Green Paper “From Challenges to Opportunities: Towards a Common Strategic Framework for EU Research and Innovation Funding”

Views from the European Federation of Pharmaceutical Industries and Associations (EFPIA) and European Biopharmaceutical Enterprises (EBE)

EFPIA and EBE

EFPIA represents the pharmaceutical industry operating in Europe. Through its direct membership of 31 national associations and 40 leading pharmaceutical companies, EFPIA provides the voice of 2,200 companies committed to researching, developing and bringing new medicines to improve health and quality of life around the world.

EFPIA member are committed to delivering innovative medicines to address the needs of patients and reducing the burden of chronic diseases for Europe’s ageing population. EFPIA believes in close cooperation with stakeholders to help create sustainable healthcare systems and to develop prompt responses to health threats.

EBE (European Biopharmaceutical Enterprises) is the European trade association that represents biopharmaceutical companies of all sizes operating in Europe. It has currently 57 member companies - of which 50% are SMEs - engaged in the research, development, manufacturing and marketing of new medicinal products using biotechnology. EBE also operates as the biotechnology arm of EFPIA.

EFPIA and EBE are pleased to contribute to the European Commission’s consultation on its Green Paper “From Challenges to Opportunities: Towards a Common Strategic Framework for EU Research and Innovation Funding”. We recognise the potential benefits that may accrue from the incorporation of the various EU research and innovation funding initiatives into a single programme. We believe that the establishment of the framework would help to ensure that the EU supports high quality research across its Member States, and that there will be greater clarity regarding the prioritisation of the EU’s research agenda, which will need to driven by industrial and societal objectives as well as scientific need.

Introduction

The EU continues to face major healthcare challenges, and the need for more and better medicines and care will become acute. Many social, economic, and political questions will need to be addressed. Effective and well-funded programmes to support science and innovation have a vital role to play in Europe’s response to these challenges. In addition to the need for an effective funding mechanism for research in the EU, there are however many barriers to innovation that need to be addressed including under-investment in our knowledge foundation, unsatisfactory framework conditions, excessive fragmentation and costly duplication. The proposed Common Strategic Framework (CSF) for EU Research and Innovation Funding could help resolve a number of these.

We consider that at present the funding environment for EU research and innovation programmes is too complex, with fragmented and not always consistent instruments and funding mechanisms. We are pleased that the Commission recognises that there is a need for further simplification in the rules of its many instruments and in the associated audit and control mechanisms. It is also important and timely that the need to help focus and make best use of the EU’s limited resources has been recognised. Difficult decisions will have to be made regarding the allocation of funding both at the EU and national level if Europe is to stand any chance in developing the critical mass needed to address the key societal challenges, remain internationally competitive whilst continuing to ensure that excellence in research and innovation is supported.
We agree that if implemented correctly the development of the CSF will enable cross-border pooling of resources to help achieve critical mass and the diffusion of knowledge, whilst promoting competition in research, important for raising levels of excellence. With the increasing costs of research it is essential that organisations come together to tackle these key scientific issues, making the availability of effective financial instruments, with high leverage, of increasing importance.

Whilst Europe must enhance its competitiveness it is essential that the EU R&D-related programmes should take more advantage of the increasingly international nature of research by attracting, whenever possible, greater participation from globally active research-based companies and by seeking synergies with international research initiatives. The EU has much to offer, and to benefit from, such increased collaboration.

EFPIA and EBE welcome the importance that is being given in this consultation to assessing the opportunities that could arise from an increased focus on public private partnerships in the tackling of key societal issues, whilst enhancing the EU’s science base and supporting Europe’s industrial competitiveness, EFPIA is a founder member of the Innovative Medicine Initiative (IMI), one of the first Joint Technology Initiatives (JTIs), where cooperation between academia, SMEs and the industry has changed the understanding and perspective of public private partnerships within life science going forward. Pooling resources, experiences and knowledge across different stakeholders has shown IMI’s unique value and great future potential. Important experiences have been learned through IMI and the success and positive learnings from this initiative should be taken into account in the development of the CSF.

There is a growing debate on the outstanding public health needs that are global in nature and that must be addressed. EFPIA and EBE suggests that public and private investments, and subsequent regulatory and market access standards, to a greater extent are aligned to meet the medical need.

In summary, EFPIA and EBE consider that three main challenges should be addressed to make the CSF an essential and integral element of European and national innovation strategies:

1. The streamlining, coordination and cross-fertilisation between various schemes and programmes (R&D, innovation, cohesion)
2. Administrative simplification
3. Increased synergies with national and international innovation-oriented programmes, whilst stimulating the participation of researchers from industrial and academic centres of excellence from other geographies in fields of research of strategic relevance to the EU.

Specific comments to consultation questions

Working together to deliver on Europe 2020

Q1. How should the Common Strategic Framework make EU research and innovation funding more attractive and easy to access for participants? What is needed in addition to a single entry point with common IT tools, a one stop shop for support, a streamlined set of funding instruments covering the full innovation chain and further steps towards administrative simplification?

The CSF offers a great opportunity to significantly streamline access to the multitude of existing research and innovation funding programmes and instruments. Although they may have separate objectives, consistency should also be sought with infrastructure and human capital development programmes under EU Structural Funds.
Bringing more consistency and the cutting of red tape are two essential elements which would increase the attractiveness of EU funding. Simplification from a users perspective should have as its focus the removal of unnecessary administrative requirements which do not translate into tangible outcomes and which delays access to funding. A key objective should be to shorten the time from idea generation to access to funding and project kick off, to make EU research programmes essential parts of Europe 2020 strategies.

Examples of concrete steps should include:

1) **Scope of the projects**: The EU programs should not be isolated, but should also take into account global research programmes, particular as the health challenges are of a global nature and the life science industry is global.

2) **Administrative simplification** should also cover streamlining of project documentation (one project/one document) and submission process.

3) **Flexibility of structures**: One size does not fit all. It is important to build into the system flexibility that would allow the adaption of the structures/funding schemes to the needs of a specific project or technology platform, while using a general framework to define objectives, eligibility criteria, payment and control mechanisms. In particular, in cutting-edge science and innovation where the need for speed and quick investments are important, the current requirement for applicants to have to address certain politically-driven aspects is seen as constituting a barrier to access to participation in some programmes. Examples of this include the requirement to involve a high minimum number of participants in consortia, the need to cover a certain geographical balance or SME ratio. One way of achieving this would be to design specific flexible instruments which suit the proposed objectives of each study. It should also be possible for example to amend the composition of a project’s consortium to enable it to adapt to the evolution of the project. This is particularly important in the case of Public Private Partnerships such as Joint Technology Initiatives. The JTIs Sherpa report offers a lot of suggestions on how this rationalisation could be achieved.

4) **Eligibility for funding**: Research is a global exercise even for the companies and academic groups based in the EU. Europe would benefit from developing closer links to centres of global excellence outside the EU of relevance to the EU’s priorities in research.

5) **Facilitate networking and dissemination**:
   - Optimising search tools for partners through the single entry point on specific projects in order to promote/encourage development of networks of competence.
   - Pre-marketing/promotion of calls for expressions of interest at national level before official launch to allow more time for building consortia and preparing projects
   - Mechanisms to stimulate exchange of best practice in the accessing of EU funding could be developed by the Commission.

**Q2. How should EU funding best cover the full innovation cycle from research to market uptake?**

Community R&D and innovation funding schemes should cover all stages of research and development, including some aspects of more near-market competitive research. Priorities for research needs should reflect both academic and commercial perspectives on opportunities and priorities.
The current mix of curiosity-driven research and industry-driven JTIs is a valuable approach. The distinct value and role of each should not be blurred. For example, funding for the IMI JTI should remain industry-driven and it should not become an additional vehicle for academia to pursue its research agenda. At the same time, in many areas of medicines research, fundamental scientific knowledge on disease mechanisms and processes is still lacking. Continuing to provide financial support for high quality academic research and the development of the EU talent pool should remain key priorities for EU and Member State research funds.

In the life science field, it is important to prioritise public and private investments towards areas with unmet medical need. Public bodies, as well as private investors, lack clear guidance at the EU or global level as to what these needs are. Such explicit wishes would also benefit from having endorsement from regulatory bodies, payers and healthcare providers so that innovation is recognised and rewarded.

Medical as well as economic value will stem from innovation if scientific discoveries can be translated into clinical advances. Reaching such an objective implies to assess the projects not only from a scientific perspective, but also to take into account a broader range of criteria such as developing of manufacturing prototypes as well as the demonstration of clinical benefits but also of medico-economic and health-outcome improvements.

More attention should be given to how the outcome of projects will ultimately be taken forwards and whether there needs to be mechanisms and approval processes in place at the start for further proof of concept stages. The possibility of providing for follow-up funding must be planned upfront.

Better use should be made of results produced in various schemes, linking consortia together, with adequate knowledge management.

Moving forwards we suggest that what will be required of the CSF is:

- The setting up of dedicated programmes for defined steps of the innovation cycle within a transparent programme structure
- The simplification and facilitation of interactions across EU-funded projects
- Simplifying interactions with other external funding organizations
- Facilitating internal cross financing of projects without impacting the EU funding levels
- The fostering of SME and industry alliances for innovative approaches to bring ideas from research to market
- The provision of support for innovation cluster models with SME, academia and industry co-investment

Developing platform technologies (stem cells, gene therapy etc) into commercially-relevant products frequently proves more time consuming than anticipated. Providing additional funding to develop technologies to a point where private investment is more viable is another potentially valuable aspect of research funding. Traditionally this has been the field of SMEs but if there is no viable route to market in a foreseeable timeframe, there may be benefits in continuing to support this work in academic settings.

Whilst there are problems across the innovation cycle in new medicines development, not all of the problems can be resolved through research-related public funding. Challenges to the innovation cycle that need to be tackled head on include excessive regulations, price constraints, limiting access to markets and the value of commercial markets.

**Q 3. What are the characteristics of EU funding that maximise the benefit of acting at the EU level? Should there be a strong emphasis on leveraging other sources of funding?**

Current funding schemes are designed to fulfil individual policy objectives. It will be important for the CSF to:
- Seek consistency and strategic direction for all R&D and innovation funding schemes in order to avoid duplicating resources. Addressing the key challenges identified in the “Europe 2020” proposals will provide a good opportunity for such streamlining.
- Focus on areas where one industry, stakeholder or country could not tackle the research challenges alone.
- Involve regulators from the onset in relevant programmes which will provide for quicker regulatory acceptance of new technologies and solutions and will therefore allow products to reach the market quicker.

In order to maximise the benefits of EU level action, we need to bring together the best researchers in Europe. However, it is sometimes of importance to extend this to a more global level with joint initiatives involving other major players, from outside the EU, including those from industry. Public Private Partnerships offer co-funding opportunities and often higher return on investment including innovative products, approaches and solutions that can be used on the market place.

Seeking complementarities and synergies with national and international initiatives in order to optimise use of resources is essential. Calls for projects or funded initiatives should not compete or duplicate other initiatives. Again, this should also mean attracting the participation in EU projects of centres of excellence (from both academia and companies) from around the globe.

Q 4. **How should EU research and innovation funding be used to pool Member States’ research and innovation resources? Should Joint Programming Initiatives between groups of Member States be supported?**

European Technology Platforms have been shown to be of value in connecting Member States with EU-funded research programmes and their further development should be encouraged.

The key question here is not one of funding but of administrative support and simplification. If two or more Member States wish to collaborate on a particular research theme, the EU could play a valuable role in the development of simple templates or processes for handling issues of IP, application criteria, payment structures etc. In some cases where EU Member States wish to collaborate, it may be appropriate for the EU to provide some specific funds to help manage the project or any overhead costs of the international elements. Joint programming, supported through the Joint Programming Initiatives (JPIs) is a key mechanism to enable Member States to address the key societal challenges by bringing together national activities under an agreed common strategy.

Any of the proposed methods of facilitating and supporting collaborative research between Member States rest on the ability of the EU to develop highly efficient and robust systems for managing research funding and projects and that these become familiar to researchers across the EU. If the EU processes remain more bureaucratic, complex and unfamiliar than Member States’ mechanisms, then any EU intervention to support collaboration between countries will probably be counter-productive. Community funding schemes should complement, not compete with national programmes.

By their nature, multiannual programmes are less flexible and their programmes, designed many years in advance, adapt poorly to rapidly evolving science and market conditions. When designing multiannual funding instruments the following should be considered:

- The need to seek complementarities with national programmes
- Prioritising activities that bring added -value to Member States initiatives – and therefore supporting those initiatives when one country alone could not offer adequate support

Q 5. **What should be the balance between smaller, targeted projects and larger, strategic ones?**
There will always be a need for both larger more strategic programmes to address major challenges as well smaller targeted programmes. We suggest however that it would seem more logical that EU funding, particularly in the context of technology platforms, should concentrate more on the bigger projects which could not be supported at national level by one country or one sector alone. Support for smaller projects could be better addressed outside technology platforms and by national funding programmes.

Some of the outstanding public health challenges require “big solutions” to overcome scientific bottlenecks, and in some cases market failure, such as the area of antibiotics.

It does however remain a matter of concern that in many cases, the current administrative burden in participating is the same independent of project size.

Q 6. How could the Commission ensure the balance between a unique set of rules allowing for radical simplification and the necessity to keep a certain degree of flexibility and diversity to achieve objectives of different instruments, and respond to the needs of different beneficiaries, in particular SMEs?

The current EU funding landscape for science and technology is very complicated and the proposed CSF must have simplification of the process as its key goal. However, at the same time it must be recognised that each of the current instruments, e.g. FP7, JTIs, EIT and CIP etc, have different objectives making the introduction of a single set of rules and operating principles difficult, if not impossible.

Setting framework structures, but ensuring there is flexibility in place for the format for projects, partnerships and other collaborations, is as important (if not more so) for SMEs and academia as it is for the larger participants. If the rules and processes are simple enough for SMEs to be willing to apply, then they should work for all other potential participants. If there are specific policy objectives that the Commission has in creating a particular funding programme, these should be achievable without changing the rules for applicants. For example, if the aim is support excellent university research across the EU, then the priority topics will reflect that and the decision on awarding the funds can be made on the basis of peer-review of research application quality. If the aim is to support SMEs or infrastructure in a particular geography, then either these should be supported using other EU instruments, or again the priority topics need to be relevant to these cases. In all cases the decision criteria for the competition adjusted accordingly. As long as the Commission is clear about these variances up front, then the core set of rules for applicants and recipients of funds should be common.

In summary:
- Multiannual programmes should consider flexibility in setting their agendas in order to adapt to scientific and market evolving environment.
- The objective and deliverables should drive the format. Rules should be limited to eligibility, transparency and accountability. The Commission’s role should be less as a “policeman”, but more as a facilitator for innovation-related projects.
- Evaluation criteria should be developed in response to the specific objectives of each funding mechanism.

Q7. What should be the measures of success for EU research and innovation funding? Which performance indicators could be used?

Many national funding bodies are seeking to introduce assessments of the impact of the research they are funding and the EU should be able to identify and implement a number of these key performance indicators (KPI). If a prime focus of the proposed strategic framework is to stimulate collaborations at the industry/academic interface then one key measure of success would be the number of new industry/academic partnerships created. Many sectors, including pharmaceuticals, operate globally and in addition to stimulating the industry/academic interface at the European level, the Commission
should also be encouraging inward-investment from outside of the EU of appropriate organisations seeking to collaborate with European academics and SMEs. Other measures of success would include:

- For blue-sky research – exploitation of results for a commercial phase, or bringing a research project to the next level, number of patents and peer reviewed scientific publications.
- For applied research – creation of spin-offs, number of new SMEs participating in EU R&D projects, new enterprises, new products and new services, competitiveness of EU-based companies, levels of investment (business enterprise R&D expenditure) in the EU compared to other regions.
- For projects - their ability to address essential challenges and R&D bottlenecks, time from beginning of project to product marketing, and - in their longer term –the impact upon Europe’s talent pool.
- Speed of uptake of new products and services across the EU should also become a core metric of the overall EU innovation agenda. However, other policy measures will be more important here than funding and this metric should not be linked to the assessment of success for research funding.

Most importantly, if there are EU- or global mechanisms for agreeing and expressing clear priorities (cf. WHO Report on Priority Medicines, 2004), success would be defined as meeting these needs.

In addition, some simple metrics such as time from application to grant should also be used in order to measure the performance of the funding processes (and should be no more than 6 months).

Q 8. **How should EU research and innovation funding relate to regional and national funding? How should this funding complement funds from the future Cohesion policy, designed to help the less developed regions of the EU, and the rural development funds?**

The commitment of Member States to achieve the 3% expenditure of GDP in research would complement the European commitment. EU-funded research and innovation programmes should not be in competition with national and regional funding initiatives, but should play to their strengths, bringing key diverse groups together where appropriate to build on agreed pan-EU research priorities. This will help provide the necessary critical mass in key areas of importance to Europe. EU research and innovation funding should focus more on strategic projects with a high-level impact on the EU.

Cohesion funding may have an important role to play in research capacity building, and there could be greater use of the EU’s Structural Funds for supporting the development of the science and technology infrastructure in some Member States, but this should not be a key focus of the proposed Common Strategic Framework. The main criteria in the allocation of the EU’s research and innovation funds should always be the quality of the research (or training) being supported.

**Tackling Societal Challenges**

Q 9. **How should a stronger focus on societal challenges affect the balance between curiosity-driven research and agenda-driven activities?**

With economic development and longevity follow different disease burden in the form of diabetes, obesity and degenerative diseases. There is significant unmet medical need in many areas, for example highlighted in the WHO report 2004 on Priority Medicines. When assessing disease burden account should be take several domains of medical need: patient outcomes, tolerability, adherence, quality of life and financial impact on health care and society at large (such as productivity gains). EU
research funding should be more clearly aligned with the public health needs, and also be reflected in success is measured.

However, this needs-driven research must be complemented by continued support within the EU for pre-competitive curiosity-driven research – the discovery and development of tomorrow’s medicines is reliant on the outcomes of long-term basic biomedical research. There is a need for an appropriate balance in the funding of curiosity-driven research and research aimed at addressing society’s grand challenges. A wide range of different funding mechanisms will be required to address the major societal challenges – from both a top down and bottom up approach. This balance between curiosity-driven research and agenda-driven activities needs to be determined in the context of the specific challenge. At the same time there needs to be an ongoing debate within the EU and its Member States as to what should be the appropriate grand challenges that need to be tackled.

Q 11. How should EU research and innovation funding best support policy-making and forward-looking activities?

EU research and innovation funding should be aligned to but not impact directly upon policy-making activities.

EU should inform national funding agencies about public health priorities, so that investments can be channelled in a meaningful direction.

By making more use of advice and nominations from national funding agencies, European and national professional bodies and industry associations, the Commission should seek to identify more appropriate experts who able to provide input on specific policy and forward-looking (Foresight) initiatives of relevance to its proposed research programmes. There will be a need for the EU to continue to support special instruments such as road-mapping initiatives. The funding programmes should facilitate the formation of consortia of key stakeholders to develop best practices / policies.

Q 13. How could EU research and innovation activities attract greater interest and involvement of citizens and civil society?

EU research programmes do need to have more proactive communication policies and mechanisms in place to explain the goals of European-funded research and innovation activities. Many of the current research and innovation issues within the biomedical research field are focussed on the key societal challenges that have a real and direct impact on EU citizens. It is essential therefore that appropriate approaches to communicating such complex issues are in place and continue to be supported.

A core objective of the Innovative Medicines Initiative is the need to focus on the patient. The EU could provide guidance to all research groups it funds on how best they could involve patient groups, user groups and other stakeholders in the design and implementation of their programmes.

The EU could support/facilitate the establishment of similar specific education and training programmes to help stimulate public understanding of recent development in emerging scientific fields. This may help maximize society’s acceptance of such new technologies.

**Strengthening competitiveness**

Q 14. How should EU funding best take account of the broad nature of innovation, including non-technological innovation, eco-innovation and social innovation?
The future strategic framework should definitely include support for addressing non-technological issues—particularly those such as regulations that may act as barriers to the uptake of innovation. Exploring the differences in the uptake of new goods and services (including new medicines) should indicate areas or countries where complementary, non-technical innovation process are working well or not working well.

Health care delivery suffer from poor integration, silo budgeting and lack of coordination which result in suboptimal patient outcomes in areas such as chronic disease. Even when technologies and medicines exist, they are not delivered in an appropriate way. Innovation that is not implemented is both a missed opportunity and a waste of money.

**Q 15. How should industrial participation in EU research and innovation programmes be strengthened? How should Joint Technology Initiatives (such as those launched in the current Framework Programmes) or different forms of 'public private partnership' be supported? What should be the role of European Technology Platforms?**

The pharmaceutical industry relies on high quality longer-term basic biomedical research funded both at a national and a coordinated EU level. There must be an appropriate level of curiosity-driven research and mechanisms in place to ensure the continued quality and relevance of the EU’s talent pool. At the same time, life sciences EU research and innovation programmes should be strengthened by reduced bureaucracy, secured relevance of topics to industry, and a greater willingness in general to support industry in pre-competitive research areas. There should also be an assessment of where and how there could be opportunities to support more near-market related studies, such as for example in supporting research to address bottlenecks in overcoming antimicrobial resistance and the development of new antimicrobials.

The development of the original European Technology Platform for IMI was a valuable exercise in bringing together key stakeholders (the industry, SMEs, patient groups, regulators, the Commission etc) to identify the real challenges in medicines discovery and development and the development of the EU’s skills base. Developing the ETP for innovative medicines was a well co-ordinated (and well-publicised) exercise which led to the development of the vision for IMI and its establishment as a JTI. There are numerous ETPs currently in existence with little interaction between key overlapping areas. As other ETPs go forward they must be better coordinated.

If the key goal of the CSF is to stimulate a greater participation of larger companies, then the Commission has already clear feedback from the current JTIs, such as the Innovative Medicines Initiative, on what is required: a much leaner and more transparent process with a major reduction in the financial oversight arrangements (particularly when companies are providing contributions and not receiving cash from the Commission); the allowing of global company participation; extending agreements to cover affiliates within large company structures etc. The problems have arisen when there are too many attempts to constrain participation. Keeping the rules simple and aiming to be inclusive should help significantly.

Whilst SMEs do have a vital role to play in the EU research base and their participation does need to be strengthened, access to EU funding and the development of active partnerships for the more “mobile” larger companies should also be supported as a priority—both are essential for the innovation “ecosystem” in biomedical R&D. Simplification of procedures, easing of skills sharing, partnership building in the medium term and predictability of EU funding are key determinants of success.

A Joint Technology Initiative such as IMI and the establishment of the individual projects/Public Private Partnerships that have arisen from it are playing a key role in the open innovation needs of R&D based pharmaceutical companies, bringing together as they are the key stakeholders in reducing R&D bottlenecks. IMI is an example of good practice and on which the Commission should capitalize as it seeks to undertake other related initiatives and funding mechanisms.
Q 16. How and what types of Small and Medium-sized Enterprises (SME) should be supported at EU level; how should this complement national and regional level schemes? What kind of measures should be taken to decisively facilitate the participation of SMEs in EU research and innovation programmes?

The European Union should aim to support the development of innovative and knowledge-intensive SMEs, particularly those working in areas of potential high growth. There are many existing networks at the national and EU-level that can be used to help identify such SMEs. Characteristics of SMEs that typically merit additional investment include a strong management team; a business built on high quality knowledge, goods or services; and a clear route to market/expanded commercial opportunities.

In developing the proposed CSF more attention should be given in European research programmes to understanding the specific needs of SMEs, especially to develop the confidence of these businesses under the legal framework, predictability and intellectual property rules. EFPIA would support proposals that call for:

- The provision of additional financial support such as “upfront payments” and the development of payments for success-based milestones
- Facilitation of SME access to programmes based on their needs (reduced administration, increased participation of SMEs before the launching of programs…)
- The facilitation of the networking activities for SMEs with other partners, including larger company partners
- The development of calls that are more target-orientated
- The identification of industrially-relevant research programmes in areas where EU-based SMEs are able to make a real impact

On the funding front, particularly in biomedical research, there may be potential gaps in the amount of funding an SME may be able to attract. If such SMEs are needed to conduct pre-clinical or early clinical studies that are sub-optimal for future product development top-up funds may be beneficial.

Any public funding directed at SMEs needs to be rapid, flexible and timely. It needs to come with minimal complications such as IP constraints or reach-through clauses or future royalty payments. Projects should enable SMEs to exploit their investment as soon as possible.

Rather than aiming to support specific SMEs, the Commission should continue to focus on services or infrastructures that may support SME growth, such as the development technology incubators, cluster formation, and IT infrastructure in key technology hubs.

Q 17. How should open, light and fast implementation schemes (e.g. building on the current FET actions and CIP eco-innovation market replication projects) be designed to allow flexible exploration and commercialisation of novel ideas, in particular by SMEs?

In view of the challenges facing many SMEs in addressing the administrative requirements of current EU funding programmes, it is surprising that the apparently user-friendly two-step submission process of FET, and the fact that the calls are always open, has not attracted further applicants.

Q 18. How should EU-level financial instruments (equity and debt based) be used more extensively?

We are not convinced that equity and debt-based financial instruments are appropriate for public funding of healthcare-related biomedical research programmes. However, the Commission should facilitate access to venture capitals in particular for SMEs.
Q 19. Should new approaches to supporting research and innovation be introduced, in particular through public procurement, including through rules on pre-commercial procurement, and/or inducement prizes?

In complement to the right policy and regulatory framework that are the necessary conditions for innovation to happen, public procurement policies and practices at national level are influential in the encouragement of innovation. It is important that public procurement policies and practices keep abreast of the evolution and innovation pace of the biopharma industry, often represented by SMEs that stand to benefit most from public procurement in their favour. One of the key areas of public procurement to consider for the support of research and innovation is the enlargement of the traditional focus on pricing to include aspects linked directly to innovation in the pharmaceutical sector, namely, and non exhaustively, the added value of drugs and the patient well being.

The Commission has recognised that the EU suffers from a slow uptake of both service and product innovation by the public sector and that improvements in the absorption capacity of social systems are urgently needed. Healthcare is a member state competence hence the “market” for healthcare innovation is largely-determined by Member State policies. There should be a measured reflection on how the EU can support the process of deployment in Member States, whether through policy or financial support. Alternatives approaches to the procurement of healthcare innovations may also be necessary in specific situations where normal market mechanisms will not yield satisfactory outcomes. Two such examples are in relation to neglected tropical diseases and antibiotics.

Q.20 How should intellectual property rules governing EU funding strike the right balance between competitiveness aspects and the need for access to and dissemination of scientific results?

Patent and other IP rights play a vital role in encouraging innovation, and in general terms it remains important that the IP framework continues to adapt in order to provide the right incentives to develop new therapies in the light of rapid technological change and research practices. Whilst IP protection remains a key issue for industry in the commercialization of its research, there is an increasing willingness of companies to collaborate at the pre-competitive level and is being reflected in the design of new collaborative research programmes and public-private partnerships. In this regard EFPIA considers that the current rules for EU-funded programmes are appropriate.

It is important to align IP and access rights in line with the specific requirements of an EU-funded programme (e.g IMI) and to ensure there is clarity amongst all participants of the programme at the onset of how is to be managed. The pressure on universities to generate revenues from their research has exacerbated problems in some IP negotiations. In the IMI for example, competing pharmaceutical companies are happy for the results of pre-competitive research to be made freely available, but some technology transfer offices in potentially participating universities want ownership over any IP generated by their work. Examples where academic centres are worried about appropriating returns but industry is happy for free access runs counter to many public expectations, but are an important trend.

The trend in pharmaceutical R&D is certainly toward increased knowledge sharing to accelerate innovation, but competition is also an important driver of quality and speed in developing novel medicines. The right balance between sharing information and creating competition will vary along the R&D path – more sharing on fundamental knowledge on disease mechanisms and biomarkers, exclusive ownership of assets for development to sustain investment and bring the medicines to patients as rapidly as possible.

With increased transparency and “freedom of information” at government bodies, such as the European Medicines Agency, there is scope for structuring data and analysing projects that have succeeded (such as approved medicines) and failed projects. EU funds for “mining” of available information could be of particular value for SMEs that lack resources to systematically review disclosed data.
Strengthening Europe's science base and the European Research Area

Q.21 How should the role of the European Research Council be strengthened in supporting world class excellence?

As the ERC is further developed and strengthened it should continue to support only high quality globally-competitive research. The support of excellence in frontier research is paramount.

The recent establishment of the ERC’s new funding initiative, the “Proof of Concept” scheme is welcomed and should be developed further under the Strategic Framework to ensure that the maximum value is captured from EU-funded frontier research. (The EU should also review the possibility of establishing a number of follow-on funding schemes to allow carefully selected researchers nearing the end of the funding of their projects the opportunity to apply for additional funds to progress their work further or to develop their outputs for potential commercialisation.)

As clearly demonstrated by the number and quality of the peer-reviewed publications arising from many industry research laboratories, excellence in science is not the prerogative of academic groups. The ERC should give serious consideration to allowing industrial scientists to apply for funding.

Q.22 How should EU support assist Member States in building up excellence?

In general Member States clearly do have the ability to identify their areas of strength, make appropriate funding decisions, and seek to build up their national excellence in their chosen fields of science, technology and skills development. It is also important for Member States to be able compete to stimulate their own knowledge economy and attract further inward investment. The key challenge on which EU support might be welcomed is on how Member States could develop an agreed strategy that would help prevent overlapping/competing initiatives, reduce duplication of expensive facilities and large infrastructures, and help build an EU-wide capability in agreed key fields.

Member States could benefit from EU support through participation in the ERC-funded programmes and through the training opportunities available through the Marie Curie schemes and through encouraging their SME and academic community to seek participation in JTIs.

Q.23 How should the role of Marie Curie Actions be strengthened in promoting researcher mobility and developing attractive careers?

The first industry-specific scheme aimed at increasing researcher mobility across Europe- the Marie Curie Industry Host Fellowship (MCIHF) was introduced into the 5th Framework Programme through the “horizontal” programme – Improving Human Potential (IHP). During FP5, of the 2857 proposals submitted to all programmes for host fellowship contracts, almost 1200 were from industry for MCIHFs. Despite calls at the time that there was a need to grow the industry host scheme and a need for greater SME involvement the MCIHF scheme was discontinued in FP6, the numbers of proposals to Marie Curie plummeted and have remained relatively low since then. MCIHF gave young researchers the opportunity to receive excellent transnational industrial research training in companies, played a key role in encouraging knowledge and technology transfer between industry and academia and made a major impact on career development. The re-introduction of some element of MCIHF should be considered.

Nevertheless, we agree that continued support for researcher mobility through the current various Marie Curie Actions (MCA) is important – but as is the case for many of the EU funding mechanisms in place, the current administrative arrangements are somewhat complicated and should be reviewed and simplified. The MCAs have shown to be a valuable mechanism to stimulate the flow of
researchers between academic institutions, but as indicated above more needs to be done to ensure
that the provision of industrial experience is fully addressed. In the context of current arrangements we
would be supportive of proposals being considered for the MCA Early Stage Researchers
programmes within the Initial Training Networks (ITNs) for the introduction of European Industrial
Doctorates where the researcher would be linked to both the public and private sector and would need
to spend more than 50% of their time in the company, and have joint supervision from the industrial
and academic sector. There would be general support for the broadening of the ITNs and their
subdivision into multi-ITNs, European Industrial Doctorates (EIDs) and Innovative Doctoral
Programmes (IDPs). It is clear that the PhD needs to continue to evolve to address the industry’s
current needs.

Q 24. What actions should be taken at EU level to further strengthen the role of women in
science and innovation?

A wide range of initiatives reviewing possible policy initiatives in this field have been funded by the 7th
and previous Framework Programmes including, for example, “genSET” funded under the EC’s
Science in Society programme. Further proposals on how to further strengthen the role of women in
science and innovation will certainly arise from the forthcoming European Gender Summit (“Scientific
Quality through Equality”) taking place in Brussels in November. There could be more effort taken by
the EC at the European level in promoting these initiatives and the practical actions that may arise
from them. It might be more cost effective for the EC in helping to share best practice across Member
States in how best to promote positive images (role models) of women in science.

Q 25. How should research infrastructures (including EU-wide e-Infrastructures) be
supported at EU level?

We acknowledge that Research Infrastructures play a crucial role in training young scientists and in
helping to attract and retain world-class scientists to Europe. In the biomedical sciences continued
support for bioinformatics, bio-banking, clinical research infrastructure needs to be maintained and
strengthened. Whilst EFPIA strongly welcomes the role of ESFRI (the European Strategy Forum on
Research Infrastructures) and its current mandate to support a coherent and strategy-led approach to
policy-making on research infrastructures in Europe, and in the facilitation of multilateral initiatives
leading to a better use and development of research infrastructures, we do have some concerns over
the current approach to implementation of the ESFRI Roadmap at Member State level and would seek
improvements in this area. The role of structural funds could be considered in this context.

One essential research infrastructure that requires ongoing support at the EU level is application of
ICT-based technologies for the collection, storage and interpretation of the increasing level of data
being generated. Issues such as data quality, interoperability, acceptance of agreed standards is
increasingly important. Funding programmes that are focussed on helping to overcome the current
technical and societal challenges surrounding the application of electronic health records in research,
epidemiological and pharmacovigilance studies would have a significant impact on attracting research
into Europe and help to protect the safety of EU citizens.

Q 26. How should international cooperation with non-EU countries be supported e.g. in terms
of priority areas of strategic interest, instruments, reciprocity (including on IPR aspects) or
cooperation with Member States?

There is excellent research in Europe in both the academic and industrial sectors. The EU is
acknowledged is playing a leading role in developing collaborative efforts particularly in precompetitive
areas and programmes like the IMI are leading the way in facilitating cooperation. It will however
become increasingly important for the EU to extend some of its programmes to a more global level
and to seek more synergies with initiatives of other major global funders of research. Getting the
appropriate balance of partnership within this global competition for research will be needed. In the
healthcare research sector the EU should certainly do more to foster networking with non-EU countries to harmonize areas of strategic interest based on patients, SME’s and industry needs.

Increased collaboration and globalisation are currently two of the major drivers for enhanced R&D productivity and accelerating the development of innovative medicines. Whilst the healthcare research sector advances science and the discovery and development of potential medicines within a global framework, many companies focus certain therapy areas and disciplines in only one of their global sites. If this is not within Europe there is little incentive – but significant disincentives- for these companies’ scientists to become involved. The CSF must address these barriers to enhanced industrial collaboration in EU-funded programmes. The EU’s role in finding approaches that work well within the context of globalisation of medical research needs to be clarified under the CSF. As the world of pharmaceutical research moves towards a disaggregated model, with external alliances and deals with SMEs forming an increasing proportion of the research that companies fund, Europe may be missing out by not embracing a global approach to scientific problem solving.

Overall, securing a major share of pharmaceutical research in Europe will require inputs and expertise from outside as well as within the EU. Exposing industrial research teams from around the world to the quality of science available in Europe will develop the reputation and trust which will drive future inward investment into EU Science base and subsequently jobs in the long term.

Final 20/05/2011