Agenzia Italiana del Farmaco

AIFA

Comments by the national Pharmacovigilance Commmittee on the proposed changes in Pharmacovigilance legislation

Creation of a Pharmacovigilance Committee

We do not understand the reasons to create a new Committee, unless it has given the whole responsibility in the risk evaluation and communication.

Payment of assessments of pharmacovigilance according to the rapporteurship system

The activities of pharmacovigilance are and should remain financed through public funding. To apply the rapporteurship system to safety evaluations (the companies pay rapporteurs and co-rappporteurs through EMEA) would create inevitably conflict of interests and would reduce the trust of the citizens towards the European system.

Transparency in acts and in decisions

Transparency should be favoured in acts and decisions at all levels of the agencies and of EMEA. An important aspect that is not foreseen in the legislative proposals is the communication of the signals that the agencies are dealing with, even before the final decisions (similarly to what FDA is doing already). This is especially urgent for EMEA, since the decisions of 27 member states requires time, and public opinion has to be informed of what is being discussed .
Some further aspects seem strongly limiting the transparency: article 101g do not foreseen neither the public access to the post-marketing studies included in the RMP or the results of these studies (Companies compliance).

Proposed definition of ADR

The new definition of ADR includes the over dosages and the drug abuse and also the medical errors.
In our opinion that can be very confounding especially when evaluating a signal: how much is that a “true signal” and how it is due to medical errors or to drug abuse?

Inclusion of a definition of “European list of intensive monitoring”

The scope of the list is not clear - Which product to be included: only those products with a RMPs? All new authorized products? The criteria for the product to be removed: when the RMP commitment has been concluded? An established period for all products 2 years ? 3 years?
In our opinion the main objective of the list should be the completion of the safety framework of the product that is now limited at the time of MA. This should not be misinterpreted as the list of dangerous products or not completely studied products.

Also it would be very useful if **the "black triangle" system** would be applied to the European list.

Risk management System- Risk management plan

When referring to the product the term RMP should be referred to.

SPC-Introduction key safety information about the medicinal product and how to minimise risks.

Some doubts concerning the usefulness and opportunity because it could distract the attention from the remaining information in the document; depending from how it will be prepared it can become the summary of the summary. Maybe slimming this document should be considered, avoiding to repeat the same concepts in the different sections with cross references and to include data which are inevitably limited and partial on clinical studies, replacing them possibly with bibliographic notes.

Reasons for refusing or withdrawn a MA

We strongly support the maintenance of the "**lacks of therapeutic efficacy"** among causes for refusing or withdrawn or non renewal a MA

Package leaflets and patient reporting

Some doubts concerning the usefulness and opportunity because it could distract the attention from the remaining information in the document -We do not support the statement proposed "All suspected adverse reactions should be reported to < the name and address of the marketing authorisation holder in the Member State where the marketing authorisation holder will receive suspected adverse reaction reports >".

In our opinion the patient should report to the Competent Authorities not to the MAH.

The patient reliability (trust) in public health authority should be promoted and strengthened . This is why in our opinion we cannot leave to the company neither the management of the relationship with patient nor the evaluation of causal relationship of the patient reports