



European Federation for Pharmaceutical Sciences

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Letter of intent to the European Commission on Fostering a European Pharmacogenetics/genomics Initiative

Introduction

This document provides a consensus statement from European representatives of the pharmacogenetics/genomics science community following the first workshop of the proposed European Network of Excellence in Pharmacogenetics and Genomics in Utrecht, The Netherlands, on November 13-14, 2006.

The purpose of the document is to brief the European Commission on the current state of research in the area of pharmacogenetics/genomics in Europe, and to request that it urgently provide funding to support the formation of a *European Network of Excellence in Pharmacogenetics and Genomics*. We feel strongly that this has to be established in addition to and in advance of specific calls for pharmacogenetic and pharmacogenomic projects within the EU FP7 programme.

The need for European funding of pharmacogenetics research

Pharmacogenetics is a major tool for improving drug therapy in moving from the 'one-dose-fits-all' model to more personalised therapy.

There are many important reasons why pharmacogenetic/genomic research needs to be strengthened in Europe:

(1) Better exploitation of Europe's initial pre-eminence in the subject.

The tradition for studying inter-individual variability in drug response at the genetic level was established originally in Europe, where there is longstanding experience in countries such as Sweden, Switzerland, Denmark, Germany, France, the Netherlands, and the UK. In contrast, the importance of pharmacogenetics has been recognised recently by non-European countries, in particular by the US and Japan, resulting in substantial initiatives to extend the knowledge base of the subject in various disease areas. For instance, the NIH in the US has

committed \$125 million over 5 years to its Pharmacogenetics Research Network. This funding was not open for foreigners. It has had several consequences:

- (a) USA investigators have been more pro-active in this area of research leading to high impact publications, patents, and translation into clinical practice.
- (b) Because of difficulties in obtaining funding in Europe, there is a significant flow of both young and senior scientists out of Europe to the USA. This will have a detrimental impact on pharmacogenetic research in Europe but also on other disciplines.
- (c) The global pharmaceutical industry has recognised the increasing role of the USA in this area, and now regards it as the first port of call for undertaking studies and getting advice on pharmacogenetics for their new drugs in development;

It is crucial that the EU urgently puts funding into pharmacogenetics to reverse these trends; Because there is already a strong, albeit dispersed, infrastructure, relatively little effort will be required to collect information on existing research activities with a view to coordinating a really powerful knowledge and research base within Europe.

(2) Additional use of information from a well-characterised population.

The European population has a unique ethnic and racial mix that is very well characterised. European researchers have already identified many differences in allele frequencies between different EU countries (e.g. the increase in frequency of ultra-rapid drug metabolisers with respect to CYP2D6 from Northern to Southern Europe). However, there are many other genetic characteristics of European populations that we need to define to ensure that they get the best drug therapy in the future

(3) Further mobilisation of the talent and information within the European pharmaceutical industry.

There is a large pharmaceutical industry in the EU, and there are many SMEs interested in the area of pharmacogenetics/genomics. It is important that the EU has an active, expanding and vibrant research community in pharmacogenetics to engage with industry and, thereby, maintain the competitiveness of the EU pharmaceutical sector. Recent efforts to increase European strengths and competitiveness include the Innovative Medicines Initiative (IMI), focussing on efficacy, safety, information management and training and education.

Objectives of the European Network of Excellence in Pharmacogenetics and Genomics

The network would be the voice of the European science community in pharmacogenetics and pharmacogenomics, with the following objectives:

- **To provide a platform for gathering and promoting knowledge about pharmacogenetics in Europe.**

This can be done with a web-based approach with the aim of making pharmacogenetic/genomic activities more visible both within the European community of scientists and internationally.

Accordingly, the website would provide:

- Information on the location and expertise of different researchers in the field, as a spur to encouraging collaboration;

- A database for the EU to facilitate access to experts who could serve as reviewers for project calls.
- A focus for the organisation of workshops and conferences around specific areas, to encourage researchers to exchange ideas and initiate European collaborations.

- **To provide a mechanism for sharing and extending existing databases and bio-banks within and outside Europe.**

Specifically, this would include:

- Promoting the need for performing larger studies to provide evidence for the value of genotyping that stands up to both rigorous statistical and clinical scrutiny;
- Developing common quality controls and management structures at a European level;
- Encouraging the dissemination of pharmacogenetics research throughout Europe, by pairing leading groups with those having less infrastructure, expertise and equipment;
- Developing a link with the US PharmGKB database with the intention of providing added value to rather than competing with a well-established system – which would enhance the global profile of European research, while minimising unnecessary duplication of effort and expense.

- **To encourage and facilitate input from and collaboration with the pharmaceutical industry both within and outside Europe.**

It is essential to integrate the efforts of academics, industry and regulators within Europe to address common issues around pharmacogenetics. These include ethical as well as scientific aspects, and examination of ways in which information can be shared without compromising intellectual property and commercial sensitivity.

Specifically, we seek to:

- Extend inclusion of key individuals from industry and the regulatory authorities within the management of the Network;
- Explore ways of improving interaction at the level of exploratory and pre-competitive industrial research, which could lead to new and wider therapeutic opportunities and underpin developments in mechanistic toxicology;
- Establish the formation of focused consortia to study disease-specific topics in pharmacogenetics

- **To establish a more formal framework for education and training in pharmacogenetics.**

This is important at two levels – the development of a future European cadre of experts in pharmacogenetics, and the dissemination of information on the subject to users and beneficiaries of pharmacogenetic research at the level of clinical practice and utilisation.

Specifically, we aim to:

- Identify existing courses on pharmacogenetics/genomics within Europe on the website, with a view to publicising their availability throughout Europe;

- Harmonise and improve education in pharmacogenetics at both undergraduate and postgraduate levels, with an emphasis on the practical and clinical implications of the subject.

For the European pharmacogenetics/genomics sciences community¹

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¹ As represented by delegates of the Workshop on Pharmacogenetics & Pharmacogenomics, on November 13-14, 2006, in Utrecht, the Netherlands – organised by the European Federation of Pharmaceutical Sciences (EUFEPS) and its Task Force for the topic, co-sponsored by the Utrecht University NL and the International Federation of Pharmaceutical Sciences (FIP) Board of Pharmaceutical Sciences (BPS)