Name- Rottapharm Italy and Delta Laboratories

Type of stakeholder- Industry

Comments:

Rottapharm Italy and Delta Laboratories welcome the opportunity to point out what they feel are the weaknesses of the European pharmacovigilance system, but they also recognize and appreciate the efforts of the European Commission and of the Health Authorities to build a robust pharmacovigilance system that will benefit all stakeholders.

On specific areas highlighted in the commission sponsored study

1) Data sources and safety issue detection

- Companies have to screen world-wide literature per active ingredient. This means that if a Company sells an active ingredient for a specific indication with a specific route of administration, literature cases regarding completely different indications and routes must be considered; this can be a very big burden, scientifically not justified. For example a Company may market triamcinolone acetonide patches for oral cavity erosions; for this indication and route of administration almost nothing is published. For triamcinolone acetonide given per intravitreal route for eye disorders, instead, an enormous number of case reports and studies is published every week. A small Company with a small sales volume can't afford the burden of preparing case reports regarding the intraocular administered drug when it markets the transdermal patch. It should also be considered that the Authorities receive reports regarding the same articles from every Company selling a specific active ingredient (i.e. an Authority may receive the same report over and over again).
  Literature searches should be focused on active ingredients having the same indication and/or route of administration as that are marketed by the Company.

- The system should facilitate electronic reporting by the health care providers, namely through a path placed in the physician's website, regulatory authorities' website, pharmacist's website, dental professional's website, between others.

- The electronic prescription software used by the physicians and that is being implemented worldwide, should include safety information of the medicines in a way that risky interactions between products could be detected and the professional be informed. Additionally this software should allow direct ADR electronic transmission to the Authorities and/or to the Industry.

2) The legal framework and new legal tools

- Both international and national regulations are constantly changing and increasing in number. The speed with which new regulations are adopted obliges Companies to constantly change their working practices and to produce a constantly increasing number of documents.
  On the other hand, local Authorities may or may not implement the new EMEA regulations/guidelines and local Authorities often change them adding their own requirements.
  This not only constitutes a cost that makes Companies less competitive, but makes it is very difficult to be compliant.

- In what electronic testing is concerned, there's a lack of agreement between Health Authorities. Every Authority does not simply accept EMEA regulations, but some of them add their own exceptions and specific amendments. For example, a Company has to do electronic testing a number of times with a number of Authorities which may have different requirements. Not only local Authorities should recognize testing done with EMEA or with another Authority, but the electronic reporting requirements should be exactly the same all over the European Union.

3) **Decision making in pharmacovigilance**
4) **Impact of communications and actions**

5) **Facilitation and monitoring of compliance with pharmacovigilance requirements**

6) **The need for quality management and continuous quality improvement**

- Pre-graduation and post-graduation courses in pharmacovigilance should be mandatory for all health care providers. As per today, the system strongly relies on collection and analysis of spontaneous reports; not only there is a clear underreporting, but the few received reports are of poor quality and obtaining follow-up information is very often almost impossible. Health care professionals lack of knowledge about the points to consider for assessing a causal relationship between a drug and an adverse event. Companies are required to produce high-quality reports with very low and/or contradictory data.

- EMEA has recently produced a guideline addressing the need of data regarding drugs taken during pregnancy. Today both GPs and gynaecologists are not sensitized on the need and importance of reporting this particular type of cases.

On your experiences of the community system overall

- There is a lack of harmonization and of mutual recognition between EMEA and single Health Authorities.

On any part of the community system

On how you could better contribute to the Community pharmacovigilance system

On suggestions to strengthen the Community pharmacovigilance system

- More interaction, contacts with and between Health Authorities' pharmacovigilance departments, through workshops and meetings organised by the RAs.
- Health Authorities should accept decisions taken by other Authorities without adding or changing requirements.

- The overall system should be simplified and kept as simple as possible.