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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

Rapid Alert system for human Tissues and Cells (RATC) and for human Blood and Blood Components (RAB)

Summary of 2019 activities

Introduction

The rapid alert platforms for blood (RAB) and for tissues and cells (RATC) give Member States' competent authorities the possibility to create and launch alerts to each other and/or to request information in case of an alert or crisis involving more than one Member State. The systems facilitate the communication of information needed to allow competent authorities in other Member States to rapidly assess risks and take adequate and timely measures.

DG SANTE hosts these two platforms, maintains the standard operating procedures (SOPs) and manages users from the national competent authorities. These national users are the ones who draft, launch and close the alerts.

This report provides an overview of the functioning of both systems and alerts submitted in 2019.

Background

Article 8 of Directive 2006/86/EC¹ requires the Member States' competent authorities for human **tissues and cells** to *"communicate to each other and to the Commission, such information as is appropriate with regard to serious adverse reactions and events, in order to guarantee that adequate actions are taken."*

Article 9 of Directive 2005/61/EC² 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reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded."*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 platform for human tissues and cells (RATC) was initiated in 2013 and the rapid alert platform for human blood and blood components (RAB) was initiated in 2014, in order to provide the Member States' competent authorities and the European Commission with an effective and secure tool for the exchange of information for situations in which there is a suspicion of serious health risks associated with tissues, cells, blood and blood components distributed across borders.

The system has been used in parallel with existing national vigilance systems, which collect and manage alerts on human tissues, cells, blood and blood components donated and used within a Member State. Additionally, messages can be communicated regarding problems in related sectors (e.g. medical devices, human or veterinary medicinal products, human organs intended for transplantation) which might imply a risk for the quality and safety of blood, tissues or cells.

¹ http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_294/l_29420061025en00320050.pdf

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:256:0032:0040:EN:PDF>

RATC alerts

The criteria established by the Member States and the European Commission for encoding rapid alerts in the RATC system remained unchanged in the reporting period (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).

Four 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 human tissues/cells potentially affecting patient safety in other Member States.

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

3) Illegal and fraudulent activities are defined as alerts used to notify Member States and the European Commission of the possible presence in the distribution network of tissues or cells resulting from actual or suspected illegal and fraudulent activities in the procurement, testing, processing, packaging, distribution, labelling, import/export or promotion of human tissues or cells.

4) 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 tissues and cells intended for human application.

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 RATC 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 RATC Standard Operating Procedures (SOP) provide guidance on when and how Member States' competent authorities should inform each other.

Rapid alerts reported in RATC during 2019

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

A total of 45 alerts were launched in 2019: 40 alerts were encoded in relation to quality and safety defects of tissues and cells (DK 39, DE 1), and 5 alerts were encoded as epidemiological notice (AT 2, ES 1, FR 1, RO 1). No alerts were encoded as information notice, bilateral enquiries, illegal/fraud or other.

All the alerts encoded as quality and safety defects concerned sperm donations identified as posing a risk for transmission of genetic disease. Authorities limited further distribution and use of the donations concerned.

The epidemiological notices encoded concerned West Nile Virus outbreaks and a confirmed case of dengue in Spain.

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

- increase attention in donors' selection; test donors or defer them when tests are not available; dismiss donors if infection is acute.
- if tests are positive organs and tissues should not be transplanted; if tests are unavailable, run an in depth risk assessment.
- recommend against donation if deceased donors showed neurological symptoms.

RAB alerts

The RAB Standard Operating Procedures (SOP) establish the criteria for encoding rapid alerts in the RAB and provide guidance on when and how Member States should communicate with each other. These have been defined by the Member States and the European Commission. They concern the need for immediate/urgent consideration or follow-up measures in two or more Member States, a known or potential risk to patients, 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 affect patient safety in other Member States.
- 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, is also possible. 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 that is deemed appropriate for such an alert.

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

Rapid alerts reported in RAB during 2019

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.

A total of 21 rapid alerts were encoded in RAB, 19 related to epidemiological notices, one to quality and safety issues and one was an information notice. These were issued by the following six Member States: AT(2), BG (1), CY (1), DE (1), FR(3), HU(3), IT(1), LU (1), RO(7), and SK(1).

Seventeen alerts were encoded as epidemiological notices in the context of West Nile Virus cases and two of Dengue.

These rapid alerts led to the usual preventive/corrective actions: application of a deferral period or testing for donors coming from affected areas.

One alert was encoded as an Information Notice (DE) concerning damaged and leaking platelet storage bags. Specific lots were identified, withdrawn from use and replaced by the supplier with new ones. No complaints were received on patients developing infections.

One alert was encoded as a Quality and Safety issue (LU) concerning connection problems on the blood bag spike port which was detected just before transfusion. The affected batch was separated and an investigation was started.

Conclusions

In comparison with 2018, the number of alerts has slightly increased for tissues and cells, but decreased for blood and blood components.

The activities of the Member States in the rapid alert platforms, RAB and RATC, have focused on blood, tissues and cells that are distributed between Member States in Europe and on exchanges of information and description of urgent measures to be taken. While most of the alerts for tissues and cells concerned quality and safety defects, epidemiological notices were the main category of alert in the blood sector.

Once more, the platforms have proved to be an effective tool to respond to the needs of authorities for communication and information dissemination in relation to immediate health threats.