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Commission proposes comprehensive reform of EU Pharmaceutical Legislation

The Commission today adopted a proposal for comprehensive reform of the current EU pharmaceutical legislation. This reform is designed to yield concrete benefits for European consumers, patients and for animal health in a rapidly changing world of scientific advances in medicines. This review is based on two fundamental objectives: the need to guarantee a high level of health protection for European citizens, and the completion of the internal market for pharmaceutical products, boosting the competitiveness of the European pharmaceutical industry and meeting the challenges of enlargement and globalisation. The proposal focuses on reinforcing the proven success of the European Medicines Evaluation Agency (EMEA) set up in 1995. It aims to provide benefits for patients by increasing access to new and innovative medicines. The pharmaceutical industry is also targeted, introducing clearer procedures and allowing tests on pharmaceuticals to be performed in advance of patent expiry. The proposal includes provisions for more and better information for selected prescription medicines at the request of patients – in order to ensure that valid, patient-orientated information is available to European patients. Attempts to cut red tape have also been made in the shape of proposals for rationalisation, simplification and better transparency, including the replacement of the 5-year renewal procedure by reinforced pharmaco-vigilance monitoring.

Erkki Liikanen, European Commissioner responsible for Enterprise said, "Today's decision will help patients all around Europe to get new and better medicines quicker than is the case today. It will also help European patients to get better information about the medicines that are available to them. Finally, today's decision is a major step towards achieving a more innovative and competitive industry in Europe, which is to the benefit of everyone. I am sure that today's decision will lead to tangible improvements in the general protection of the health of European citizens within a short time".

Objectives of the review

Today's Commission decision comprises three proposals: a draft regulation on marketing authorisations and the functioning of EMEA; a draft directive on medicinal products for human use; and a draft directive on veterinary medicinal products. This major and comprehensive review of pharmaceutical legislation is based on the need to continue to guarantee a high level of health protection for European citizens. It is also based on the need to complete the internal market for pharmaceutical products in a context that favours the competitiveness of the European pharmaceutical industry and which meets the challenges of globalisation and the need to prepare for the future enlargement of the EU. Important attempts to optimise, rationalise and simplify the current regulatory processes have also been made, with a view towards better transparency of procedures and decision making, without changing the basic

principles of the existing structure in which two regulatory procedures (centralised and mutual recognition) co-exist.

Building on the success of the EMEA

Based on the success of the London-based European Medicines Evaluation Agency (EMEA) and the centralised European procedure for the authorisation of pharmaceuticals established and operational since 1995, rather than change its fundamental principles of operation, the opportunity has been taken to reinforce the positive aspects. These changes include the opening of the procedure to more types of new medicines and the strengthening of the scientific committees by the addition of additional working groups and experts. In addition the role of the EMEA in all scientific matters relating to medicinal products, international activities and its role in providing scientific advice to companies before they embark on all the trial and tests necessary for authorisation has been strengthened.

Increasing and accelerating the availability of products

In terms of tangible benefits for patients, the opportunity has been taken to respond to several challenges. The proposal aims to increase the availability and speed of access of new medicines to the European market, while at the same time ensuring that the basic criteria of safety, quality and effectiveness are met. A **"fast-track" registration procedure** for products of significant therapeutic interest has been introduced, allowing these products to be assessed and authorised quickly and bringing Europe into line with US procedures in this regard. In addition the possibility of a **conditional marketing authorisation** has been introduced. This would allow a one-year authorisation to be granted provided that there is an important expected health benefit for the patients concerned and that the company undertakes to perform additional monitoring and clinical studies, which will be reviewed at the end of this period. Subject to further additional provisions, a European wide system for the availability of medicinal products **in advance of authorisation** for "compassionate use" will also be possible. This will help to ensure that patients are not discriminated against on the basis, in particular, of the location of the clinical trials performed by a particular company.

In addition to the first two provisions, specific measures concerning the availability of **veterinary products** are also proposed. A harmonised system allowing the controlled prescription of veterinary medicines for use in conditions other than those authorised ("extra-label use"), the waiver of certain requirements for veterinary medicines whose use has been well established in practice. An incentive scheme to encourage companies to develop older products for use in neglected indications or minor species is also proposed.

Moving with the times – better access to information for patients

The current ban on public advertising of prescription medicines in Europe will be complemented by a pilot system aimed to ensure the availability of better, clear and reliable information on authorised pharmaceuticals. This pilot system will apply to three specific disease groups: **diabetes, AIDS and asthma**. These diseases are long-term and chronic, there is a strong patient demand for information and the results of the 5-year pilot should be relatively easy to monitor among these patient populations. This will be coupled with strict control measures.

A competitive European pharmaceutical industry in a world market

The proposal introduces mechanisms to improve the competitiveness of both the innovative pharmaceutical and the generic industrial sectors. A harmonisation to 10 years of the current national administrative protection periods concerning data submitted by companies for the approval of medicines is proposed, thus removing current ambiguities of application and allowing the innovative pharmaceutical industry more time to recoup its investments before a generic product may be authorised. For the generic pharmaceutical sector, the possibility for tests to support generic medicine authorisation to be performed in Europe in advance of the expiry of intellectual property provisions has been introduced as well as a definition facilitating greater legal security and better application of the regulatory procedures for generic medicines.

Cutting red tape

The review includes important changes aiming to optimise, simplify and rationalise the current regulatory processes. The proposal removes the “renewal procedure” for marketing authorisations, replacing it by reinforced pharmaco-vigilance and information sharing provisions. Measures to accelerate the Commission’s decision making process so that the gap between the scientific assessment and the actual placing on the market can be reduced, are also proposed.

For more details, see MEMO/01/267. The text of the proposals are available at: http://pharmacos.eudra.org

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