

Cancer Research UK submission to European Commission consultation on the Future of Pharmaceuticals for Human Use in Europe

October 2007

Introduction

Cancer Research UK is Europe's major non-commercial funder of research into drug innovation with an annual research spend of over £315 million. Cancer Research UK funds research into all aspects of cancer from exploratory biology to clinical trials of novel and existing drugs as well as population-based studies and prevention research. We aim to work with partners to ensure that research into cancer is translated and developed to the benefit of cancer patients.

Our research is supported through a combination of project-based and long term funding. The latter underpins funding of specific clinical trials by supporting areas such as exploratory biology and the development of predictive biomarkers for drug efficacy and toxicity. In addition, funding basic scientific laboratory research within our clinical centres brings together scientist and oncologist, and provides unique opportunities for the development of translational research programmes.

We also undertake world-leading innovation in terms of technology transfer, through our Development and Commercialisation company, Cancer Research Technology (CRT). The main focus of CRT's activities is to drive companies to achieve patient benefit from scientists' discoveries, rather than necessarily creating revenue from their own research. In collaboration with Cancer Research UK, CRT also funds activities all the way along the pipeline where a need to do so has been identified.

Response to questions

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

Cancer Research UK is largely in agreement with the challenges as outlined in the consultation document.

We believe that the EU regulatory framework is a central issue affecting organisations such as Cancer Research UK who are involved in the development of pharmaceuticals. We are supportive of necessary legislation relating to the development, marketing and selling of pharmaceuticals. We also believe that the introduction of the EU Clinical Trials Directive (CTD) has been successful in improving the design of trials being carried out. However the CTD has resulted in a disproportionate increase in the bureaucracy involved in gaining approval to conduct trials. A direct effect of this has been an increase in the cost and resource required to undertake trials, which may ultimately lead to less trials being carried out in the EU. The lack of a coherent approach to the development of legislation such as the First in Man guidance, issued by the EMEA, and Directive 86/609/ECC, on the protection of animals used for experimental and other scientific

purposes, sends out conflicting and confusing messages that can be detrimental to the research environment.

In addition, the way in which legislation can be interpreted and implemented within and between Member States leads to ambiguity and is not conducive to supporting and promoting research.

We do not believe that there is currently a need to strengthen and rationalise drug safety monitoring. The balance of adverse affects and patient benefit in the development of treatments for cancer patients is particularly fine. We believe current drug safety monitoring and approval processes overseen by the EMEA and the MHRA are sufficient to support this.

We also believe that when developing strategies relating to the ‘increasingly proactive role that patients are taking with regard to their health’ the EU must be clear in its support of the role of medical professionals in the diagnosis and treatment of patients. The importance of clear and accurate public health information, through which people can understand how to lead a healthier life, is vital in reducing the disease burden in all Member States. To this end, we support strategies that would help in the delivery of this. In addition, we would be supportive of any EU level activity to discourage patients from self-medicating by restricting the purchase of prescription medications over the internet and better regulation of patient information available online. However we do not support any liberalisation of current EU rules regarding direct to consumer advertising by the pharmaceutical industry.

In addition, we believe that it is the responsibility of the pharmaceutical industry, not the EU, to develop a strategy to overcome the hurdles presented by ‘the emergence of new technologies, with a focus on regenerative medicine, more personalised treatments and the development of nanomedicines’.

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

Cancer Research UK does not believe that any further legislation or regulatory action is required at this time. However it is important for the Commission to have good horizon-scanning mechanisms in place to foresee any future issues and to consult with all the relevant stakeholders to ensure that any legislation produced is appropriate.

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

This is not an area of expertise for Cancer Research UK. However we would be supportive of measures promoting the provision of high quality and affordable medicines and vaccines, such as the Human Papilloma Virus (HPV) vaccines, to low and middle income countries.

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

Europe can not compete with the cheap resources available for Research and Development (R&D) in Asia. If we are to meet the aspiration set out by the Lisbon Council in March 2000 to be the most competitive and dynamic knowledge-based economy in the world by 2010, and develop an innovative environment to ensure that we continue to attract investment, we must focus on and build on the strengths that we currently have.

In order to do this it is vital that the regulatory environment within the EU is permissive to research needs. The development and implementation of overly restrictive and burdensome legislation will continue to drive investment to other geographical areas where the regulatory environment is more supportive, or, at the very least, less constraining. The UK currently has comprehensive legislation regulating the development and use embryonic stem cells for research purposes. The supportive nature of the legislation, together with that of other Member States, is facilitating a global competitive advantage in this area. The introduction of EU wide legislation to restrict this type of research will be detrimental to this area of research and our current competitive advantage. In addition, will also drive this area of research to countries where the ethical issues are less diligently regulated.

In addition, there must be a continued investment in the required skills base for research. This should include the development of educational and training programmes central to drug development. Cancer Research UK has had much success with medicinal chemistry and pathology PhD programmes, aimed at encouraging the skilled workforce to stay within the EU and would be happy to share our experience as part of this consultation process.

The UK is the most successful world economy at attracting foreign investment in research. A major reason for this is the open nature of the UK economy. Encouraging other European states to adopt similar approaches will make Europe a more attractive investment opportunity.

Finally, a key issue facing all who develop intellectual property (IP) is noncompliance with laws in place to protect it. Europe must put more pressure upon those countries where the IP and patent laws are not implemented or adhered to.

5.What can be done to foster convergence and transparency as regards pricing and reimbursement in the EU?

It is clear that action needs to be taken to address confusion and disparities in pricing and reimbursement between the countries of the EU. The differing nature of healthcare systems throughout the union means that processes are not well coordinated.

Cancer Research UK is currently working with the UK Government to look at the way that drugs are priced in England and the devolved nations with the aim of improving access to treatment for cancer patients. We believe that it is important that the value to patients of pharmaceuticals is the key driver in price setting, and will thus enable patients to access the most clinically cost effective treatments on an equal basis.

We would welcome further debate on how drug prices are set in an increasingly integrated Europe where patients should have the right to expect access to the best possible treatments for them, regardless of where in Europe they live. To this end we

would welcome greater transparency in the work of the G10 High Level Group on Innovation and Provision of Medicines which is looking at pricing mechanisms in the EU with the objective of increasing the availability of medicinal products in all Member States by speeding up access to the market.

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

The overly burdensome nature of the EU regulatory framework is driving up the cost of conducting research in the EU. This, together with the confusing nature of individual pieces of legislation and guidelines, does not provide a supportive environment for research, especially the new and emerging areas such as those detailed above.

For further information please contact the Cancer Research UK Policy and Public Affairs Department on publicaffairs@cancer.org.uk or 020 7061 8360.