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Rapid Alert system for Blood and Blood Components (RAB)
Summary of 2016 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reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded."

In its third year of activity, the Rapid Alert system for Blood and Blood Components (RAB) provided 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 RAB Standard Operating Procedures - SOP established the criteria for encoding rapid alerts in the RAB. These have been defined by the Member States and the European Commission and concerned the need for immediate/urgent consideration or follow-up measures in two or more Member States, the known or potential risk to patients, the issues of a serious or potentially serious nature and 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 2016

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 third year of activity of the RAB platform seven rapid alerts have been encoded in relation to Information and Epidemiological Notices. These were issued by the following six Member States: BE (1), EL (2), FR (1), HU (1), IE (1), IT (1)

Five alerts were encoded as Epidemiological Notices (EL, FR, HU, IT) in the context of Malaria, West Nile Virus and Zika cases.

Two alerts were encoded as Information Notices (BE, IE) concerning an *in vitro* diagnostic kit for syphilis. Positive samples were incorrectly tested as negative by a defective lot in routine use for screening of blood donors in Belgium. The failure was identified in a proficiency testing scheme run by the Council of Europe (EDQM). The kits were manufactured in Ireland and distributed in a number of EU Member States.

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 and voluntary withdrawal from the market of the testing kit.

In comparison with the two previous years the number of alerts has further decreased. This regards in particular procedural changes agreed between National Competent Authorities and the European Commission on the encoding of Epidemiological alerts related to a given outbreak. The new disease cases, related to the same outbreak, are now reported as part of an

update of the original alert instead of being the subject of a new alert. This has produced a clear outbreak history and a more consistent 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.

In 2016, 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 exchange information effectively on different rapid alert types, in particular to communicate disease outbreaks and on issues related to detection of device failures.

In the second half of 2016 the RAB platform benefitted from a set of changes and improvements implemented in the rapid alert for tissues and cells platform, which shares the same informatics frame.