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Rapid Alert system for Blood and Blood Components (RAB)
Summary of 2014 activities

Background

Article 9 of Directive 2005/61/EC[1] regarding communication of information between Member States' blood competent authorities and to the Commission provides for the Member States to "ensure that their competent authorities communicate to each other such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded."

In the framework of the rapid alert platform for substances of human origin (SoHO) a second module covering Blood and Blood Components (RAB) was launched in February 2014.

The purpose of the rapid alert system for human blood and blood components is to provide the Member States' competent authorities and the European Commission with an effective and secure network tool for the exchange of information on urgent measures, to ensure the safety of human blood and blood components. This rapid exchange of information allows Member States to immediately verify whether they are affected by a problem initially raised by a Member State, and for which a precautionary/corrective measure should be implemented.

RAB alerts

The criteria established by the Member States and the European Commission for encoding rapid alerts in the RAB have been defined during the development of the module and the drafting of the RAB Standard Operating Procedures - SOP (e.g. the need for immediate/urgent consideration or follow-up measures in two or more Member States; known or potential risk to patients; issues of a serious or potentially serious nature; potential public health risk to other countries).

Three types of rapid alert were defined and used as follows:

1) Quality and Safety Defects are understood as alerts requiring field corrective actions (e.g. recall, quarantine, discard, etc.) of the concerned blood or blood component, potentially impacting patient safety in other Member States.

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:256:0032:0040:EN:PDF

2) Information Notices are defined as alerts related to field corrective actions performed in the medical device sector, medicinal products sector or other sector(s), which were of relevance to blood and blood components sector.

3) Epidemiological Notices are alerts related to the development of significant epidemiological situations (e.g. disease outbreaks) which may have cross-border implications in the field of blood and blood components donation and transfusion.

A fourth type of alert, a bilateral communication, was also implemented. Bilateral inquiries are defined as rapid ways of communication between competent authorities of only two Member States related to any type of alert to be used in particular situations:

- the need to substantiate/confirm information related to a potential rapid alert before the official submission in the RAB system;
- any other situation which is deemed appropriate for such an alert.

At a later stage, an inquiry can be either closed or converted into another type of alert.

The RAB Standard Operating Procedures and User Manual provide guidance on when and how Member States should inform each other.

Rapid alerts reported in RAB during 2014

In the interest of openness and transparency to regulatory authorities, professional organisations and other interested parties, the communications via the RAB system, reported by the competent authorities, are collectively presented below.

During the first year of activity of the RAB platform 38 rapid alerts have been encoded in relation to Epidemiological Notices on West Nile Virus cases. These were issued by the following six Member States: AT (1), EL (1), HU (4), IT (29), RO (3).

One alert was encoded as an Epidemiological Notice (PT) in the context of Legionnaires disease cases.

One alert was encoded as an Information Notice (EL) concerning contamination during a platelet transfusion.

These rapid alerts led to the following types of preventive/corrective actions:

- Application of a deferral period for donors coming from affected areas;

- Definition of preventive and corrective measures to be taken to address the contamination issue.

Conclusions

This platform represents a response to a request from the competent authorities for blood and blood components concerning the need for communication and information dissemination in relation to rapid alerts.

Even though the distribution of blood and blood components is not very frequent across national borders, and only in a small number of specific situations are bilateral agreements set up, the need for such a rapid alert system has been raised by national competent authorities in relation to epidemiological issues and medical device defects.

During its first year of activity the Epidemiological and Information Notices are the types of rapid alerts used to communicate disease outbreaks and potentially detected devices contamination.