MEMO/07/190

Brussels, 15 May 2007

Faster access to better medicines: the Innovative Medicines Initiative

Proposed today by the European Commission, the Innovative Medicines Initiative (IMI) seeks to overcome research bottlenecks in the drug development process. Its vision is to create real European leadership in biomedical research and development and thereby reinvigorate the European biopharmaceuticals sector as well as benefiting patients and society in general. IMI will embody a new approach to research financing at the European level, bringing together public and private funds, involving industry, SMEs, and non-profit research institutions. IMI was identified as a candidate Joint Technology Initiative when the EU's 7th Research Framework programme was launched at the beginning of 2007.

What is the goal of IMI?

IMI's goal is the reinvigoration of the European bio-pharmaceutical sector, making Europe a more attractive destination for private R&D investment in this sector. In the longer term it will allow faster access to better medicines for Europe's citizens.

By developing new methodologies and tools that are better at predicting the safety and efficacy of possible new drugs and medicines, IMI will bring these innovative medicines on stream more quickly and with greater certainty about their use. IMI's goal is not the development of new medicines as such, but making sure the tools exist to bring them to market as quickly as possible with the highest safety standards. Research will focus on four areas:

- Safety evaluation
- Efficacy evaluation
- Knowledge management
- Education and training

Why does Europe need IMI?

The pharmaceutical sector in Europe is faced with a number of severe obstacles such as escalating development costs, decreasing productivity, fragmentation of knowledge, difficulties in attracting and retaining a skilled workforce, and lower level of private and public investment than in the other parts of the world, particularly US and Japan.

In addition, over the past ten years, Europe’s pharmaceutical research and development basis has gradually eroded, with new leading-edge technology research units being increasingly transferred out of Europe, mainly to the United States and recently also to Asia. A key factor for this development is the trend of pharmaceutical industry to relocate to larger markets, where innovation reaps greater awards and where public research spending is highest (Europe spends 30% less on R&D than the US, while only 20% of top-selling drugs are sold in Europe and this figure is decreasing).

It is recognised in many quarters that the EU needs to improve the way in which it harnesses the scientific know-how and expertise that exists across the European Union in the pharmaceutical sector. The Commission has, as a response, called for "A stronger European-based Pharmaceutical industry for the Benefit of the Patient" with emphasis on the strengthening of innovation in medicines' R&D as one of Europe's key policies.

IMI will provide an operational R&D framework to combine the benefits of European integration with fast adaptation to industrial goals and policies and flexible participation. A focused and coherent industrial R&D programme that is able to draw on all sources of R&D investment (public and private) at European level will mean an end to efforts addressing the research bottlenecks continuing in a scattered and unstructured manner. Progress will be helped by better coordination of industrial R&D objectives, avoiding duplication of effort, unnecessary bureaucracy, and suboptimal use of limited research funding. Traditional EU collaborative research instruments cannot achieve the co-ordination of research efforts necessary to cope with the scale and complexity of the research challenges involved.

What is the importance of IMI?

The JTI will be the first time that competitors in the pharmaceutical sector work together. The participation of academia and clinical centres, small and medium sized enterprises (SMEs), patient organisations and public authorities (including regulators) is a key element and will lead to faster uptake of results. Knowledge Management is an essential component of IMI that provides the data-pooling and data processing infrastructure to support this public/private collaboration. IMI will bridge gaps in education and training to ensure a more skilled workforce in Europe for this sector

What budget will IMI have?

Once agreed, IMI will receive an EU contribution of up to €1 billion from the EU's 7th Research Framework Programme. This will be matched by funds from industry, leading to a total budget of up to €2 billion.

Who will make the decisions once IMI is up and running?

The Commission has proposed that the executive bodies of the IMI Joint Undertaking shall be the Board (composed of the founding members, i.e. European Commission and the industry organisation EFPIA), the Scientific Committee and the Executive Office. The JTI would involve two additional groups: a Member States Group and a Stakeholders' Forum, representing all stakeholders (researchers from academia, SMEs, industry, clinicians, regulators, patients, etc.).

Who will participate in IMI?

The research activities will be conducted through collaborative projects between public and private organisations selected though open calls for proposals and a peer review process. Any legal entity can participate in such projects provided the research is done in Europe (in Member States or countries associated with FP7).

For more information

On IMI and the industry organisation EFPIA: http://www.imi-europe.org/

IMI on the Commission's website:
http://ec.europa.eu/research/fp6/index_en.cfm?p=1_innomed (under construction)

The Strategic Research Agenda:
http://www.imi-europe.org/Publications.aspx?viewCategory=Researchx20Agenda