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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Medicinal products – authorisations, European Medicines Agency

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Subject: Regulatory Information 01/2016 - Variations - Article 57 database

As of 1 February 2016 marketing authorisation holders of human medicinal products are no longer required to submit type IA variations in relation to administrative changes to the Qualified Person Responsible for Pharmacovigilance and the Pharmacovigilance System Master File.

1. BACKGROUND

Marketing authorisation holders (MAH) are obliged to inform competent authorities about changes of the Qualified Person responsible for Pharmacovigilance (QPPV) including contact details and/or changes in the location of the Pharmacovigilance System Master File (PSMF).

Currently, those changes are subject to a type IA_{IN} variation. However, the Commission guideline on details of categories of variations[1] foresee that: "*Once the Article 57 database is functional, changes in QPPV, including contact details (telephone and fax numbers, postal address and email address) and changes to the location of the PSMF (street, city, postcode, country) may be updated through the Article 57 database only (without the need for a variation). Where the MAH makes use of the possibility to update the above information through the Article 57 database, the MAH must indicate in the marketing authorisation that the updated information of those particulars is included in the database.*"

The Article 57 database owes its name to a legal provision in Regulation (EC) No 726/2004, namely Article 57(2). According to this Article, marketing authorisation holders have to submit to the European Medicines Agency product-related data. This includes full contact information on the QPPV and location of the Pharmacovigilance System Master File. The information needs to be kept up to date by the marketing authorisation holder.

At its December 2015 meeting, the European Medicines Agency's (EMA) Management Board confirmed that the Article 57 database of medicines authorised in the European Union (EU) can now be relied upon to provide the name and contact details of the QPPV for each authorised medicine in the EU and the location where the Pharmacovigilance System Master File of the marketing authorisation holder of a given medicine is held.

This endorsement by the Board allows EMA, the Commission and the national competent authorities in the EU to fully rely on the Article 57 database for this

[1] OJ C 223, 2.8.2013, p.1.

information, in accordance with the Commission variation guideline. As a result, companies are no longer required to submit type IA variations to notify those changes.

2. NEW APPROACH EFFECTIVE FROM 1 FEBRUARY 2016

This simplification applies from 1 February 2016. From that date, type IA variations for QPPV and PSMF location no longer need to be submitted. Instead, in line with legal requirements, marketing authorisation holders will need to provide changes through the Article 57 database. Subject to the applicable rules, it is not expected that marketing authorisation holders submit a specific (final) variation to switch to the new system.

For further questions on the Article 57 database and the business process for change management of EU marketing authorisations, marketing authorisation holders may refer to the European Medicines Agency (for centrally authorised products) or national competent authorities (for nationally authorised products).

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