

Commission gives qualified welcome to European Parliament's vote on Pharmaceutical Legislation

Today the European Parliament voted on the European Commission's proposals to reform European legislation on pharmaceutical products. The Commission welcomes today's vote, but hopes that agreement on a series of important issues, such as the balance between innovation and generic medicines and better information to patients, may be reached in the future. The Commission's wide-ranging proposals to review the EU pharmaceutical legislation aim to strike a balance between a high level of health protection for European citizens and the need to boost the competitiveness and innovative capability of the European pharmaceutical industry. These proposals will also facilitate the free movement of medicines and pave the way for EU enlargement. Swift action is necessary to ensure that patients have access to innovative medicines and to high-quality information on these products. Since European industry is lagging behind its international competitors, more incentives are needed to trigger innovative research and development. At the same time, the viability of health-care services necessitates reinforced generic competition. The proposals consist of one Regulation and two Directives.¹ Today's vote was the first of two readings of the European Parliament under the co-decision procedure. The proposals now need to be endorsed by the EU's Council of Ministers before the European Parliament may complete its second reading.

Erkki Liikanen, European Commissioner responsible for Enterprise said: "I welcome today's vote by the European Parliament as it brings us closer to the final adoption of this comprehensive reform package. The proposed reform of Europe's pharmaceutical legislation will provide great added value for Europe's citizens, it will increase the availability of innovative medicines while favouring competition with generics and will prepare the overall system for enlargement. I am particularly pleased that the European Parliament supported our proposal to introduce a central authorisation procedure for all new medicines. This will help to improve and speed up the authorisation procedure for new medicines. This proposal is designed to give Europe's patients access to better quality and innovative medicines quicker than is the case today.

But, there are still some outstanding points on which I hope we can agree in the future in order to achieve the objectives of our comprehensive reform proposals. I

¹ - Proposal for a European Parliament and Council regulation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products
- Proposal for a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, and
- Proposal for a European Parliament and Council directive amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products

The proposals are available at: <http://pharmacos.eudra.org/F2/review/index.htm>

regret that the European Parliament today rejected our proposal to allow patients suffering from AIDS, asthma or diabetes to be able to get information on medicines used to treat these diseases from the pharmaceutical companies that manufacture them. Our proposal would not allow non-solicited advertising for such medicines – as is the case in the United States. But it would enable these patients to get good, appropriate and officially authorised information if they so request. Patients interested in such information today generally find it via the Internet from US based web-sites. Obviously, not all Europe's patients have access to the Internet or understand English. Also, as medicines marketed in the US are often not identical to those marketed in the EU, even if they bear the same name, this might even constitute a health risk. We must therefore ensure that the information for which there is a strong demand is available to all Europe's patients, that it is correct, appropriate, and authorised by the European Medicines Evaluation Agency in London so patients in Europe are better informed. Nothing is further from our minds than introducing advertising for prescription medicines in Europe. What we are proposing is to allow Europe's patients to obtain appropriate and authorised information if they ask for it.

Our proposals also provide a balance between innovation on the one hand and competition from generic medicines on the other. We need innovative medicines for the benefits of patients – but generic medicines can help reduce prices and thus the pressure on health care costs. I am looking forward to continuing our discussions with Member States and the European Parliament on this issue and hope that we can reach an agreement on this and the other issues that are still outstanding.”

For further information

<http://pharmacos.eudra.org/F2/home.html>

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