Introduction

The European Brain Council (EBC) is a coordinating council formed by European organisations in neurology, neurosurgery, psychiatry, basic brain research (neuroscience), as well as patient organisations and industry. It therefore represents a vast network of patients, doctors and scientists, and these stakeholders along with its industrial partners make it eminently suited to work in close partnership with the European Union commissions, the European Parliament and the World Health Organization (WHO), as well as other decision-making bodies. The EBC was officially founded on 22 March 2002 in Brussels, and has offices in Brussels and Florence.

The EBC is determined to eliminate the discrepancy between the huge impact of brain diseases and the implications of understanding normal brain function on the one hand, and the modest financial and time resources allocated to brain research, teaching and the care of brain diseases on the other.

The mission of the EBC is to promote brain research in Europe and to improve the quality of life of those affected by brain diseases.

The EBC will achieve this by:

- Collaborating with our member organisations, while avoiding duplication of their work
- Interacting with the European Commission, European Parliament and other relevant EU and international institutions
- Promoting education in brain-related subjects
- Disseminating information about brain research and brain diseases in Europe
- Promoting dialogue between scientists and society

Through cooperation with the Research Directorate of the European Commission, the EBC aims to:

- Address fragmentation in European brain research
- Attract young people to work in brain research
- Attract more investment in brain research
- Bring science and society closer together and include patient organisations

Finally, the EBC aims to be a partner for European-wide foundations and businesses with an interest in brain research and the treatment of brain disorders.

EBC is 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”. There are many potential benefits 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, of which Brain disorders plays a major part, but that there should be
greater clarity regarding the prioritisation of the research agenda, which should reflect the needs of society and the citizens from across all of Europe and its’ changing demographics.

The EU continues to face major healthcare challenges, approaching a societal crisis and European citizens need more research and better medicines and care, particularly in the area of the Brain. Science, research and innovation have a vital role to play in Europe’s response to these challenges and to its’ competitiveness. Overall funding for research in the EU and a simplification of the process needs to be made. In addition multiple barriers to innovation need to be addressed including under-investment, excessive fragmentation, complexity and duplication. The proposed Common Strategic Framework (CSF) for EU Research and Innovation Funding could help resolve a number of these.

EBC believes it is vital that further simplification occurs and that prioritisation should be given to those areas of greatest unmet need, particularly at a time of limited resources. Reducing the overlap between national and EU level approaches should be made with clarity on who will take responsibility for what to avoid duplication, the appearance of a lack of a coherent strategy encompassing both the needs of member states and across the EU as a whole.

We must address the key societal challenges, such as brain disorders, remain and become more internationally competitive whilst continuing to ensure that excellence in research and innovation is supported, driven by data and across all aspects of research from bench to bedside and through into the marketplace.

The development of the CSF could enable cross-border pooling of resources to help achieve critical mass and the diffusion of knowledge, whilst promoting competition in research. Care must be taken however that this does not undermine overall quality which is essential to achieve research excellence and maintain and build Europe’s position in this area.

Whilst acknowledging European competitiveness as a key component to its growth potential, much of current and future research is global and partnerships between Europe and other parts of the world must be developed utilizing strengths apparent in the different parts of the world.

**Specific comments to consultation questions**

Several main challenges should be addressed to make the CSF success;

- simplification of all bureaucratic and administrative burdens, a particular issue for smaller organisations, this would include simpler tools and speedier access to funds (prompter payments) once projects are agreed;
- prioritisation to address the areas of greatest societal need and encourage greater input from patient groups and associations in this prioritisation;
- reduction of duplication between national and EU wide programmes;
- partnership with a more diverse group of stakeholders and international groups where global programmes are clearly the way forward.
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?

If the CSF truly what is outlined above, a single entry point, common IT tools, streamlined funding instruments and simplification it will have addressed many of the concerns EBC has with the current arrangements. Providing for process that reflects the size, scale and complexity of projects is also necessary, the simpler the project the simpler the rules should be, the easier access should be, the hurdles lessened and so on.

Cutting of red tape, reducing duplication, and unnecessary administration are essential to increase the attractiveness of EU funding. The time taken from application to funding being available and research start up must be reduced.

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

Priorities for research needs should reflect the needs of society and patients and input should be made from those most affected by the major disease areas as well as the more conventional sources.

Whilst a mix of curiosity-driven research and industry-driven research is valuable, the balance needs to be right and should be more focussed on addressing questions of greatest societal need, e.g. brain disorders, not to the exclusion of all else but in major priorities. This should also reflect European strengths and competitiveness and ensuring that the EU is an attractive place for research, both small and large.

In many areas of health research, fundamental scientific knowledge on disease mechanisms and processes is still lacking and therefore academic research and the application of it should be supported. Partnership with industry should be encouraged.

Creating an environment conducive to the development of innovative new medicines is critical and all areas should be explored for barriers to this. This should include the regulatory process which some argue is no longer fit for purpose.

Q3. 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?

For most areas of research that address issues common to several member states or the whole of Europe, EU funding mechanisms are most appropriate, reducing potential duplication from multiple member state involvement and providing a one stop shop to address critical questions of benefit to citizens of more than one EU member state. These approaches should utilise European wide networks better than ever before. Bringing together scientists and researchers from throughout Europe and utilising their skills and experience and using this as an opportunity to encourage and nurture academically talented but inexperienced European scientists should be facilitated by the EU.

In addition many programmes will have global reach and would benefit from participation of stakeholders from outside the EU. In this situation consideration of leveraging other sources of funding or partnering with funders from outside the EU should be considered.
Q4. 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?

The Joint Programming Initiatives (JPIs) is a key mechanism which should enable Member States to address the key societal challenges, such as brain disorders by bringing together national activities under an agreed common strategy, complementing work done at an above country level. 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.

Q5. What should be the balance between smaller, targeted projects and larger, strategic ones?

There is a need for both larger more strategic programmes to address major societal challenges as well smaller targeted (potentially member state level programmes). Our view is that EU funding should concentrate on larger projects which could not be supported at national level by one member state alone. Smaller projects could be better dealt with member state level programmes. To avoid duplication this should be agreed by all parties as part of an overall EU wide strategy. As previously stated the administrative burden should reflect the scale and complexity of a project and not be the same for all projects regardless of size.

Q6. 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?

Simplification must remain a main driver of the approach being taken, regardless of the different instruments, even if they have different objectives. Some flexibility and diversity is of course welcome but the key elements of simplification should remain, utilising the same IT tools, reducing administrative burden and so on.

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

A set of key performance indicators (KPI) are needed and should be identified and then discussed with all interested parties. These should include partnerships, networks, practical application of the research and speed to market of ideas generated, involvement of end users e.g. patients, societal benefit, relevance to key societal challenges and so on. 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.

Q8. 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?

EU funding should be complementary to member state funding and each should play to their strengths not be in competition. Above country projects, projects where more than one member state is contributing, particularly from the less developed regions should be supported but only if the quality can be assured.
**Tackling Societal Challenges**

**Q9. How should a stronger focus on societal challenges affect the balance between curiosity-driven research and agenda-driven activities?**

The European Brain Council has for a number of years been promoting research into the largest and growing societal need, disorders of the brain. The growth of neurodegenerative diseases and mental health disorders represents the biggest challenge health care funders will have over the coming years. A clearer focus on research into these areas would benefit Europe, not only in the societal context but also as this is an area where Europe can be demonstrably innovative, embracing partnerships between academia, industry, both small and large, and patients and their carers. EU decision-makers should embrace this more than ever before, not at the expense of other disease areas which are of course important, but through a recognition that the successes in cancer and heart disease create a bigger burden in brain disease and incremental funding is the only true way to address this need. Member state funding of 3% of GDP is a worthy aim and must happen if Europe is to remain competitive.

**Q11. How should EU research and innovation funding best support policy-making and forward-looking activities?**

Policy makers should focus on the largest societal challenges and EU research and innovation funding should follow the needs of society with a forward, long term strategic process geared to this. Utilising the expertise present in scientific societies, patient organisations, health care professionals and academia and umbrella organisations able to represent a broad range of stakeholders in this is essential.

**Q13. How could EU research and innovation activities attract greater interest and involvement of citizens and civil society?**

EBC welcomes any approach that stimulates the engagement and greater involvement of patients, their families and carers alongside the usual players in EU research and innovation. We have called for 2014 to be made the European Year of the Brain and this would encapsulate a range of ambitious public facing educational and information delivery mechanisms, not just for the year itself but as part of a lasting legacy to involve society with scientific issues including research and innovation. Today this involvement is almost non-existent. Patients and their representatives should be involved at all stages of process not just as tokenism but as real partners, actively involved in decision making and engagement.
Strengthening competitiveness

Q14. How should EU funding best take account of the broad nature of innovation, including non-technological innovation, eco-innovation and social innovation?

Removing barriers to innovation, such as unnecessary bureaucracy and administration, simplification could be regarded itself as non-technological innovation and could bring the biggest benefit to innovation in this whole process. The same could be said of regulatory hurdles in the bringing of innovative new medicines to market and at a member state level on simplifying the whole health technology assessment process with better use of patient reported outcomes and addressing the true needs of patients.

Q15. 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?

Simplification of rules as in all areas, network development, partnership and a better understanding of the issues facing EU industry would be welcomed. Focussing efforts on multiple small SMEs is short sighted if the benefits brought by big Pharma are ignored.

A Joint Technology Initiative such as IMI is welcomed in bringing together key stakeholders and reducing R&D barriers and could be modeled in other areas.

Q16. 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?

Participation in EU programmes for all groups, particularly SMEs, patient organisations and smaller bodies requires a dramatic reduction in administrative/bureaucratic burden, prompt availability of funds, rather than the very extensive timeframes seen now and support to get things off the ground. Funding of SMEs per se should not be necessary, rather the infrastructure surrounding them, their environment, should be conducive to fast decision making, prompt payments, simple process and so on.

Q17. 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?

This is not an area EBC has any experience in.

Q18. How should EU-level financial instruments (equity and debt based) be used more extensively?

Again we have no experience in this area.
Q19. 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?
Creating prize funds for innovative ideas, particularly in areas where industrial partners are not clear on the commercial benefits, but where there is the potential for long term patient benefit, is a good idea. Not just for the funding but also for the kudos this creates, publicity will encourage further entrepreneurial spirit in this sector, especially in rarer disease areas.

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?

Intellectual property is a key driver for innovation and will remain so in the future. Because of the length of time taken to take new innovative medicines all the way into the hands of patients continues to grow, consideration should be given to either extending IP rights to reflect this or to address the length of the regulatory and access process.
**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?

The ERC should support high quality research and high quality researchers and should encourage the movement of these high quality individuals back to Europe once they have extended their experience outside of Europe. Maintaining and growing the intellectual capital and capability is vital to the future growth of Europe and should be supported. Support for networks of high calibre individuals and teams should also be supported.

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

Simplification, avoiding duplication as mentioned previously and encouraging Member states and the EU to support complementary approaches, but different ones, through a clear strategy and discussions between both groups of stakeholders.

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

Continued support for researcher mobility through the current various Marie Curie Programmes is important but as with other areas needs a simplification of funding mechanisms.

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

Showcasing of the role of women in science and innovation through public awareness campaigns, prizes for women only researcher, sharing best practice amongst Member States should all be encouraged by the EU.

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

Support for the creation of networks of researchers to build capability in order to compete effectively with areas outside of Europe. Funding for the building of research infrastructure in newer member states may yield longer term benefit to Europe as a whole.

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?

Brain disorders, which are the key area of interest for EBC, are globally important and therefore, where appropriate, collaboration with global partners in this area of critical societal importance should be encouraged. Creating an environment for global players to invest in Europe is essential. We have seen the major loss of some Pharmaceutical companies in some areas of brain research e.g. psychiatry and steps should be taken wherever possible to reverse this trend.