EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 692

PHARMACEUTICAL COMMITTEE
21 October 2015

Subject: **Variations and the use of the Article 57 database**

Agenda item 1c

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

Currently, those changes are subject to a type IA_{IN} variation. However, the Commission guideline on details of categories of variations 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 Master File.

A first version of the Article 57 database was established in 2012 and by the end of 2014 contained approximately 500,000 medicinal product entries. Over the past years, the functionalities of the database have been further developed. Since January 2015 marketing authorisation holders are required to notify any changes impacting on the data included in the database through an electronic interface.

The Commission was recently informed by the Agency that the submission of information to the Article 57 database with regards to the collection of information on QPPV and the location of PSMF is operational and is covered by established quality assurance processes.

Subsequently, in order for the EU network to benefit from the functional Article 57 database, the National competent authorities will have constant access to these data and this is currently being rolled out together with training.

In accordance with the Variation Guidelines the Agency and national competent authorities will therefore rely operationally on the Article 57 database for this type of information. The submission of Type IAIN variations will no longer be required.

The finalisation of this project will simplify the notification process for the concerned information and ease administrative burden.

The Agency will ensure that national competent authorities are informed sufficiently in advance about the date to allow internal operational processes to be adapted.

Action to be taken:
For information