

## EUROPEAN COMMISSION CONSULTATION

### THE FUTURE OF PHARMACEUTICALS FOR HUMAN USE IN EUROPE

#### **RESPONSE FROM THE FACULTY OF PHARMACEUTICAL MEDICINE**

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom exists to advance the science and practice of pharmaceutical medicine for the benefit of patients and the public. It is registered as a charity in England and Wales. The Faculty currently has approximately 1350 members based in over 40 countries worldwide. Most members of the Faculty are pharmaceutical physicians who are employed in the pharmaceutical industry, contract research organisations, regulatory authorities, academia or as independent consultants.

The Faculty has reviewed the European Commission Consultation: *The Future Of Pharmaceuticals For Human Use In Europe* (19<sup>th</sup> July 2007) and welcomes this opportunity to contribute. The Faculty's response to the six key questions are as follows:

1. **Do you agree with the analysis of the main challenges outlined above? Do you see other challenges?**

The analysis of the main challenges outlined is fully understood by the Faculty of Pharmaceutical Medicine. There are however additional challenges and these include not only the consistency and transparency but also the speed and effectiveness of the European Union response.

The Faculty of Pharmaceutical Medicine recommends the development and monitoring of standards in the education and training of those involved in the development, monitoring and regulation of medicines and the harmonisation of these standards as far as is possible within Europe and beyond.

2. **Do you see other areas than those already targeted by the Commission where regulatory action should be taken?**

The Faculty of Pharmaceutical Medicine recommends measures to improve the speed and effectiveness by which new medicines can be safely introduced across Europe with equity and fairness to all stakeholders.

Adequate provision for quality scientific advice for Ethics Committees must be made to enable the Committees to evaluate the information that is presented to them. This is often difficult where Ethics submissions are made on behalf of a Principal Investigator or a company to a distant Ethics Committee.

There is a clear need for the level of bureaucracy to be reduced in relation to pharmacovigilance where it does not add value or contribute to patient safety. It can appear that the emphasis is often placed on the process rather than the science of pharmacovigilance. This has the inevitable result that timelines and deadlines can take precedence over scientific data. Consideration should be given to simplifying processes with a new emphasis on the identification of safety signals within collected data. This would be better for patients whilst also reducing study timelines.

The quandary for the EU and the regulatory bodies surrounding the distribution of information on new medicines released to the public is that such information is restricted in access. Clearly, some method of improving access in a safe sensible and reliable way is required.

3. **What would you suggest as concrete measures to ensure the safety of medicine supplied in the EU, addressing in particular counterfeit medicines and provision of high quality and affordable medicines also to third countries?**

This is a complex area. The Faculty of Pharmaceutical Medicine encourages further debate because its resolution is critically important to the health and well-being of patients in the EU and wider.

4. **What can be done to improve Europe's international competitiveness?**

Currently, the European Union and the Commission in particular are strangling the opportunities for research and development within the Union. Nowhere is this seen more clearly than in the UK where initial and innovative research and development opportunities funded by both small and large pharmaceutical operation are moving steadily and inexorably towards the Far East. A significant structural change both in approach to and in implementation of R & D within the Union is required. This involves, in particular, revisiting the regulation of clinical trials, the revision of Ethics Committees and their function and the implementation of European based policies through the EMEA and its sister organisations in the Member States to produce informed opinions at an early stage for medicines evaluation. The Faculty supports all initiatives which are intended to achieve cost effective drug development in the EU.

5. **What can be done to foster convergence and transparency as regards pricing and re-imburement in the EU?**

This aspect is outside the remit of the Faculty of Pharmaceutical Medicine.

6. **Do you think the current EU regulatory framework can accommodate emerging technologies like regenerative and personalized medicine, as well as nanobiotechnology?**

The Faculty of Pharmaceutical Medicine believes that it is essential to ensure that these and any other technologies are accommodated by the EU regulatory framework.

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