

EN

EN

EN

Citizen's Summary

Legal proposals on pharmacovigilance

1. WHAT IS THE ISSUE?

The existing Community legislation on medicines contains strict provisions on the market surveillance of medicines once they have been authorised ("pharmacovigilance"). They set out how to watch for adverse effects of authorised medicines, how to assess and how to respond in case of problems.

Experience has shown that these provisions need to be improved. They do not sufficiently take into account the different characteristics and risk profile of medicines on the market and do not make best use of knowledge about adverse effects which are occurring.

2. WHAT IS THE BACKGROUND TO THE PROBLEM? WHY SHOULD THE EU BE INVOLVED?

The objective of the proposals is to improve the protection of public health in the Community. The proposals are to change the existing EU legislation relevant to pharmacovigilance. If the proposals of the Commission are adopted, it is estimated that between 591 and 5910 lives will be saved per year across the EU. Furthermore, it is estimated that the saving to society of the proposals is between €37 Million and €2.4 Billion per year.

The proposals seek to change existing legislation which is already fully harmonised at Community level. They build on the experience gained with the existing regulatory framework. Community rules in the area of pharmacovigilance allow the best protection of public health according to the same standards across the Community.

3. WHAT ARE THE PROPOSED ACTIONS?

The improvement in the protection of public health will be achieved through:

- Providing for clear roles and responsibilities for the key responsible parties;
- Rationalising EU decision-making on drug safety issues;
- Strengthening medicines safety transparency and communication;
- Strengthen companies' pharmacovigilance systems;
- Ensure the proactive and proportionate collection of high quality data;
- Involve stakeholders in pharmacovigilance including through direct patient reporting of suspected adverse reactions;
- Improve the availability of medicines in small Member States.

In addition to achieving better protection of public health the proposals will also bring simplification of the current Community pharmacovigilance procedures with consequent efficiency gains for both the pharmaceutical industry and medicines regulators.

4. WHY ARE THESE ACTIONS USEFUL FOR EUROPEAN CITIZENS?

The proposals ensure a high level of safety of medicines once placed on the market after obtaining marketing authorisation. Citizens in smaller Member States will also benefit from a better availability of medicines.

5. WHAT ARE THE NEXT STEPS?

The legal proposals will now be debated in the European Parliament¹, representing citizens, and in the Council, representing Member States².

¹ <http://www.europarl.europa.eu/>

² <http://www.consilium.europa.eu/>