

Executive Summary

The Innovative Medicines Initiative (IMI) is a unique pan-European public and private sector collaboration between large and small biopharmaceutical and healthcare companies, regulators, academia and patients. The aim of IMI is to support the faster discovery and development of better medicines for patients and enhance Europe's competitiveness by ensuring that its biopharmaceutical sector remains a dynamic high-technology sector. The Innovative Medicines Initiative will ensure that Europe's biomedical sciences receive targeted strategic support for the benefit of patients, as well as the scientists and citizens of Europe.

IMI proposes a number of clear, practical paths that will accelerate the discovery and development of more effective innovative medicines with fewer side-effects. IMI will implement innovative Patient Centred Projects that address the principle causes of delay or bottlenecks in the current biomedical R&D process. These bottlenecks have been identified as: predicting safety, predicting efficacy, bridging gaps in knowledge management and bridging gaps in education and training. The Strategic Research Agenda (SRA) describes the recommendations to address these bottlenecks and a plan to guide their implementation. These recommendations represent the outcome of an extensive consultation between Europe's key stakeholders in the biomedical sector. The Strategic Research Agenda is a 'living' document and will be up-dated based on scientific advances.

To implement the Innovative Medicines Initiative, the European Commission and the European Federation of Pharmaceutical Industries and Associations will hold joint responsibility for creating and operating a new non-profit international organisation. This organisation will have a legal mandate to award research grants to European Public-Private Collaborations conducting innovative research projects focused on implementing the recommendations of the SRA.

The SRA consists of recommendations across four strategic areas ('Four-Pillars') that address the principal causes of delay in the biomedical R&D process as summarised below:

- Predictivity of Safety Evaluation (Pillar I): Nine recommendations are presented. These include the creation of a European Centre of Drug Safety Research, and establishing a framework to develop biomarkers that will have human relevance and regulatory utility;
- Predictivity of Efficacy Evaluation (Pillar II): Five recommendations are presented related to each of the five disease areas that have been identified as priorities for Europe, based on unmet medical need. These recommendations include creating disease-specific European Imaging Networks, developing regional centres of excellence, creating disease-specific European centres for the validation of new biomarkers and enhancing collaborations with patients and regulatory authorities;
- Knowledge Management (Pillar III): Fifteen recommendations are presented. These include establishing a Translational Knowledge Management team to support Pillar I and Pillar II projects, and creating a Knowledge Management Platform to develop effective data integration and analysis tools;
- Education and Training (Pillar IV): Five recommendations are presented that include establishing a European Medicines Research Academy, and the implementation of multi-disciplinary programmes to develop skills in integrating biology and medicine expertise.

As part of the European Union's 7th Framework Programme, the Innovative Medicines Initiative will be proposed by the European Commission for Joint Technology Initiative status, subject to approval by Member States. To implement the recommendations of the Strategic Research Agenda fully will require an investment of about €460 million per year, or more than €3 billion across seven years starting in 2007. The European Commission and the biopharmaceutical companies will contribute equally towards this investment. The European Commission will fund academic participants in research collaborations, and support Small and Medium-Sized Enterprises, while the biopharmaceutical company participants in research collaborations will completely fund their own contributions to the Initiative.

Creating Biomedical R&D Leadership for Europe to Benefit Patients and Society is the vision of this powerful partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations, who are supporting the Innovative Medicines Initiative with strategic and financial resources.