**COUNCIL OF
THE EUROPEAN UNION**

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Council further strengthens action against adverse effects of medicines

The Council adopted today[1] new rules aimed at strengthening the post-authorisation monitoring of medicines for human use ("pharmacovigilance"), hereby further improving patient safety (*42/12* + *13918/12 ADD 1 REV 1* + *43/12*). This follows a first-reading agreement with the European Parliament.

The new legislation focuses in particular on obligations on marketing authorisation holders in relation to adverse reactions to medicinal products and further clarifying the procedures when competent authorities follow up such reporting. It entails a further strengthening of the pharmacovigilance rules adopted by the Council on 29 November 2010 (*17054/10*) and respond to the lessons learnt from the Mediator case.[2]

An important aim for the Council has been to secure that the new provisions lead to the early discovery of potentially dangerous medicinal products and do not lead to adverse reactions not being noticed due to "information overflow".

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1 The decision was taken by the Employment, Social Policy, Health and Consumer Affairs Council.

2 Mediator is an anti-diabetic drug that is suspected of having caused the deaths of several hundreds of patients in France at a time when it was already withdrawn from the market in other member states.

P R E S S

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An example of the strengthened rules is that marketing authorisation holders that withdraw a medicine from the market will have to notify the competent authority and explain the reasons for their decision even if the withdrawal is voluntary. This also applies if the marketing authorisation holder withdraws a medicine from a third country market. This provision aims to avoid that the withdrawal of a medicine for safety reasons go unnoticed by or is hidden from competent authorities.

In order to better inform patients and medical professionals additional groups of pharmaceutical products will be included on the publicly available list maintained by the European Medicines Agency (EMA) of medicinal products subject to additional monitoring (for instance for safety reasons).

The amendments to the existing pharmaceutical legislation also contain a further strengthening of the rules concerning wholesale distribution of medicinal products to third countries.

The new regulation and the directive will enter into force 20 days after their publication in the Official Journal of the EU. The provisions of the directive will have to be applied twelve months after publication. The main provisions of the regulation must be applied six months after its entry into force, the rest being applicable from the date of entry into force.