an average of EUR 1.58 billion/year under Horizon Europe (FP9) compared to the United States, which invests an average of USD 52 billion/year. While Figure 1 does not include Member State R&I funding, it showcases the level of investment needed to stay competitive in this innovative sector.

Figure 1 **Business enterprise expenditure on pharmaceutical R&D and government budgets for health-related R&D, 2021 or the latest year available**



1 European Federation of Pharmaceutical Industries and Associations (EFPIA), *The pharmaceutical industry in figures*, 2024. https://efpia.eu/media/2rxdkn43/the-pharmaceutical-industry-in-figures-2024.pdf

2 European Commission, *EU Competitiveness: Looking ahead*, 2024, https://commission.europa.eu/topics/strengthening-european-competitiveness/eu-competitiveness-looking-ahead_en

3 European Commission, Directorate-General for Research and Innovation, *Horizon Europe, the EU Research & Innovation programme 2021-2027 – Horizon Europe - Investing to shape our future*, 2021, https://research-and-innovation.ec.europa.eu/document/download/9224c3b4-f529-4b48-b21b-879c442002a2_en?filename=ec_rtd_he-investing-to-shape-our-future.pdf;
European Commission, *Commission presents its evaluation of the 7th Framework Programme for Research*, European Commission Press corner, 2016, https://ec.europa.eu/commission/presscorner/detail/hu/MEMO_16_146

Partnering is an essential and unique European value. The European Federation of Pharmaceutical Industries (EFPIA) is proud to have jointly founded the Innovative Medicines Initiative (IMI) and its successor, the Innovative Health Initiative (IHI), with the European Commission. To progress biomedical research and address patient and societal needs, EFPIA members have committed nearly EUR 3 billion across IMI1, IMI2, and IHI. Increasing industry participation in framework programmes will not only contribute to addressing health challenges but also strengthen the translational research ecosystem in Europe and, therefore, Europe's competitiveness. In this vein, EFPIA published a call for a competitiveness strategy for health and life sciences in Europe in June 2024.[4] The EU's next R&I programme is critical to deliver on these aspirations. Discussions around including FP10 within a future broad Competitiveness Fund should be considered with care so that the strengths of the Horizon programmes can be preserved and leveraged.

Ahead of the budgetary and FP negotiations that are set to begin in mid-2025, the following recommendations build on two decades of hands-on experience and outline EFPIA's vision for the health and life sciences aspects of the EU's next FP.

4 European Federation of Pharmaceutical Industries and Associations (EFPIA), *European pharmaceutical industry calls for Competitiveness Strategy and dedicated Office for European Life Sciences*, 2024, https://efpia.eu/news-events/the-efpia-view/statements-press-releases/european-pharmaceutical-industry-calls-for-competitiveness-industrial-strategy-and-dedicated-office-for-life-sciences/

FP10 in support of a competitive life science R&D ecosystem in Europe

Based on the experience and reflections of EFPIA members, we believe that the development of the next FP should be driven by three core objectives:

Improve continuity of funding for a globally competitive and impactful FP10,

to increase Europe's global competitiveness in research and innovation by 2034 and beyond

Strengthen industry participation across FP pillars from planning to execution

to strengthen Europe's innovation capacity and address Europe's long-term needs

Embrace flexibility and reduce administrative burdens

to facilitate smoother collaboration and a greater return on European investment.

Improve continuity of funding for a globally competitive and impacting FP10

Health and life sciences are amongst the most intensive R&D sectors and have great potential to support and strengthen Europe's competitiveness. This requires a closer look at all "valleys of death" in the journey from scientific concept to healthcare solution and ensuring that budgets and tools help address those gaps. The rising non-communicable disease incidence, an ageing population, and a growing shortage of healthcare workers call for adequate and stable budgets that support science, its translation, and upscaling to meet the needs of patients and healthcare systems.

In this view, this paper puts forward three supporting recommendations in this regard, including:

01 Create funding instruments and resources for impact, with funding tools for late-stage

02 Increase and ringfence R&I budget to meet the needs of patients and health challenges, and fund large-scale projects

03 Attract and involve the best world experts in EU projects

RECOMMENDATION 01

Create funding instruments and resources for impact, with funding tools for late-stage

Description

While the three-pillar architecture of Horizon Europe reflects the innovation lifecycle—from fundamental research to translational application and close-to-market programmes— some activities do not fit with the current funding instruments. Furthermore, there are no mechanisms or funding tools to proactively identify top-tier projects and guide those towards other specific opportunities that could support the next milestone.

Recommendation relevance

Full programme | Pillar 1 | Pillar 2 | Pillar 3 | Partnerships

Supporting evidence

Reflections from Horizon Europe	Considerations for Framework Programme 10
Lack of perspectives for promising projects and results: European programmes are meant to provide an initial impetus and are not designed to drive projects through different milestones.	**Create a fluid interplay between parts of the R&I programme and support the sustainability of project results:** It is critical that the EU develops a mechanism to guide best-in-class research projects along the R&I lifecycle and develops synergies across the FP where appropriate. FP10 should set up **mechanisms to identify and accelerate top-tier research that helps foster end-to-end R&I, including specific funding for sustainability, further uptake of Horizon results,** and collaboration between projects and programmes.
Some "valleys of death" are not covered by funding tools: There are gaps in the funding instruments, and this prevents impact and response to some R&I challenges,	**Fill gaps in the funding tools for late-stage research and upscaling:** Areas not sufficiently covered by funding rules or tools include **late-stage development** of countermeasures for biopreparedness (Barda-like instruments with single lead beneficiary), **translational research** (incl. sustainability of infrastructure[5]), **implementation science** (e.g. regulatory acceptance processes, and health systems readiness for new health solutions). Additionally, **upscaling** is not covered and may require a connected programme in EU4Health.

5 European Commission, *Mission Letter to Ekaterina Zaharieva, Commissioner-Designate for Startups, Research and Innovation*, 2024 https://commission.europa.eu/document/130e9159-8616-4c29-9f61-04592557cf4c_en

RECOMMENDATION 02

Increase and ringfence R&I budget to meet the needs of patients and health challenges, and fund large-scale projects

Description

Health and life sciences are amongst the most intensive R&I sectors. Therefore, calls under the health priorities should be supported by 20% of the overall budget and be exempt from any cuts during the funding cycle. The programme should also encourage larger-scale projects and allow for budget adjustments in case of a crisis.

Recommendation relevance

Full programme	Pillar 1	Pillar 2	Pillar 3	Partnerships

Supporting evidence

Reflections from Horizon Europe	Considerations for Framework Programme 10
Unstable health budget: The overall Horizon Europe budget and the specific health R&I budget experienced significant cuts under the current cycle[6].	**Have a ringfenced stable budget for health research across pillars:** **The budget allocated to health priorities under FP10 should be ring-fenced** to prevent them from being repurposed for other policy goals. In addition, more flexibility is needed to reallocate funding in case of a health crisis.
Numerous projects with limited funding: Due to budget constraints, Horizon Europe topics provide a low budget per project. This leads to a **scattered budget across multiple priorities**. For example, the 2023-2024 Horizon Europe Work Programme for the Health Cluster[7] has an indicated budget of EUR 1-10 million for most projects (except cofund/partnership topics).	**"Focus on scale"[8] by funding larger-scale projects that can deliver on strategic priorities:** In addition to small projects, there is also a need to **invest in big transformative initiatives** (considering a budget of EUR 20-30 million or above when needed). This approach would increase the programme's impact, helping the EU and participating organisations achieve better and more focused outcomes, especially for later-stage projects..

6 Eu4health Civil Society Alliance, *For a Strong and Stable EU4Health Programme: The EU4Halth Civil Society Alliance's Statement* , 7 May 2024, https://eu4health.eu/for-a-strong-and-stable-eu4health-programme/

7 European Commission, *Horizon Europe – Work Programme 2023-2025, Health*, April 2024, https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-4-health_horizon-2023-2024_en.pdf

8 Mario Draghi, *The future of European competitiveness Part B | In-depth analysis and recommendations*, p.245, https://commission.europa.eu/topics/strengthening-european-competitiveness/eu-competitiveness-looking-ahead_en

RECOMMENDATION 03

Attract and involve the best world experts in EU projects

Description

Global cooperation is critical to ensuring scientific excellence in the geopolitical context and the need for strategic autonomy. FP10 should focus on a science-based approach rather than a geography-based approach to determining the ability to participate in EU R&I. FP10 rules should allow non-EU entities that actively contribute to FP projects to become full participants without requesting EU funding.

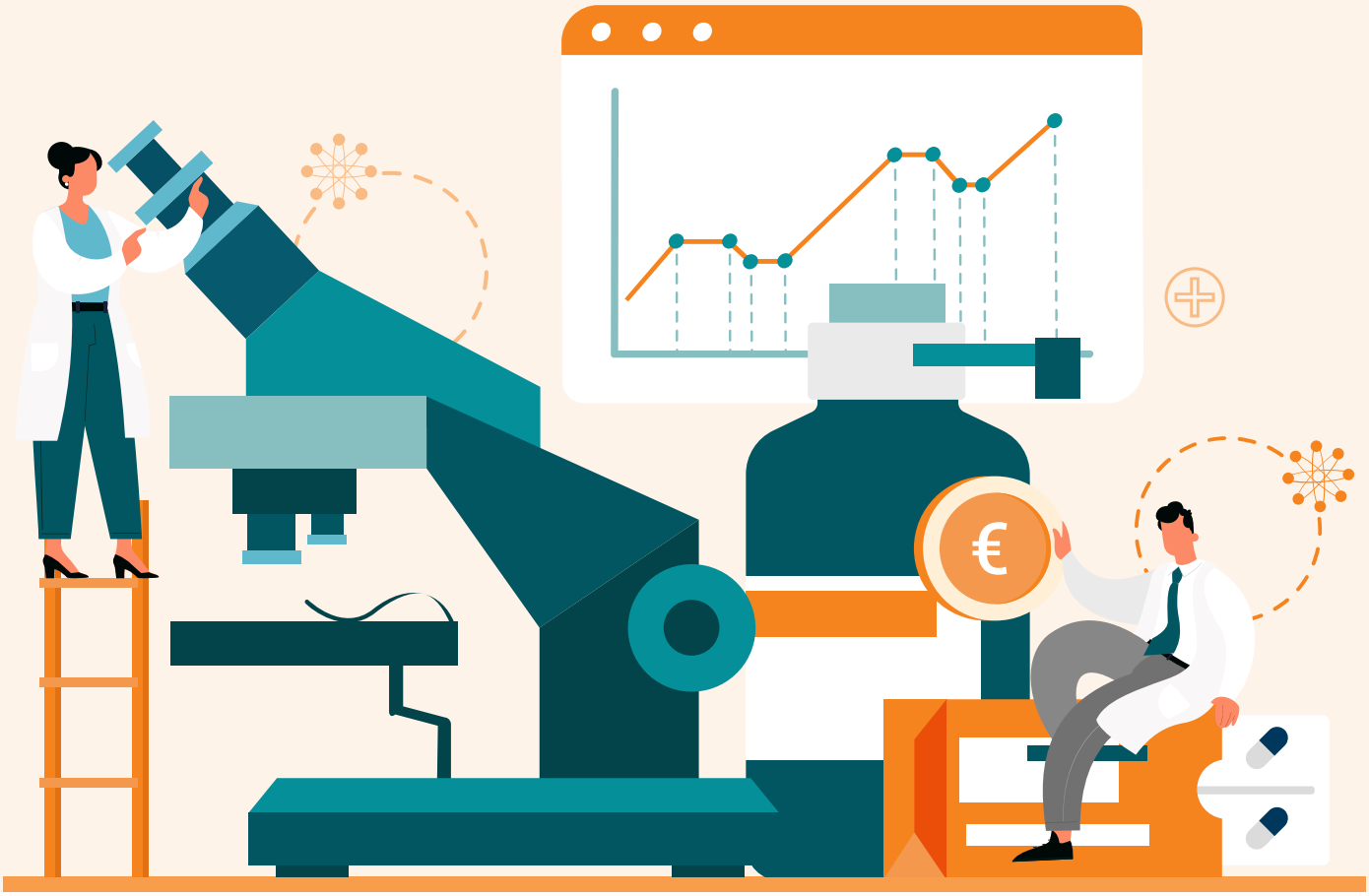
Recommendation relevance

Full programme	Pillar 1	Pillar 2	Pillar 3	Partnerships

Supporting evidence

Reflections from Horizon Europe	Considerations for Framework Programme 10
Limited differentiation between eligibility to participate and eligibility to receive funding: Since Horizon Europe does not differentiate between eligibility to *participate* and eligibility to *receive funding*, many non-EU participants who intend to contribute to projects without requesting any EU funding turn out not to be eligible to participate.	**Allow non-EU entities that actively contribute to FP projects:** Under FP10, specific rules should **allow non-EU entities to become full participants** (and not only associated partners), especially companies who are not requesting funding but actively contributing to EU projects. As a first step, the FP10 rules should **differentiate between eligibility to participate and eligibility to receive funding.**

Strengthen industry participation across FP pillars from planning to execution



To maximise the long-term impact of the EU's R&I framework, forging a strong partnership between the public and private sectors is critical. The partnerships in Horizon Europe are one area where this has worked well, and public-private collaborations should be encouraged and facilitated wherever they bring value across the programme. This requires identification of such areas through joint planning, and conditions to enable participation of companies of all sizes and origins where they add value and impact.

In this view, this paper puts forward three supporting recommendations in this regard, including:

04 Coordinate FP10 programming with industrial policies, under the steering of an EU Office of Life Sciences

05 Strengthen collaborative research and European competitiveness via an adequate budget in Pillar II, including public-private partnerships

06 Tailor participation requirements to different stages of the R&I lifecycle to support translational and late-stage research

RECOMMENDATION 04

Coordinate FP10 programming with industrial policies, under the steering of an EU Office of Life Sciences

Description

Strategic planning and programme co-creation should be **aligned with industrial policies** across all relevant Directorate General (DGs) and Agencies. In the Life Sciences sector, this should be coordinated by an **EU Office of Life Sciences.**

Recommendation relevance

Full programme	Pillar 1	Pillar 2	Pillar 3	Partnerships

Supporting evidence

Reflections from Horizon Europe	Considerations for Framework Programme 10
Limited industry involvement in priority setting The Life Sciences sector in the EU faces significant bureaucratic challenges due to a complex and fragmented environment. Despite some efforts to streamline processes, this fragmentation can translate into Horizon calls not adapted to the specificities of the sector. Moreover, industry is often not involved early on, thereby limiting the sector's potential as an economic and innovation driver essential for maintaining Europe's global edge. This stands in contrast to Europe's global competitors, who view Life Sciences as a strategic asset requiring a coherent strategy and comprehensive industry-wide consideration.	**FP10 priorities should be fully coordinated with industrial policies and, in the Life Sciences Sector, be coordinated with a dedicated EU Office of Life Sciences:** Europe needs a holistic approach, led by a dedicated Life Sciences office within the Commission that can steer and coordinate policymaking guided by a vision, accelerate translation and development as well as uptake of technologies in R&D, and deliver for patients and society. This Office should regularly engage with the industry and stakeholders, coordinate with national efforts to foster synergies, oversee the programming of FP10 priorities for research and innovation in healthcare[9], and be a key player in any new multi-disciplinary Strategy for European Life Sciences[10].

9 European Federation of Pharmaceutical Industries and Associations (EFPIA), *European pharmaceutical industry calls for Competitiveness Strategy and dedicated Office for European Life Sciences*, June 2024, https://efpia.eu/news-events/the-efpia-view/statements-press-releases/european-pharmaceutical-industry-calls-for-competitiveness-industrial-strategy-and-dedicated-office-for-life-sciences/

10 European Commission, *Mission Letter to Ekaterina Zaharieva, Commissioner-Designate for Startups*, Research and Innovation, 2024, https://commission.europa.eu/document/130e9159-8616-4c29-9f61-04592557cf4c_en

RECOMMENDATION 05

Strengthen collaborative research and European competitiveness via an adequate budget in Pillar II, including public-private partnerships

Description

Collaborative research under Pillar II (which includes the Health cluster and Partnerships) is key to enabling large-scale and impactful collaborations, as shown by the Innovative Medicines Initiative (IMI) and the Innovative Health Initiative (IHI). FP10 should maintain and strengthen this Pillar with its relevant clusters and instruments: these support an attractive and competitive EU R&I ecosystem involving all key stakeholders, which no other Pillar can achieve.

Recommendation relevance

Full programme	Pillar 1	Pillar 2	Pillar 3	Partnerships
		Pillar 2		

Supporting evidence

Reflections from Horizon Europe	Considerations for Framework Programme 10
Collaborative research under Pillar II (is key to enabling large-scale and impactful collaborations and strengthening an EU R&I ecosystem involving all stakeholders: Projects in IMI and IHI develop solutions and validate them in industry R&D practice. This accelerates translation and helps build a strong public-private ecosystem at the EU level.	**Maintain a strong Pillar II with well-funded instruments, including public-private Partnerships leveraging in-kind contributions from industry:** Having well funded instruments will enable collaborative research and public-private partnerships, support European competitiveness, and accelerate the translation of innovations into solutions for the benefit of patients in Europe.[11]

11 European Commission, *Mission Letter to Ekaterina Zaharieva, Commissioner-Designate for Startups*, Research and Innovation, 2024, https://commission.europa.eu/document/130e9159-8616-4c29-9f61-04592557cf4c_en;
European Federation of Pharmaceutical Industries and Associations (EFPIA), *Joint Statement for an ambitious FP10*, July 2024, https://efpia.eu/news-events/the-efpia-view/statements-press-releases/joint-statement-for-an-ambitious-fp10

RECOMMENDATION 06

Tailor participation requirements to different stages of the R&I lifecycle to support translational and late-stage research

Description

FP10's rules need to be tailored to the requirements of different stages of research. Translational research or late-stage development of critical health solutions requires the participation of larger industry players. Under Pillar II, for example, consortia-driven projects work well for early-stage research but are challenging for translational late-stage research. Additionally, where it makes sense—and in particular for health emergencies—Pillar II should allow for flexibility on eligibility for participation. Under Pillar III, the selection criteria tend to discourage the participation of larger players who can contribute valuable expertise.

Recommendation relevance

Full programme

Pillar 1

Pillar 2

Pillar 3


Partnerships

Supporting evidence

Reflections from Horizon Europe	Considerations for Framework Programme 10
Pillar III is restrictive towards larger companies: Despite focusing on supporting innovation and market deployment, the eligibility criteria under Pillar III present challenges for larger entities. The funding is often directed towards smaller-scale initiatives or startups, which might limit opportunities for larger entities to engage. Overall, these factors limit larger entities from applying for funding under Pillar III, despite the reduced emphasis on consortia, which is favourable.	**Adapt the eligibility criteria for Pillar III, facilitating larger industry player participation:** **Revise eligibility criteria under Pillar III to better accommodate the capabilities and needs of larger companies.** This includes reevaluating project size and scope to leverage the resources of larger entities and ensuring that **selection criteria prioritise innovation and market deployment potential**, rather than favouring smaller-scale initiatives. Going forward, Pillar III should also cater for projects whose size and scope leverage the resources of larger players, to the benefit of innovation.

Embrace flexibility instead of one-size-fits-all, and reduce administrative burdens

Reporting requirements under EU R&I programmes are heavier than any other R&I programme that EFPIA members are involved with elsewhere in the world. Since large companies typically involve multiple affiliates that contribute to projects, the detailed accounting required for in-kind resources creates a significant administrative burden. Instead of asking for a large amount of detailed administration, we need a trust-based system whereby the Commission can trust that industry is doing its utmost based on established practices. One such example is accepting the internal audits of companies, which are almost always carried out by independent external auditors. EFPIA's ambition is in line with the 2024-2029 Political guidelines, where Commission President von der Leyen highlights the need to reduce administrative burdens.[12] The prospect of a possible ***single*** rulebook under a common future Competitiveness Fund could further increase the existing administrative burden if it fails to allow flexible and adaptable rules from a fit-for-purpose perspective.

In this view, this paper puts forward three supporting recommendations in this regard, including:

07 Adapt a Model Grant Agreement that also responds to industry operational reality

08 Build public-private partnerships on in-kind contributions with fit-for-purpose reporting rules, with reporting and certification of in-kind based on companies' usual practices, aligned with business operations and commercial accounting requirements

09 Intellectual property rules should enable the fast uptake, exploitation, and deployment of research results by industry

12 European Commission, *Europe's Choice: Political Guidelines for the Next Commission 2024-2029*, July 2024 https://commission.europa.eu/document/download/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en?filename=Political%20Guidelines%202024-2029_EN.pdf

RECOMMENDATION 07

Adapt a Model Grant Agreement that also responds to industry operational reality

Description

The Horizon Europe Model Grant Agreement (MGA) intends to harmonise processes across HE. Building on academia, it fails to recognise private sector operations and industry-specific context. This generates a lot of bureaucracy that does not translate into any scientific, budget management, or impact benefits. To **alleviate administrative burdens and enhance project efficiency, a departure from the single corporate MGA approach** or broader allowance for **derogations or specific rules** is imperative to enable better alignment with diverse project categories and industries. The **status of participants not requesting EU funding** should be embedded in the FP10 legislation and applicable grant agreements, with specific clauses, in particular regarding reporting and exploitation obligations.

Recommendation Relevance

Full programme	Pillar 1	Pillar 2	Pillar 3	Partnerships

Supporting evidence

Reflections from Horizon Europe	Considerations for Framework Programme 10
A one-size-fits-all MGA model: The MGA is the legal backbone of EU-funded projects, delineating responsibilities, partnerships, activities, and budgets. However, under the "corporate" approach upheld by the Commission, its current one-size-fits-all framework fails to accommodate industry-specific nuances, thus impeding streamlined collaboration. Industry partners, for example, are not funded in the same way as academic partners and have more complex intellectual property protection needs to accommodate. The lack of adaptability in the MGA not only complicates processes but also burdens applicants with often irrelevant regulations, hindering project effectiveness.	**Depart from the single MGA approach:** The MGA should consider the specific nature of different instruments and the imperatives of global industrial players. Key improvements should include: • Introducing the concept of **beneficiaries not receiving funding** (who contribute in kind or otherwise to projects and do not receive money), with specific status and simplified rules compared to those receiving public funds. • Allowing **one company to complete all processes centrally for all its affiliates** (contracting, reporting, auditing), rather than separately for each affiliate (the savings will be invested in research) In order to enable this flexible approach, the legislation and rules on FP10 should be much more open to specific rules and to a few key derogations where needed.

RECOMMENDATION 08

Build public-private partnerships on in-kind contributions with fit-for-purpose reporting rules

Description

The **in-kind contributions in partnerships and other collaborations foster solid connections between industry and academia, help alignment on problems and codesigning solutions, and enable translational work** which would otherwise not be possible in a solely academic set-up. To maximise the impact of in-kind contributions, adjustments should be made to the costing approaches to align them with business operations and commercial accounting requirements. Adapted costing methodologies (unit cost and other specific certified methodologies based on usual accounting practices) will enable more impactful collaborations.

Recommendation relevance

Full programme	Pillar 1	Pillar 2	Pillar 3	Partnerships

Supporting evidence

Reflections from Horizon Europe	Considerations for Framework Programme 10
Recognise the value of in-kind contributions for achieving R&I objectives: Public-private collaborations (such as Joint Undertakings and other public-private projects) demonstrated the value of in-kind contributions to progress science and deliver impact. Industry contributions consist of a mix of people who bring unique expertise and industrial and regulatory consideration, as well as assets such as infrastructure, data, and development programmes that are otherwise not available to academia. The complexity of problems that are addressed by EU research depends on this mix to change the status quo. Yet, in an economic downturn, these contributions are questioned as their value is not clearly communicated.	**FP10 should continue building on in-kind contributions as the cornerstone of public-private partnerships:** This will help attract resources, expertise, and assets that global industry can contribute to EU projects. In-kind contributions should combine **direct** contributions in projects but also **additional** activities which can play a key role in ensuring the uptake, sustainability, and impact of project results.

Costing of in-kind contributions is challenging:

The EU rules based on costs of goods are not suitable for non-financial assets, such as infrastructure, molecules and compounds, diagnostics, assays, and software licences. For programmes such as IHI/IMI, it means that not all contributions are recognised and can be matched by EU funding. Consequently, companies often opt to become subcontractors, selling their assets instead of collaborating as partners. This practice shifts EU funds towards procurement rather than promoting collaborative research, which in turn reduces resource efficiency and hampers the potential for innovative results.

Adopt costing methodologies aligned with market realities to enable more in-kind contributions:

The commitment to partnerships through in-kind contributions enables companies to contribute with expertise and assets that are not always present in the public sector and from which public partners and SMEs can benefit (data, compounds/medicines, diagnostic kits or services, lab work, infrastructure, etc.). The **rules for costing and certifying direct and indirect in-kind contributions should align with business reality. This implies accepting companies' usual practices (such as fully-loaded FTEs) in line with international standards, and allowing for unit costs** or other certified methodologies agreed upon at the instrument level, complying with confidentiality and competition law, and meeting the IP protection needs of the industry.

RECOMMENDATION 09

Intellectual property rules should enable the fast uptake, exploitation, and deployment of research results by industry

Description

Intellectual property protection is the cornerstone of European competitiveness. Adequate rules for protection, including transfer of ownership and other technology transfer mechanisms, are essential for the further development of an asset and for the implementation of results in standard research practice. Clear differentiation between research use and commercial exploitation, as well as the ability to transfer rights between affiliates of the same companies, is critical. Any strings attached to the future results have also to be proportionate to the project objectives and value of the grant in light of the total R&D investment to achieve this result.

Recommendation relevance

Full programme	Pillar 1	Pillar 2	Pillar 3	Partnerships

Supporting evidence

Reflections from Horizon Europe	Considerations for Framework Programme 10
Lack of binding rules on the differentiation between commercial exploitation and research use: The lack of clear differentiation between research use and commercial exploitation generates uncertainty about companies' ability to access results for further research activities and, therefore, does not incentivise participation.	**Differentiate between access rights to results for commercial exploitation and research use:** FP10 rules should **differentiate between "Direct Exploitation" and "Research Use" regarding access rights to results.** This approach would promote fair resource distribution from companies, foster genuine innovation, and uphold accountability, thus nurturing a strong Research and Innovation ecosystem in Europe.
Transfer of ownership between affiliates is a challenge for multinationals: The rule within Horizon Europe that allows the EU to object to ownership transfers between affiliates not based in the EU is challenging for multinational industries. This restriction creates legal uncertainties and complicates the operations of companies with global footprints, potentially impeding their ability to allocate resources efficiently and collaborate across borders.	**Amend transfer of ownership rules between affiliates:** The **right to object to the transfer or licensing of project results should be applied judiciously only on a case-by-case basis on call topics involving strategic assets**. It should also apply only to beneficiaries of EU funding and not to participants who do not receive EU funding. The use of targeted international initiatives should be integrated into calls as appropriate.

	Introduction of far-reaching additional exploitation obligations: Specific exploitation obligations to address public health emergencies appeared in Horizon 2020 and were used for projects related to the COVID-19 crisis. In Horizon Europe, the 3A rule (access, affordability, availability) was introduced in several partnerships (e.g., EDCTP and IHIArticle 125a of the SBA). It acts as a deterrent to ambitious collaborations involving clinical research. Originally meant for EU direct investment in product development, the conditions became too broad and far-reaching and are a **disincentive for companies to run clinical studies or share clinical data within public-private collaborative projects.**	**Exclude any pre-defined broad additional exploitation obligations and rely on relevant sectoral legislation:** The introduction of additional exploitation conditions in Partnerships on top of existing sectoral legislation and general rules of Horizon / FP10 for dissemination and exploitation risks creating confusion and legal uncertainty. This is particularly important for companies, in particular SMEs, where such rules would create uncertainty about their crucial (sometimes unique) asset. Instead, partners should be encouraged to share knowledge and data. **Specific rules should only be applicable to public health emergencies for participants who receive EU funding.**