EUROPEAN COMMISSION
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 2023 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 2023.

Background

Article 8 of Directive 2006/86/EC[1] 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/EC[2] 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reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded.*"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, 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 (i.e. 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 when:

- There is the need to substantiate/confirm information related to a potential rapid alert before the official submission in the RATC system.
- In 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 2023

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 presented below.

A total of 30 alerts were launched in 2023: 23 alerts were encoded in relation to' quality and safety defects of tissues and cells' (21 from Denmark, one from The Nederland and one from Malta), and seven alerts were encoded as 'epidemiological notice' (one from Austria and six from France). There were no bilateral enquiries, information notices or alerts regarding illegal activities/fraud. When compared with 2022, the number of alerts has slightly increased for tissues and cells. There was a significant reduction in the

number of submitted alerts compared to before the Covid-19 pandemic, in 2019, indicating that the figures seem to have stabilised at a lower level since the end of the pandemic.

All the 21 alerts encoded by Denmark 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 one encoded by Malta was a request of updates on a Field Safety Corrective Action asking for the recall of Soft Denudation Tips used for the manipulation and transfer of oocytes in the context of ART treatment. The one encoded by The Nederland informed the Competent Authorities of about a potential sterility packaging seal defect recommending a need to recall of the product.

The epidemiological notices encoded concerned the implementation of preventive measures against West Nile Virus and Dengue transmission (donor surveillance and/or deferral and donation testing) in Austria and France. These were also reported to the RAB network.

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 when:

- There is the need to substantiate/confirm information related to a potential rapid alert before the official submission in the RAB system.

- In 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 2023

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 presented below.

A total of nine rapid alerts were encoded in RAB, eight related to epidemiological notices, and one was an information notice. These were issued by the following Member States: Austria (1), Cyprus (1), France (4), and Italy (3).

The number of alerts submitted to the blood network is slightly decreased compared to 2022. Similar to the RATC, there was a significant reduction in the number of submitted blood alerts compared to before the Covid-19 pandemic, in 2019, indicating that the figures have stabilised at a lower level the since the end of the pandemic.

The epidemiological notices encoded concerned the implementation of preventive measures against West Nile Virus and Dengue transmission (donor surveillance and/or deferral and donation testing) in Austria, France, and Italy. Austria and France reported the same alerts to the RATC network.

One alert was encoded as an Information Notice (from France) concerning a medical device manufacturer established on French territory reporting a drop in factor XI in the plasma intended for transfusion. It was concluded, however, that the effect had no clinical significance for patients.

Conclusions

In comparison with the period prior to the Covid-19 pandemic (2019), the number of alerts has considerably decreased for both tissues & cells and blood & blood components, but it has been relatively stable in the last four years. When compared with 2022, the number of alerts has slightly decreased for blood and blood components while it has slightly increased for tissues and cells.

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