EU Balance of Competences Consultation – Semester 2
Sanofi Response

About Sanofi
Sanofi is an integrated global healthcare leader which discovers, develops and distributes therapeutic solutions focused on patients' needs. We have over 110,000 employees worldwide, including 18,000 in North America, 56,000 in Europe and 36,000 in the rest of the world. Sanofi is headquartered in France and has 54 industrial sites and 9 R&D sites in Europe. We are present in 100 countries globally and run 112 industrial sites in 40 countries, including over 20 R&D sites worldwide.

In the UK, we currently employ over 2,000 people across our six UK sites; which include manufacturing hubs at Fawdon and Holmes Chapel; a distribution centre at Chapeltown, Sheffield; our vaccines division based in Maidenhead; our animal health division, Merial; and Genzyme. Our portfolio of products and services include diabetes, cardiovascular disease, thrombosis, oncology, vaccines, prescription medicines, consumer healthcare, generics and rare diseases (Genzyme).

Sanofi is a member of the Association of the British Pharmaceutical Industry (ABPI) and we support the points made in the ABPI submission to this review. However, we would also like to provide a separate submission, with a broader set of views on three key topics of concern to the R&D-based pharmaceutical industry, namely free movement of goods/internal market issues, trade & investment and R&D.

INTERNAL MARKET ISSUES

Business and consumers benefit from a well-functioning single market in many areas of economic activity by creating competitive markets. Enforcement of the rules of the single market has led to a substantial reduction of protectionism and the discriminatory treatment of foreign vs. domestic companies. It has also created more equitable and timely access conditions for economic operators to all EU member states – for the pharmaceutical industry this came through the 'Transparency Directive' of 1989.

In the area of pharmaceuticals, EU legislation has pursued both the overarching goal of protection of people's health and the creation of the right framework conditions for encouraging R&D and innovation. The former was most notably supported through the creation of the European regulatory system and the European Medicines Authority, headquartered in London, as well as subsequent legislation on key areas such as pharmacovigilance. The latter includes the introduction of measures and directives such as the Orphan Drugs Directive and the harmonisation of data protection rules.

The pharmaceutical industry is an important contributor to the economic strength of the European Union. It remains one of the most important sources of employment in Europe, with over 700,000 people directly employed by industry, and a further three to four times more people employed indirectly, as a result of industry's activities.[1] Alongside this, it dedicates significant resources to R&D compared to similar industrial sectors – in 2012 it invested an estimated €30 billion in R&D in Europe. The industry also has a larger positive trade balance than other major high-tech sectors, with over €80 billion in 2012 for Europe alone. As the above demonstrates, Europe remains an important hub for pharmaceutical research and manufacturing.

[1] See http://www.efpia.eu/documents/80/61/The-Pharmaceutical-Industry-in-figures-Edition-2013

It is therefore important to maintain a legislative and regulatory framework that protects public health, creates competitive markets and incentivises R&D at the same time as scrutinising single market rules in terms of their impact on the pharmaceutical industry.

National Governments have a responsibility to ensure access to innovation for their citizens in a sustainable way. It is therefore legitimate that they should want to control national reimbursement mechanisms and decisions. However, the combination of price controls, and other types of national supply-side and/or demand-side cost control measures, and single market rules have a distorting effect on pharmaceutical markets. This effect can be seen in arbitrage by parallel traders and the practice of international reference pricing by member states' authorities. While it is right that member states retain their national competence in pricing and reimbursement decisions, the impact of their decisions has cross-border implications.

The result is market fragmentation and a high degree of complexity rather than integration, and this comes at a cost to patients, to healthcare systems and to the pharmaceutical industry. The rate of uptake of new products is falling in the EU in comparison to the rest of the world and, critically, the UK lags behind many other European countries in the adoption of new medicines. In addition, across the EU, differences in the speed of administrative pricing and reimbursement decision-making remain. The clearest signs of non-integration of markets and of fragmentation are instances of certain EU member states experiencing reduced availability of medicines. There are a number of reasons for reduced availability and many of them are, to some extent, made worse by the current economic situation.

We believe that flexible and pragmatic solutions are needed to improve equitable access to medicines across Europe and ensure a dynamic market for innovation. These are unlikely to be found in legislative measures, which risk introducing even more complexity and will raise significant competence issues. Instead, inter-governmental and policy initiatives should be sought out as they have the advantage of bringing different stakeholders around the table. Through improved dialogue, we believe the way can be paved for improving equitable access to medicines in the context of the single market, while maintaining a competitive environment in Europe. Some potential solutions are set out below:

- Flexible solutions need to be found to address the increasingly important differences in terms of affordability between member states. International reference pricing, a practice that has existed for many years in a majority of member states, today acts as an important obstacle to finding such flexible solutions.
- The European Commission's proposal for an updated industrial policy includes plans for a chapter on the pharmaceutical industry. We welcome this initiative but also believe that the overall context must be a realisation by policy-makers that health policies more broadly have to become a much more integrated feature of any strategy to re-energise growth in Europe.
- The World Health Organization's *Priority Medicines for Europe and the World* 2013 update was published recently and calls for improved alignment between public health needs and incentives for biomedical innovation. Considering incentives for innovation alongside health needs could open an improved dialogue between authorities and industry on creating added value for healthcare systems and society through pharmaceutical R&D. The Innovative Medicines Initiative 2 (IMI2) offers the opportunity to further advance work in this area.
- Other forms of cooperation, notably in the area of Health Technology Assessment (HTA), can also have added value, as long as it increases speed of access to innovation, reduces duplication of efforts and avoids adding another layer of complexity to an already complex environment.

TRADE

The EU has a well-defined and long-standing competence in the field of trade through its Common Commercial Policy. This enables it to act as a single trading bloc at the international level, thus creating a significant advantage for the 28 EU member states.

Trade is an essential element for the competitiveness of Europe's industry. The role of the EU as a single negotiator and trading partner is crucial in advancing trade liberalisation and the defence of trade rules. The strong bilateral agendas currently being negotiated by the European Commission are of particular importance for us and we greatly value the European Commission's sustained efforts in dealing with growing protectionism and market access barriers that put foreign companies at a disadvantage.

The Commission recently pointed out that "*a quarter of EU bilateral trade already benefits from Free Trade Agreements (FTAs). Several further negotiations have been concluded…Overall, about 30 million jobs in the EU, or more than 10 % of the total workforce, depend on sales to the rest of the world, an increase of almost 50 % since 1995. The Commission estimates that the potential agreements currently being negotiated or discussed with third countries could permanently add more than 2% to the EU's GDP or some EUR275 billion annually. This is equivalent to adding a country as big as Austria or Denmark to the EU economy. In terms of jobs, these agreements could generate more than 2 million new jobs (equivalent to one tenth of the current number of unemployed).*"[2]

Trade also has a key role to play in the economic recovery. This is crucial at a time when the European economy faces considerable challenges. Removing trade barriers of large or fast growing economies is essential to stimulate growth and create jobs. This is particularly notable for leading exporters of high technological added value products such as the pharmaceutical industry. Opening markets, fighting against protectionism and enforcing Intellectual Property Rights (IPR) are important factors enabling us to contribute to Europe's growth.

The European Commission services also conduct regulatory dialogues with a number of 'third countries' in order to achieve greater alignment of standards and processes. Industry supports this approach as it creates greater clarity and predictability.

The points outlined above clearly show the many benefits of the EU's trade agenda. Member states gain from being part of the EU as it allows them to benefit from the preferential arrangements included in EU trade agreements. Moreover, as the European Commission recently pointed out, "*a third country offers concessions to the EU on a reciprocal basis, expecting market access to the Union as a whole. Third countries would be unlikely to offer as generous concessions*"[3] to a non-EU Member State.

[2] Parliamentary Question E-008158/2012, answer provided by Commissioner Karel de Gucht, 24 September 2012
[3] idem

RESEARCH AND DEVELOPMENT

The best chance Europe has to maintain its leadership in R&D activities, not only in the area of life-sciences, is to pool its efforts and foster cooperation between the public and private sectors. The EU's Framework Programmes in the area of R&D are an integral part of the overall effort to create a genuine European research and innovation space. In a highly competitive globalised economy, Europe's capital in terms of skills, entrepreneurship and creativity must be safeguarded and fostered. This is particularly critical for the pharmaceutical industry at a time when R&D productivity is falling, while at the same time important scientific discoveries that will transform the way patients are diagnosed and treated are being made.

One of the key initiatives in the area of pharmaceutical R&D is the EU's Innovative Medicines Initiative (IMI), Europe's largest public-private initiative aimed at speeding up the research and development of better and safer medicines for patients. Its focus is to tackle bottlenecks within R&D in non/pre-competitive spaces to make R&D processes in Europe more efficient and effective and enhance Europe's competitiveness.

IMI Projects successfully explore a challenging new operating model for the collaboration of multiple industry partners with academia. They have served to validate R&D translational models and tools to enable the development of highly innovative therapies in areas of unmet medical need. IMI is to evolve to "IMI 2.0", starting in January 2014, to include worldwide resources and downstream 'competitive' development projects. This is in line with the start of the next EU Framework Program in 2013, "Horizon 2020", which seeks to tackle major public health challenges and further strengthen the public-private initiatives.

IMI 2.0 will address additional healthcare and societal challenges, including unmet need, using a holistic view of the burden of disease in order to benefit patients. It will pick up on the therapeutic areas reported by the WHO as having the highest societal burden and will look across the entire R&D cycle including regulatory pathways, health technology assessment, and healthcare delivery.

We strongly support pan-European initiatives that help to address public health needs. However, we firmly believe that, to be successful, these require a framework that values innovation and fully recognizes the life sciences industry as a key economic growth driver for Europe.

Contact person: Louise Brant, Government Affairs Manager, UK
Email: Louise.brant@sanofi.com
Telephone: 01483 554074 or 07740 935 233