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Rapid Alert system for Blood and Blood Components (RAB)
Summary of 2015 activities

Background

Article 9 of Directive 2005/61/EC[1] regarding communication of information between Member States' blood competent authorities and to the Commission requires that Member States "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reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded."

The Rapid Alert system for Blood and Blood Components (RAB) was launched in February 2014.The purpose of the platform 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 and are available in 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.) for the blood or blood components that might impact 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 are of relevance to the blood and blood components sector.

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

A fourth type of alert, a bilateral communication, was also implemented. Bilateral inquiries are defined as rapid ways of communicating 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 communicate with each other.

Rapid alerts reported in RAB during 2015

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 second year of activity of the RAB platform 13 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), FR (1), HU (1), IT (1), PT (1), RO (8).

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

One alert was encoded as an Information Notice (IE) concerning a medical device malfunctioning (calibration defect).

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 device defect.

In comparison with the first year of activity (2014) the number of alerts has decreased. This is the result of some relevant discussion between National Competent Authorities and the European Commission with regard to the encoding Epidemiological alerts related to a given outbreak (e.g. if the same outbreak results in new disease cases, it was suggested to update the original alert instead of opening a new alert). This has produced a more clear alert history and final report in the Epidemiological alerts.

Conclusions

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

The 2015 activity is a confirmation that this platform represents a response to the competent authorities for blood and blood components' need for a communication and information dissemination tool in relation to rapid alerts.

Since the launch of the system in 2014, national competent authorities have been using this communication and information dissemination tool in relation to rapid alerts for blood and blood components.

In 2015, the Member States' activities in the rapid alert system focused mainly on Epidemiological alerts and Information Notices. National competent authorities emphasized that the system is important to effectively exchange information on different rapid alert types, in particular to communicate disease outbreaks and detected device issues.