



Worldwide BioPharmaceutical Businesses Public Affairs

Public consultation on the future EU 2020 strategy

Introduction

Pfizer welcomes the opportunity to contribute to the consultation on the future “EU 2020” strategy. Pfizer is the world’s largest biopharmaceutical company: for us, Europe is not only an essential market, but our European operations are central to our product development, and Pfizer’s products contribute to the health of Europe. Pfizer invests over €4.7bn on R&D worldwide each year to develop innovative medicines, and conducts R&D at locations across Europe, including Europe’s largest private biomedical R&D centre in Sandwich, UK.

Our organisation is changing rapidly to respond to scientific advances and market conditions around the world, and as such the focus on innovation in the consultation document, as well as the work towards a European Innovation Act, are very important to us. However, whilst Pfizer recognises the constraints facing policy-makers, the prospect of a mismanaged exit from the financial crisis threatens to delay progress in the European knowledge economy and put at risk improvements in European health, thus impacting future prosperity. Integrated policy-making according to strategic priorities, with the EU and Member States working together, will be essential in ensuring the future competitiveness and wellbeing of Europe.

This response is structured according to the three ‘thematic drivers’ identified in the consultation document, and the two identified stages of ‘making it happen’. However, throughout this response it should be borne in mind that to the two ‘forward looking’ areas identified in the consultation, research and education, Pfizer would add a third: health.

1. Creating value by basing growth on knowledge

Pfizer agrees with the communication’s assessment that ‘In a fast changing world, what makes the difference is education and research, innovation and creativity’ (p.4). The social benefits of innovation in health, and why health should be considered a ‘forward looking’ priority, are discussed in our response to driver 2. Social progress as a result of innovation will be most rapid and most thorough in a coordinated policy environment, including IPR.

Focus on excellence and facilitating collaboration in a global context

As part of driving the effectiveness of Europe’s knowledge economy, Pfizer supports the argument of the European Research Area Board that excellence in the ambition of the science and calibre of individuals must always be the first criterion in decisions regarding research. This is imperative when considering how best to link academic and industrial

research expertise. The launch of the Innovative Medicines Initiative (IMI) in 2007 can be seen as a model of a successful European initiative linking the public and private sectors, building new science and contributing to public health needs whilst facilitating long-term innovation and business growth.

However, Europe needs to recognise the global nature of innovative high tech businesses, and look beyond its borders to see where working in a global context can most efficiently or effectively support innovation and its positive social outcomes within the EU. Collaboration is an essential part of Pfizer's business: every year we undertake around 2,000 collaborative agreements globally, many of which are with European partners in academia and bio-SMEs. Some of these collaborations are linked in part to European research programmes within the Framework Programme or IMI. However, engagement in such initiatives can be limited by EU rulings that result in companies headquartered outside of Europe being treated less favourably. We would argue that the Commission needs to revise its position on this matter. To decide the terms of engagement under EU supported R&D programmes on the basis of accounting, rather than on the R&D activity on the ground, is to disregard all of the EU-funded research on clusters and networks as a mechanism for advancing innovation.

'More and quicker'

The Commission's recent review of innovation policy rightly identifies a major aim of innovation policy as "helping to trigger more and quicker market uptake of innovative products and services"¹. Wider and faster uptake of innovative products and services benefit users (in the case of healthcare, patients) and allow better reward for innovative companies. With this in mind, Pfizer would encourage the comparative analysis of launch dates and speed of uptake of novel products and services, across the EU, US and other regions.

IPR and dynamic efficiency

The pharmaceuticals sector is Europe's biggest spender on R&D, and its expenditure is growing.² Investment in originating new biopharmaceutical medicines now will continue to be paying off in 20 years time, and continued leadership in biopharmaceuticals will provide Europe with a high added-value, growing export market.

However, this position and opportunity is dependent upon official recognition of how the pharmaceuticals market works, including its strong reliance on IPR: new inventions are brought to market and recoup the costs of their development (and those of failed projects) during the protected period, thus incentivising further investment in research; the patent system contributes to advancing science more effectively than other mechanisms of protecting IP, such as trade secrecy, and thus supports the public interest in further innovation, including investment in targeted drugs for smaller populations. As in all innovative industries, there is an inherent trade-off between the public interest in low prices now (static efficiency) and the public interest in improved products in the future (dynamic efficiency). This recognition of market dynamics and the need for effective IPR are prerequisites for designing policy for competitiveness in innovation, and part of the integrated policy environment discussed further in our response to the second section of 'making it happen'. By seeking to work with payors and patients, Pfizer aims to build greater value throughout the lifecycle of our medicines to ensure that we reveal opportunities for savings, which provide the "headroom" for innovative new medicines and value to patients.

¹ COM(2009) 442 final, p.5

² 2009 EU Industrial R&D Scoreboard, <http://iri.jrc.ec.europa.eu/research/docs/2009/JRC54920.pdf> p.7

2. Empowering people in inclusive societies

Pfizer is surprised to see improvements in health not considered as part of the social focus of the communication, not least because of good public health's beneficial economic as well as personal and cohesion impacts. This is reflected in the 2005 adoption of Healthy Life Years as a Lisbon Structural Indicator, with part of the rationale in its introduction being to raise the profile of health within non-health policies, as well as in the 2009 Communication on Solidarity in Health.³ Commitment to forward-looking areas such as education and research must be matched by commitment to the forward-looking area of health.

In the words of a recent paper from DGs SANCO, ECFIN and EMPL, 'a healthy population is the keystone for economic growth and prosperity in Europe'⁴. Between 2010 and 2020 the population of the EU over 65 years of age is projected to grow by nearly 20%, while the working-age population (15-64) is projected to decline by 1%⁵. In the absence of significant EU-wide change this demographic evolution is likely to present a more fundamental brake on sustainable growth than the current financial crisis. In this context, if Europe is to succeed in even maintaining current levels of overall productivity and retaining global competitiveness, a key priority is to increase economic participation, particularly at older ages, and to reduce the burden of ill health and incapacity. As EU-wide around 20% of working age incapacity and a similar proportion of early retirements are primarily attributable to illness or disability⁶, an active and coherent health strategy will be a vital component of any successful strategy to maintain and increase Europe's competitiveness and productivity.

Similarly, labour productivity - output per worker - is significantly affected by workforce health status⁷. A traditional source of competitive advantage for Europe, in the absence of growth in the working population, increasing labour productivity will be indispensable to the EU's capacity to maintain its social model alongside economic growth in a global market. Indeed, 'over time, labour productivity will become the only driver of growth in the EU'⁸.

Health is also a significant dimension of inequality in Europe. In most countries health status is strongly correlated with economic status and it is widely recognised that there is a two-way causal relationship between the two: i.e. health impacts economic status and economic status impacts health⁹. For instance, health constraints are likely to reduce individuals' mobility and adaptability to the labour market, and thus their capacity to find work and to integrate socially in 'a world which will offer more jobs in exchange for greater adaptability'¹⁰. There is also evidence to show that health status is positively linked to personal investment in education (or re-education), which stands to likewise underpin both economic and social progress in an era of technological development.¹¹ Therefore a successful strategy to empower people and create inclusive societies will need to address the health obstacles to empowerment, mobility and social integration, if it is effectively to prevent growing inequality and the exclusion of those facing self-reinforcing health and economic disadvantage.

³ COM(2009) 567/4

⁴ 'Healthy ageing: keystone for a sustainable Europe', DGs SANCO, ECFIN and EMPL, 2007, p.1

⁵ Source: Eurostat

⁶ Source: Eurostat

⁷ 'The contribution of health to the economy in the European Union, DG SANCO, 2005, p.39

⁸ 2009 Ageing Report, European Commission (DG ECFIN), 2009, p.22

⁹ Cf. DG SANCO, 2005, *op. cit.*, p.11

¹⁰ Consultation document, p.4

¹¹ DG SANCO 2005, *op. cit.*, p.56

Social inclusion policy is also an area where the EU has the opportunity to introduce integrated policy that can be of benefit not just to individual targeted groups, but also other areas of society. For example, redressing the lack of portability of social and pension rights, discussed in the Consultation in the context of encouraging entrepreneurship and self-employment, are also highly beneficial to the innovation community, where barriers to geographic mobility, and mobility between the public and private sectors, can be highlighted as hindering the development of the European Knowledge Area, and thus Europe's ambition to be the world's foremost knowledge economy. This is discussed further in the second section of 'making it happen'.

In addition to the vital contribution of health to Europe's future economic growth and social solidarity, the healthcare sector itself can play an instrumental role in delivering the Commission's vision of growth based on knowledge, since it is a high-productivity, R&D intensive sector. Thus a commitment to long-term investment in new medical and biopharmaceutical technologies can reap double dividends for Europe, underpinning progress on economic and social priorities whilst solidifying the EU's position at the forefront of the knowledge economy and securing an ongoing source of high-end employment for EU citizens.

In the context of the above Pfizer strongly advocates a comprehensive European health strategy as a fully integrated component of the EU 2020 strategy. A focus on improving healthcare can make a clear contribution to the 2020 aim of increased productivity, opportunities, and inclusion in the labour market.

3. Creating a competitive, connected and greener economy

Pfizer welcomes the possibility of a 'fresh approach to industrial policy [with] the emphasis on sustainability, innovation and the human skills needed to keep the EU industry competitive in world markets.' (p.8). Pfizer considers integration of diverse policies towards strategic ends, including societal, economic and environmental challenges, as a high priority for the EU, and the 2020 strategy as a great opportunity to work towards this goal. This is discussed more fully in the response to the second section of 'Making it happen'.

Just as excellence in the academic sector is necessary for growth through innovation, so too, in the healthcare sector, is a healthy community of bio-SMEs. Collaboration between SMEs and larger companies, which offer the benefits of scale and expertise, is important in ensuring future growth through innovation. With this in mind, enhancing the investment environment for innovative SMEs through the European Investment Fund should be a strategic policy priority for the EU. It is the overall success of this network or 'ecosystem' of different partners and influencing agencies that determines our ability to innovate. All partners require an optimal innovation policy environment.

Making it happen: Starting with a successful exit from the crisis

Pfizer recognises the strain that the last 18 months have put on national budgets. However, we are pleased to see the recommendation that 'New priorities need to be reflected in budgetary policies' (p.9), particularly in light of the intention that 'EU and national levels work together to move beyond the current crisis' (p.3).

The EU has an important role in influencing the strategic priorities of Member States even in areas where it does not have direct competency, such as pricing and reimbursement of medicines. If the EU and its Member States are committed to increasing the competitiveness of knowledge-based economies, and improving the health of their populations, policy makers must work with healthcare providers and the healthcare industry, of which Pfizer is a key player in Europe, to develop constructive approaches that

yield value to the patient and which identify savings which allow for 'headroom' for new innovative medicines within the short-, medium- and long-term planning of our healthcare budgets in Europe. If Europe succeeds in leading this challenge, we will have built a comparative advantage for Europe's citizens, healthcare systems, and life sciences industry.

A successful exit from the crisis should not be defined only as having satisfied narrow financial measures, but also having protected both the innovation capacity and health standards of Europe.

Making it happen: Harnessing existing instruments in a new approach

Pfizer welcomes the consultation's recognition of the interdependence between policies and the need for connected policy-making and for measures which fully exploit the potential of the single market. Interdependence between different layers of government and interdependence between different policies are discussed below. An example of how policy can best recognise interdependence at global level is given under driver 1.

In 2008, after its wide-ranging examination of pharmaceuticals-related policies, the EU's High Level Pharmaceutical Forum concluded that:

Member States are called upon to set clear and common expectations on what innovation they consider valuable and would reward. This will give companies a clear direction on healthcare priorities and indications on the evidence needed by authorities, while bringing authorities clarity on the mid- to long-term budget needs. Companies are called upon to deliver the innovative medicines that society needs. [...] National pricing and reimbursement policies should reflect and recognize these expectations and give a consistent reward to benefits considered valuable.¹²

In this recommendation, whilst areas such as pricing and reimbursement and Health Technology Assessment remain Member State competencies, the Forum outlines an example of what integrated policy making can look like, and an area where 'strengthened partnership between the EU and Member States in the design and delivery of public policies' (p.9) can be effective, especially in light of cost-containment as discussed above. Successful outcomes from the innovation policy at the heart of the 2020 strategy require consistency in the broader political context: policy makers must work with common purpose. There has been recent progress in some 'supply side' policy initiatives, such as the IMI; this needs to be matched by support for innovation in the wider policy environment. Innovation policy goals need to be considered in all policy areas. The following brief examination of some current policy issues illustrates the room that exists for better consistency and integration:

- *Competition policy and IPR*: Consistency in the protection of innovation IP is vital for investor confidence: misguided criticism of the legitimate defence of patent rights sends the wrong signal to investors in all innovative sectors. Also, progress towards a Community patent and single litigation procedure is welcomed, and opportunities need to be fulfilled. Pfizer would also wish the EU to encourage best practice in innovation and IP policy in Member States, such as the UK's recently announced 'Innovation Pass', which facilitates market access innovative new medicines addressing urgent unmet medical needs. This initiative is especially noteworthy for its focus on market drivers for science and innovation.
- *Regulatory policy*: Increased productivity requires efficient procedures that help innovation reach users more quickly, whilst maintaining the risk/benefit balance. Key challenges include ensuring effective market access and effective outcomes from

¹² http://ec.europa.eu/pharmaforum/docs/final_conclusions_en.pdf p.9

the proposed revision of the Clinical Trials Directive, to the consultation on which Pfizer has responded separately.

- *Mobility*: Movement of highly skilled people within Europe is extremely important in the context of creating a competitive and connected economy. The 2020 aim (for driver 1) of achieving a 'genuine European knowledge area [which will] benefit from the free circulation of people, knowledge and technology' should be an integral part of both social and industrial policy. For example, the mobility of students and researchers requires social policies, such as the portability of pension rights, which ensure they do not lose out when taking roles that allow them to use their skills to best contribute to the competitiveness of Europe. Cross-border mobility of patients, ensuring rapid access to the best treatment, would also benefit from being viewed from an integrated, innovation focused perspective. Cross-border rights should be based on removing restrictions to patient access to beneficial, innovative medicines rather than reinforcing them, and as such patients need to trust that any national or EU-wide HTA systems are operating in their interests and not as a smokescreen for cost-containment.

Pfizer would like to express our hope that the 2020 strategy, especially in conjunction with the forthcoming Innovation Act and the consideration of 'health in all policies', can make a significant contribution towards a healthier, cohesive Europe with a sound, knowledge-based economy, and life-long opportunities and quality of life for citizens.