20/11/2013

Department
Pharmacovigilance

EUDRAVIGILANCE and the transmission of declarations

Questions / answers for MA holders

For more information, the EMA (European Medicines Agency) has published various guides on EUDRAVIGILANCE (http://eudravigilance.ema.europa.eu/veterinary/)

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1. **How can MA holders submit their declarations to ANSES-ANMV?**

   Declarations must be submitted on line through the EUDRAVIGILANCE network.

   Please note: *When an MA holder has only a small number of MAs and few adverse event reports (AERs), ANSES-ANMV will accept reports being submitted using the simplified form available on the EMA's website.*

2. **Must MA holders be registered with EUDRAVIGILANCE?**

   For all new MA applications, a copy of the registration of the qualified person for pharmacovigilance must be included in the Detailed Description of the Pharmacovigilance System (DDPS)section.

   For all MA holders, the person in charge of pharmacovigilance must be registered with EUDRAVIGILANCE (see question 3).

   This registration makes it possible to receive and collect declarations submitted by the competent authorities, and also to submit declarations made in non-European countries concerning their products directly into the EUDRAVIGILANCE system.

3. **How does ANSES-ANMV send declarations to the relevant MA holders?**

   ANSES-ANMV sends all its reports via the EUDRAVIGILANCE network.

4. **When must any additional information for a previously submitted declaration be sent to the ANMV?**

   - As soon as new and important information for the administrative management and/or scientific interpretation of a given case comes to the attention of the MA holder, they must submit this additional data to the ANMV as a “follow-up” report.

In addition, in France, each report undergoes an evaluation and causality assessment by the ANMV or by the CPVL. In order to maintain a harmonised approach with the MA holders, it is important to

identify any discrepancies and discuss them if necessary. As a result, the ANMV recommends that MA holders also submit additional information as soon as a conclusion and/or causality assessment of the MA holder differs from that submitted by the ANMV (even if there is no other new data).

5. **When a report is submitted by an MA holder to ANSES-ANMV, does the latter entity send its conclusions to the MA holder in question?**

   ANSES-ANMV only provides updates via Eudravigilance for cases in which the conclusion and/or causality assessment by ANSES-ANMV differs from that submitted by the MA holder.

   Please note: *ANSES-ANMV also transmits the case reports via Eudravigilance to all the other MA holders who may be concerned (including any updates of these cases, as soon as new information is added).*

6. **What nominative data do reporting professionals need to provide?**

   The decision by ANSES Director General of 29 July 2011 requires that ANSES be provided with the following:

   - The identity of the reporting professional
   - The address and telephone number of the reporter
   - The profession of the reporter

   However, in the absence of EU-level harmonisation, the following **minimum** information shall be accepted:

   - The first letter of the last name of the reporting professional
   - The first letter of the first name of the reporting professional
   - The first two digits of the postal code

   If requested, the MA holder must provide ANSES-ANMV with the full contact information of the reporting professional (primary reporter) within two weeks, except in cases of written refusal by the professional in question.