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Commission's proposal to review EU pharmaceutical legislation

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Adoption of Commission legislative proposal to review the pharmaceutical legislation

There are four main goals of the review that we have proposed today. These are:

- To guarantee a high level of public health
- To complete the single market
- To increase transparency
- To favour competitiveness of the industry
- To prepare EU enlargement

- The need to continue to guarantee a high level of health protection for European citizens;
- 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;
- Preparation for an enlarged Europe; and
- Rationalisation and simplification of the regulatory process with a view towards better procedures and decision-making.
Reinforcing the success of the European Medicines Evaluation Agency in London (London Agency)

European Medicines Evaluation Agency

- No revolution but evolution
- Scientific expertise to be reinforced
- Competence for all new active substances
- Increased scientific advice to companies
  (in particular for small sized companies & biotech companies)
- Administrative changes to cope with future EU enlargement

The establishment of the London Agency in 1995 and the setting up of a centralised European procedure for the authorisation of pharmaceuticals has been generally considered as a great success.

For this reason, we are proposing no major changes to the fundamental principles. Instead we concentrate more on reinforcing the positive aspects. For example we are proposing to allowing more products to have access to the centralised procedure and by reinforcing the potential of the scientific committees.

In addition the role of the London Agency in all scientific matters relating to medicinal products and also international activities (vis-à-vis for example the World Health Organisation).

We are also proposing to allow the London Agency to provide scientific advice to companies before they embark on all the trial and tests necessary for authorisation.
For European patients and citizens, we want to respond to several challenges. We want to increase the availability of new and innovative medicines on the European market, while at the same time ensuring that the basic criteria of safety, quality and efficacy are met.

This will also ensure that EU scientific assessments for major new medicines are as fast, if not faster than those performed by the US FDA. We aim to do this in three main ways:

- Introducing a “fast-track” registration procedure for products of significant therapeutic interest allowing these products to be assessed and authorised in an expeditious way – by giving a certain drug top priority. This is in line with a similar existing provision in the US.

- Introducing a conditional marketing authorisation, in particular cases when there is a specific and identified patient need. This will allow the authorisation of new medicines on the basis of sufficient, but perhaps not definitive scientific data. This conditional authorisation will be granted only provided that there is an important expected health benefit for these patients and that the company undertakes to perform additional monitoring and in some case clinical studies, the results of which will be monitored on an annual basis.

- Promoting a European wide system for the availability of medicinal products in advance of authorisation on a “compassionate use” basis. This will help to ensure that patients are not discriminated against on – for instance - the location of the clinical trials performed by a particular company.

Today’s review also covers veterinary drugs. The details of these provisions are in the papers handed out to you today.
Now what does today’s proposals mean in practice in terms of concrete improvements from the viewpoint of patients?

Moving with the times – better access to information for patients

Better access to information for patients

- For certain products subject to prescription
- Patient orientated and controlled information
- Not Direct to Consumer Advertising type
- EU set of “Good Information Practice” to be adopted
- Pilot phase
  - 3 Specific groups of long term and chronic diseases: AIDS, Asthma and chronic bronchitis, Diabetes
  - Based on strong and specific patient demand
  - Effects to be monitored and assessed
  - To be reviewed in 5 years

Still with the patient in mind, we are also introducing a pilot system aimed to ensure the availability of better, patient orientated and valid information on authorised prescription drugs – for three types of illnesses: AIDS, diabetes and asthma.
This is not direct to consumer advertising. We are not introducing of advertising for prescription drugs.

What we want to do is, as a test case, with respect to three specific disease groups, to make sure that validated and patient orientated information can be made available – when this information is requested by patients or groups of patients.

The diseases chosen: diabetes, AIDS and asthma are diseases which are long-term and chronic, where there is a strong and specific patient demand for information, where the types of drugs used are the same throughout Europe, and in which populations the results of the 5-year pilot should be relatively easy to monitor.

The current practice means that European patients looking for information about their diseases and medicines are forced to rely - in fact, they often do so - on information produced by companies outside Europe through the internet. The availability of information on non-EU web-sites – in combination with the current ban in Europe on providing information to consumers has created a differentiation between patients who can go on-line and those who cannot and a differentiation between those who understand American English and those who do not.

In addition, often information from web-sites outside Europe is not even accurate as products marketed elsewhere may be different from those marketed in the EU - even though they have the same name.

Today's decision is designed to correct this situation – allowing all European patients with these three diseases to get good, reliable and correct information in an appropriate and well-controlled way.

Our proposal requires industry to follow a code of conduct – which will be worked out by the Commission in co-operation with the industry, patients and the Member States.

The London Agency will ensure the control of the compliance with this code of conduct. Companies will have to notify the information they intend to distribute to the London Agency – and if the Agency does not object thereto within one month, the information is authorised. The London Agency will issue an annual report on the application of the Code of Conduct.
Promoting the competitiveness of the European pharmaceutical industry in a global context

The pharmaceutical industry is the source of the majority of the innovative advances in medicines.

In the process of completing the internal market, we need to make it easier for the industry to operate and to eliminate problems that have historically led to difficult challenges.

We are proposing to harmonise the current national administrative protection periods concerning the data submitted in order to obtain a marketing authorisation from the current ambiguity of either 6 or 10 years to 10 years across the board. This will give more opportunity for the innovative pharmaceutical industry to recoup their investments before a generic product may be authorised.
At the same time, there is a need to support the European generics industry because we need to promote a fair competition in the pharmaceutical field. We are specifically introducing the possibility for trials to support generic medicines to be done in Europe, before expiry of a patent or other intellectual property protection.

It must be recalled that this is currently not authorised in Europe unlike the situation in US and Canada where the so-called “bolar” provisions are operational.

This will mean, on the one hand, that generic companies can make marketing authorisation applications the day after the patent of the innovator expires and thus arrive on the European market with a minimum of delay. It is estimated that this might save European generic companies up to two years.
On the other hand, it will mean that these companies do not look outside Europe to perform the necessary tests. This will be particularly important in the context of enlargement, where many local pharmaceutical companies have developed specific expertise in this regard.

**Cutting the red tape**

- **Removal of the five year renewal rule** for marketing authorisations
- **Strengthening pharmacovigilance** in particular through **systematic electronic exchange of data**
- **Accelerated and simplified decision-making process**

Last but not least, no major legislative review would be complete without an administrative overhaul with a view towards simplification, rationalisation and overall improvement and transparency of procedures.
We are proposing the removal of the famous “renewal procedure”. This has been mainly an administrative procedure which requires pharmaceutical companies to renew all their marketing authorisations every 5 years.

The removal of the renewal procedure is largely compensated by a strengthening in pharmacovigilance requirements. This means that there will be an obligation for companies to monitor and analyse all adverse drug reactions.

In addition we aim 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.

**Conclusion**

These are but some of a long list of major amendments of the current system. These changes will streamline procedures and will increase regulatory efficiency and flexibility. Today’s proposals are made with the aim of producing a transparent, stable and predictable regulatory environment in the interests of patients, consumers and a globally competitive European pharmaceutical industry. Our proposal will also contribute substantially towards completing the internal market for pharmaceuticals.

Thank you.