**COUNCIL OF
THE EUROPEAN UNION**

EN

Brussels, 8 May 2014
9355/14
(OR. en)
PRESSE 250

Council ensures funding of strengthened monitoring of medicines

The Council today approved[1] a draft regulation aimed at ensuring the funding of strengthened post-authorisation monitoring of medicines for human use ("pharmacovigilance") conducted at EU level (*PE-CONS 44/14* + *8795/1/14 REV 1 ADD 1 REV 1*). This follows a first-reading agreement reached with the European Parliament in February.

This means that the regulation is now adopted. It will enter into force 20 days following its publication in the Official Journal of the European Union.

The EU rules on pharmacovigilance have been reinforced in 2010 and, following the Mediator case[2], in 2012. The agreement endorsed today is expected to provide the means to finance the work of addressing the safety concerns and maintain high standards of quality, safety and efficacy of medicinal products.

The fees introduced by this regulation will be charged by the European Medicines Agency (EMA) and will allow EMA also to remunerate national competent authorities for the work provided by them in the EU-wide pharmacovigilance assessment procedures. The revised pharmacovigilance legislation has significantly widened the tasks of EMA, which acquired pharmacovigilance competences also for nationally authorised medicines, in addition to reinforced competences for centrally authorised medicines.

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1 The decision was taken by the Council for Foreign Affairs (Trade).

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that is suspected of having caused the deaths of several hundreds of patients in France at a time when it was already withdrawn from the market in other member states.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

Rue de la Loi 175 B – 1048 BRUSSELS Tel.: +32 (0)2 281 6319 Fax: +32 (0)2 281 8026
press.office@consilium.europa.eu http://www.consilium.europa.eu/press

The regulation provides for two types of fees charged to marketing authorisation holders:

– **fees designed to cover** the costs of three pharmacovigilance assessment **procedures** performed at EU level. These fees will be charged to marketing authorisation holders having at least one product involved in such a Union-wide pharmacovigilance procedure.

– The amount of the fees varies for each procedure: the assessment of periodic safety update reports (fee of EUR 19500 per procedure, out of which EUR 13100 for national competent authorities), the assessment of post-authorisation safety studies (EUR 43000, out of which EUR 18200 for national competent authorities) and assessments in the context of referrals initiated as a result of pharmacovigilance data (standard fee of EUR 179000, which can reach up to EUR 295000 in exceptional cases involving five and more active substances).

– In the case of the referral procedure the agreement provides for a sharing of the referral fee revenue between the involved three authorities: EMA will receive one third and the national competent authorities two thirds. The payment of the fee is divided between the marketing authorisation holders, each of them being charged a share of the fee that is proportionate to its share of products covered by the procedure. The agency will start charging these procedure-based fees shortly after the entry into force of the regulation;

– **an annual flat-rate fee** of EUR 67 per pharmaceutical form (e.g. tablets, drops, injectables etc.) of medicinal products authorised at national level. This fee is intended to cover the costs of general pharmacovigilance activities of EMA, such as safety data management, literature monitoring and information technology, notably maintenance of the EudraVigilance[3] database. The annual flat fee will be charged as from 1 July 2015.

In order to avoid double charging, the fees paid for activities performed at EU level and covered by the regulation cannot be charged at national level. Small and medium-sized enterprises will benefit of a fee reduction of 40% from all fees covered by the regulation and micro-enterprises are exempted from any fees. Additional reductions from the annual flat-rate fee apply to specific types of medicinal products, such as generic medicinal products or authorised homeopathic and herbal medicinal products.

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[3] EudraVigilance is a data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area.