EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods

THE FUTURE OF PHARMACEUTICALS FOR HUMAN USE IN EUROPE

MAKING EUROPE A HUB FOR SAFE AND INNOVATIVE MEDICINES

– HAVE YOUR SAY –

Version: 19 July 2007

INTRODUCTION

The European pharmaceutical industry makes an irreplaceable contribution to Europe's well-being through the availability of medicines, economic growth and employment. The pharmaceutical sector has been and remains a key strategic sector for Europe.

Since 1965, Community action in the field of medicines for human use has always had the dual mission of safeguarding public health while providing an environment that stimulates innovation and supports the competitiveness of the EU industry. Much has been achieved in the last forty years. However, at the beginning of the 21st century Europe is now facing new public health, scientific and economic challenges:

- the **globalisation of the sector** and the increasing internationalisation of the value chain;
- the **smooth functioning of the internal market** in a widening Europe; and
- **advances in science and technology**.

Globalisation brings both challenges and opportunities. The emergence of worldwide health threats, such as the increasing number of counterfeit medicines or pandemic influenza, the internationalisation of the value chain and the rise of new players in the global competition provide compelling grounds to intensify international cooperation. Two objectives must be met: first, to better protect the health of EU citizens; but also, to strengthen the competitiveness of European companies by removing regulatory and non-regulatory barriers which impede access to foreign markets and by ensuring fair international competition.

Today's globalisation also means that, due to structural factors which go beyond the pharmaceutical sector (*e.g.* labour costs), the centre of gravity for worldwide R&D investment in the field is gradually moving to the United States and Asia. Europe should strive to regain territory it covered for most of the 20th century, when it used to be the home for pharmaceutical innovation.

The smooth functioning of the EU internal market is also a major challenge for the future. On the regulatory side, the implementation and interpretation of Community legislation by Member States still create obstacles to the free movement of medicines. Overburdening requirements also affect competitiveness, especially for small and medium-sized enterprises, without always bringing public health benefits. There is scope for better regulation, e.g. in the area of variations to existing authorisations and possibly also for clinical trials.

On the non-regulatory side, and despite efforts currently carried out under the Pharmaceutical Forum[1], different national pricing & reimbursement schemes still coexist, leading to market fragmentation, parallel trade, disparities in prices and time-to-market delays. In certain countries, medicines are not even made available due to administrative requirements and poor economic rewards. A lack of transparency and harmonisation with regard to pricing, reimbursement and relative effectiveness remains a challenge.

Recent events such as the 'Vioxx' case[2] or the failed clinical trial in the UK[3] demonstrate that the safety of medicines remains a major EU internal market issue. Recent analysis has demonstrated the existence of multiple and sometimes inefficient requirements as regards pharmacovigilance in the EU. The challenge is thus to strengthen and rationalise drug safety monitoring, while avoiding unnecessary requirements that would impair patients' access to treatments.

The Commission services are also analysing patients' safety aspects of medicines in the distribution chain, including aspects related to parallel trade and to counterfeiting of medicines. In light of the outcome, it will consider appropriate policy action.

Another trend shaping the EU pharmaceutical sector is the increasingly proactive role of patients regarding their health. Patients require better access to quality information. At the same time, information provided currently varies amongst Member States, and media such as the internet may not always provide reliable data. The industry possesses information on their medicines but today this information cannot, for legal reasons, always be made available to patients throughout the EU.

Finally, new technologies, therapies and medicines are emerging. This includes in particular regenerative medicine, more personalised treatments, and the development of nanomedicines. These developments are already affecting the business strategy of EU companies, the industry structure -with the creation of highly innovative small and medium-sized enterprises-, the design of clinical trials and the way medicines are prescribed. These elements have to be gradually translated into the EU pharmaceutical framework of the 21st century.

WHAT IS THE PURPOSE OF THIS CONSULTATION?

The Commission intends to improve the regulatory, non-regulatory and RTD framework for pharmaceuticals. For example, specific initiatives in the field of pharmacovigilance and variations have already been announced.

Against this background, the Commission intends to launch **a broad public debate** on the future of pharmaceuticals in Europe. The outcome of this debate should enable the EU to better understand stakeholders' views on the key challenges of the sector and how to tackle them. With this consultation, the Commission is committed to **giving all stakeholders** the opportunity to make their opinion known on these strategic issues.

[1] http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm
[2] See http://en.wikipedia.org/wiki/Vioxx
[3] TGN1412, see http://en.wikipedia.org/wiki/TGN1412

WHO IS CONSULTED?

Contributions are invited from all stakeholders dealing with medicines for human use. This consultation does not cover veterinary medicines. This includes for example patients organisations, Member States authorities, international bodies, industry associations and individual companies (innovative, generic and self-medication sectors), healthcare professionals, or any other person or legal entity interested in this field. Stakeholders who are not established within the EU are equally invited to comment.

Comments from **Small and Medium-sized Enterprises (SMEs)** involved in the pharmaceutical sector are especially welcomed.

HOW CAN I CONTRIBUTE?

Contributions should be sent by e-mail to nicolas.rossignol@ec.europa.eu **before 12 October 2007**. An acknowledgement of receipt will be issued for each contribution received within five working days. Contributions will be made publicly available on the 'Pharmaceuticals' website of the European Commission[4] once the consultation period is over, unless a specific request for confidentiality is made, in which case only an indication of the contributor will be disclosed.

Contributions should preferably not exceed 5 pages. The questions outlined in the grey box at the end of this document provide guidance for your contributions to the debate although stakeholders' input may go beyond these questions. Contributions may touch upon legislative and non-legislative issues falling under Community and/or Member States' competences, focusing on concrete actions at Community, international, and/or national level**.**

WHAT WILL HAPPEN NEXT?

All contributions will be carefully analysed. A summary of the outcome of the consultation will be published on the 'Pharmaceuticals' website and also sent directly to all contributors.

Following this public debate, the Commission intends to address a **Communication** to the Council of the European Union and to the European Parliament on the future of the EU single market in pharmaceuticals for human use, **outlining its vision and strategy** for the sector, as well as **concrete action items**. The Communication will build on this consultation and will outline how its outcome was taken into account.

ANY QUESTIONS?

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[4] http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm and http://ec.europa.eu/enterprise/phabiocom/index_en.htm

KEY QUESTIONS

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

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

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

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

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

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

THANK YOU FOR YOUR CONTRIBUTION.