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Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU to Mr Javier SOLANA, Secretary-General/High Representative.

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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Proposal for the Council Regulation concerning the setting up the Innovative Medicines Initiative Joint Undertaking

Executive Summary of the analysis of the effects of a Joint Technology Initiative (JTI) in the area of INNOVATIVE MEDICINES

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

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COMMISSION STAFF WORKING DOCUMENT

Executive Summary of the analysis of the effects of a Joint Technology Initiative (JTI) in the area of INNOVATIVE MEDICINES

Annex to the Proposal for the Council Regulation concerning the setting up the Innovative Medicines Initiative Joint Undertaking

BACKGROUND

This impact assessment examines options for stimulating innovation and investment at European level in pharmaceutical research, particularly through the establishment of a Joint Technology Initiative (JTI) on Innovative Medicines.

European pharmaceutical research suffers from fragmentation of stakeholders in different countries and sectors (academia, industry, SMEs, clinicians, regulators, patients). To harness the know-how and expertise across Europe in the pharmaceutical sector, action at community level was called for by the G10 group on innovation and provision of medicines, and by the "Aho report". The pharmaceutical industry has also repeatedly expressed a wish for closer collaboration with other stakeholders throughout Europe.

The Seventh Framework Programme (FP7; 2007-2013) introduces **Joint Technology Initiatives** (JTI) as a response to research needs of industry and other stakeholders. The European Commission (EC) proposed that JTIs should support a limited number of European Technology Platforms in reaching their objectives. Through the commitment of massive financial, organisational and human resources, JTIs should implement ambitious research agendas in public-private partnerships at European level. JTIs should pursue activities of common European interest and contribute to the Lisbon competitiveness objective and the Barcelona targets for research spending. JTIs should offer a legal and organisational scheme for effective pooling of resources from both the public and the private sector in a specific area and across Europe.

The Innovative Medicines Initiative (IMI) is derived from the "Innovative Medicines for Europe" Technology Platform. It addresses the European pharmaceutical sector, and was identified by the EC as a suitable area for a JTI. A key feature of the proposed IMI JTI is that research contributions from the EC must be equally matched by industry funds. The Industry contributions shall be based on research investments in Europe (not world wide). The main research objectives of the IMI JTI will be development and validation of new and better techniques and methods to predict safety and efficacy of new medicines. Importantly, the research results achieved by IMI will be available to benefit the entire European pharmaceutical sector.

CONSULTATION

The impact assessment of the IMI JTI is based on two reports. The first report, "Assessment of Economic and Societal Effects", was prepared by an independent expert group and focused on the current situation for the European pharmaceutical sector, the identification of policy options and an assessment of economic and societal effects.

The second report, "The Innovative Medicines Initiative – Keys for Success", was submitted by the European Federation of Pharmaceutical Industries and Associations ("EFPIA"). It expresses the opinion of 24 major pharmaceutical companies with substantial R&D operations in Europe.

The impact assessment also reflects extensive consultations with stakeholders in the pharmaceutical sector, which were conducted by the "Innovative Medicines for Europe" Technology Platform in May 2004. Nine dedicated workshops, involving more than 300 representatives from all stakeholders in the drug development process, were organised to elaborate the Strategic Research Agenda (SRA). Additionally, more than 20 meetings were held by dedicated Task Forces on Governance and IPR issues between stakeholders, experts, Commission staff and EFPIA representatives. Finally, 5 meetings took place in the "Member State Group", which gathers representatives from 28 Member States and Associated Countries.

MARKET FAILURE: THE NATURE OF THE PROBLEM

Insufficient R&D investment in Europe

The European pharmaceutical industry has grown steadily in the last 10-15 years with increased production and contribution to Europe's trade balance and employment. The industry invests 15.3% of total turnover in R&D, making it more research intensive than any other sector. For traditional pharmaceutical companies, R&D investments in Europe seem to have kept pace with the US, at least until 2003. However, for the biotechnology part of the industry, the US is significantly better than Europe in terms of private R&D expenditure and venture capital (VC) availability. This is vital as the biotechnology segment comprises the high end of knowledge-based activities, which are likely to contribute more to future earnings and competitiveness of the industry.

European public investments are also inferior to the US, both in absolute terms and as a proportion of GDP. Government expenditure on health related R&D (GBAORD) in the US is some 0,26 % of GDP, while the European figure is only 0,04%. Similarly, the average growth rate (2000-2004) of health-related GBAORD is about 10% in the US, but only around a third of that in the major European countries (e.g. UK 3%, France 2,6%, Germany, 4%). The R&D gap between the US and EU is therefore growing. This, in combination with very favourable market conditions (one patent, free pricing, etc.) has made the US more attractive for R&D investments by pharmaceutical companies.

Pharmaceutical R&D is moving out of Europe

Over the past 10-15 years, Europe's pharmaceutical research basis has gradually eroded. Whereas R&D investment in the United States grew by 4.6 times between 1990 and 2005, the corresponding increase in Europe was only 2.8 times. Companies are increasingly transferring leading-edge technology research units out of Europe, mainly to the US and recently to Asia.

The loss of leading edge technology units could be serious for European competitiveness, as innovation and cutting edge technologies are pivotal for long-term economic growth. The relocation of R&D investments could fuel a "brain-drain" as young talented researchers will follow R&D investments out of Europe. In combination with the modest public research spending, this could make Europe even less attractive for pharmaceutical research in the future, thus creating a vicious circle. Targeted and intelligent investments are therefore necessary to re-establish Europe as a highly attractive place for research activities and reverse the current relocation trend.

Technological Complexity is a Major Challenge

The cost of developing a new drug is currently 4-900 million USD, but R&D expenditure in the pharmaceutical sector has steadily increased during the last 10 years, without a corresponding increase in new medicines reaching the market and patients.

Increasing clinical development times and investments in drug candidates that fail during late stages of development are driving the cost of developing a new medicine upwards. The pharmaceutical industry is therefore eager to identify promising drug candidates with greater certainty as early as possible, i.e. before they have consumed too many resources. This is currently hampered by a lack of tools for predicting safety and efficacy at an early stage of the drug development process.

Pharmaceutical research in the EU is fragmented

Better prediction of safety and efficacy in early stages of drug development is so complex that no single company or public institution can achieve it alone. Companies, regulators, governmental institutions, academics and patients must share resources and expertise to address the challenges. Unfortunately, the European pharmaceutical sector suffers from compartmentalisation of stakeholders in different countries and activity areas. This restricts the free exchange and pooling of knowledge between the different actors. The activity and growth of innovative, research-intensive SMEs is, in addition, hampered by limited availability of capital due to financial fragmentation in Europe.

Furthermore, pharmaceutical companies are focused on competitive research (i.e. research to deliver a new medicine), whereas there is no market incentive for a single company to generate knowledge that benefits the entire sector (including competitors). Due to this, a new system for research collaboration is necessary to allow companies to collaborate between themselves and with other stakeholders.

THE CASE FOR EU ACTION (SUBSIDIARITY TEST)

While governments plan nationally, industry plans globally. Large countries like US and China have a unified investment strategy that allows industry to better plan and leverage resources. In Europe, national administrations do not coordinate their R&D investments and the pharmaceutical industry must use resources to adapt their activities to local conditions.

Only Community legislation can establish a focused and coherent R&D programme that can draw on all sources of R&D investment (public and private) at European level. Alternatively, efforts addressing the research bottlenecks in drug development will remain scattered and progress will be held back by lack of coordination, duplication of efforts, unnecessary bureaucracy, and suboptimal use of limited research funding.

OBJECTIVES

Public intervention at European level should address 3 strategic objectives: 1) the growing R&D gap (with the US, and increasingly with China and India), by attracting more public and private investments; 2) position Europe as the most attractive place for pharmaceutical R&D; and 3) develop a network of public institutions, industries, and other stakeholders to increase collaboration and foster creativity, entrepreneurship and critical mass.

The "Research Agenda" (RA) for the IMI JTI outlines 4 bottlenecks in drug development that should be targeted:

- improved prediction of *safety* (early indications of safety problems)
- improved prediction of efficacy (early indication of efficacy)
- knowledge management gaps – break information barriers at the interfaces
- bridge educational gaps – breaking barriers between disciplines

Importantly, the SRA addresses the drug development process itself, rather than the development of new pharmaceuticals or vaccines.

POLICY OPTIONS AND ANALYSIS

The following 4 policy options have been considered for analysis:

1. **Do nothing** and support other health research in FP7. In this option, the pharmaceutical industry is left on its own. The "Do Nothing" option would neither address productivity problems nor the European R&D gap, and it would not contribute to the Lisbon objectives. Without public intervention, individual companies are unlikely to invest in pre-competitive research that may benefit other companies. Even if some actions would take place, they would probably be fragmented and would not address the systemic failures of the pharmaceutical R&D process. The do nothing option appears as a clearly undesirable option.

2. Address problems at **national level**. This would not solve the fragmentation. The problems to be addressed are Europe-wide, and national intervention would not create a long-term structural improvement. Actions at national level would gather a smaller mass of industrial and academic scientific expertise. Individual national activities are also unlikely to create a better EU regulatory framework for the pharmaceutical industry.

3. **'Business-as-usual'** with action at EU level within the traditional FP instruments. Parts of the IMI SRA could be implemented through existing EU instruments and, separately, through national programmes. Based on past experience, it is unlikely that traditional instruments could attract sufficient industry involvement, let alone collaboration and data sharing between several companies or the sector as a whole. This option is therefore unlikely to take full advantage of possible additionality.

4. The fourth option is **a JTI**, which should implement IMI through the establishment of a joint undertaking (JU) on the basis of Art. 171 of the Treaty. The JU should be a

public-private partnership between the EC and the pharmaceutical industry. This could create a strong and efficient coordination mechanism, able to structure and handle contributions from different fields and sectors. Implementing IMI through a JU would make it more attractive for industry, mainly due to their influence on priority settings; the possibility to access results from a large number of studies; the possibility to enter a network of multiple stakeholders with the European Commission as "an honest broker". IMI would also provide a level of predictability that is absent in most public models, including traditional FP funding. The IMI model may also provide a framework for closer interaction between industry and EMEA, which has often been requested by the pharmaceutical industry. It seems therefore clear that implementing IMI through a JU would be the best option for reaching the strategic objectives.

ECONOMIC IMPACT

IMI's potential impacts are likely to be manifold and substantial, both on the pharmaceutical sector, national levels and European level. The most significant impacts are expected to be:

Additionality:

Public funding of industrial R&D leads to 'crowding-in': it stimulates companies to invest more in R&D than they would otherwise have done. It is estimated that €1 of public R&D investment induced €0.93 of additional private investment on average. With IMI, the larger pharmaceutical companies will not receive any public funds, but must invest in-kind research at an equal level to the EC funds. This means that €1 of public investment will minimum elicit €1 of additional private investment. Due to this co-financing principle, IMI will mobilise a minimum of €1 bn of private research investment in Europe. However, the real figure should be significantly higher, as contributions from SMEs and supporting industries are not included when calculating the matching funds from industry. The financial leverage of IMI is therefore significantly greater than traditional public interventions. IMI's anchoring of industry's R&D funds in Europe should also increase the general activity level of the sector. This should generate a positive effect on venture capitalists and potentially lead to creation of new companies. It seems clear that IMI can provide a significantly higher additionality than traditional public interventions.

Competitiveness:

The technological objective of IMI is to develop and disseminate new tools for faster and more efficient drug development. The most obvious benefits will be increased productivity and competitiveness of the pharmaceutical industry. The short term outcomes of IMI (i.e. 2-3 years after launch) will relate to improved scientific quality and knowledge production. IMI will ensure that dispersed research results are gathered and validated. New tools and methodologies for the drug development process should appear on the medium term. On the medium to long term, this should result in shorter drug development times, lower failure rates, and increased productivity, which will translate into improved economic performance and competitiveness.

The EC Directorate General "Enterprise and Industry" and the European Medicines Agency (EMEA) are foreseen to be affiliated with IMI. IMI may therefore catalyze better contact between the pharmaceutical industry and the EU regulatory system. This may eventually

result in faster approval of new drug candidates, which will have a knock-on effect on productivity as research results are brought to market more rapidly. Such reduced time-to-market is, potentially, one of the most significant benefits of IMI.

Innovativeness:

The large pharmaceutical companies rarely share data. IMI will provide an opportunity for companies to develop closer cooperation, and connect to other knowledge suppliers in both the private and public sector. IMI will make it possible to deliver and access pre-competitive knowledge that was previously out of reach for individual companies.

New innovation partnerships will develop between big companies, SMEs and public institutions. This should improve the uptake and exploitation of new research results, and may particularly benefit SMEs by lowering their business risks when developing new technology. This occurs as development takes place in collaboration with end-users (mostly the big pharmaceutical firms). IMI may thus provide a low-risk seed bed for SMEs to develop new technologies.

Growth and job creation:

The main beneficiaries of IMI will be research organisations involved in pre-competitive pharmaceutical research. This comprises a high density of SMEs and specialised research institutes with skills and expertise in cutting-edge technologies. A more R&D intensive, competitive and innovative pharmaceutical sector could reverse the current European "brain drain" of high skilled, high-productivity jobs, and instead lead to an influx of non-European pharmaceutical companies that want to benefit from an improved research environment.

Research environment:

IMI will highlight Europe as an attractive, dynamic and politically friendly environment for private investments in pharmaceutical research. Another positive effect will be an increased awareness and access to European knowledge, cutting edge technologies, expertise and top-level experts. IMI can thus act as an interface for transfer of skills and knowledge through people across national frontiers and institutions to create European-wide synergies. This would further raise the profile of Europe as an attractive location for pharmaceutical research.

Public Health:

Successful implementation of IMI will have positive effects on European public health on the long term. Faster development of safer and efficient drugs with fewer adverse effects should result in fewer days of life lost to sickness and death. This should give a better quality of life for European citizens, while more effective treatments should also result in savings for the public purse due to reduced hospitalisation.

MEASUREMENTS AND INDICATORS

The implementation of IMI will be followed through a set of performance indicators. The most important performance indicators should measure the impact on EU competitiveness in the pharmaceutical sector and the European scientific environment.

Besides an ongoing, internal monitoring by IMIs executive management, an annual reporting to the European Council will be performed by the EC. This will include the annual IMI progress report together with an update on the financial situation of the IMI JU.

Before 2010, the IMI JU will be evaluated by independent experts. This evaluation shall cover the quality of the IMI JU and its progress towards the objectives. At the end of 2017, the EC shall conduct a final evaluation, and present the results to the European Parliament and Council.

CONCLUSION

The proposed Joint Technology Initiative for Innovative Medicines (IMI) is an appropriate instrument to realise Europe's potential in the area of pharmaceutical research, in particular for pre-competitive research aimed at improving the process of drug development.

The IMI JTI addresses the core of the Lisbon agenda: it will pursue objectives of high strategic value for EU competitiveness in an area with market failure; it will allow Community funding to be used as a lever for additional private investments; it will align national and industrial European research in the area towards common goals and objectives; and it will contribute to establishing Europe as the most attractive location for pharmaceutical research.