

Revitalising the European biopharmaceutical research environment

★ Although home to great scientific expertise, Europe's failure over recent times to invest in biomedical research and development at the same level as its key competitors has seen the continent fall behind. We take a closer look at the InnoMed Initiative, an EC-backed project that aims to change this

Recent years have seen Europe lose its place as a major global centre for biomedical research. Although pharmaceutical companies are among the most influential businesses on the globe, and their willingness to invest significant sums on research and development can bring real economic benefits to the countries at which it is targeted, the failure of Europe's public bodies to invest in the field at the same level as its key global competitors has seen the continent fall behind its rivals. Indeed, despite a five-fold increase in the pharmaceutical trade surplus over the last five years, the last decade overall has seen the USA invest in public sector-sponsored biomedical research at a level that Europe has been unable to match. This is affecting, and will continue to affect, the prospect of Europe achieving further medical research advances, greatly to the detriment of both patients and society.

Against this backdrop the work of the Innovative Medicines for Europe (InnoMed) Initiative, an EC-funded project that brings industrial partners together with the European Commission with the shared goal of revitalising the European biopharmaceutical research environment, takes on real significance. Addressing a number of the major issues affecting the future of biomedical research, InnoMed encompasses two major sub-projects – AddNeuroMed and Predtox – that in themselves will form the focus of the following pages, and represents a concerted effort by stakeholders to boost what is an area of crucial importance to Europe's economic future. The development of a Strategic Research Agenda (SRA) has been identified as being a crucial first step, and the main part has already been

developed via meetings and workshops which have identified four key bottlenecks in drug development; namely safety, efficacy, knowledge management and training and education.

The creation of this SRA has been undertaken within the frame of the European Technology Platform (ETP), and will be regularly updated as research advances and new drugs are developed. The resulting comprehensive strategy has revealed a variety of concrete research topics to be deployed. The implementation of these research topics will deliver added value to the drug discovery and development process, and also to individual stakeholders themselves. This is work crucial to the overall goal of accelerating the development of safer, more effective medicines, while also providing tangible evidence of the importance of this work to key stakeholders. To this end the EFPIA's (European Federation of Pharmaceutical Industries and Associations) Research Directors Group has identified pre-competitive barriers in the drug development process, around which industry and the other stakeholders involved can collaborate to achieve this goal.

The barriers on which this proposal is focused are the failure of preclinical studies to predict safety and efficacy in the clinic and regulatory process, which in itself has not been able to keep pace with scientific developments. Improvements in predictive biology and the incorporation of new concepts into an improved regulatory framework would decrease the cost of drug development and speed up the delivery of innovative medicines to patients, an objective which is at the core of

InnoMed's work. However, this is not to suggest that the InnoMed project is focused on a narrow set of objectives, quite the opposite in fact. To illustrate, the LifeSciHealth thematic priority aims to stimulate and sustain multi-disciplinary basic research so as to fully exploit the potential of human genome information to underpin applications to human health.

The InnoMed project's focus on integrating genomics information in the drug discovery and development process, addresses this directly. Advances in molecular genetics and molecular biology offer the possibility of identifying novel drugable targets that could be modulated in order to prevent, control, or even cure, many of the diseases of which we currently have only a limited understanding in terms of their pathophysiology and aetiology. Furthermore, by identifying those populations whose genetic profile determines how they may, or may not, respond to a specific drug treatment, advances in pharmacogenetics have the potential to dramatically improve the treatment of patients. Advances in the technology of genetic screening might help to predict favourable drug responses, and hence lead to the development of 'tailored medicine'. These are ambitious goals, and yet the potential benefits they offer are such that they demand to be pursued. The project's results will not only accelerate the process of drug development, but will revolutionise the entire field and thereby completely change the process by which drugs are developed, reaffirming European scientific excellence and helping the continent regain its status as global leader in biomedical research and development. ★