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 2022 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 2022.

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reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded.*"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 2022

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 25 alerts were launched in 2022: 18 alerts were encoded in relation to quality and safety defects of tissues and cells (all from DK), six alerts were encoded as epidemiological notice (four from AT and two from FR) and one alert was encoded as bilateral enquiry (NL). There were no information notices or alerts regarding illegal activities/fraud. There was a significant reduction in the number of submitted alerts compared to 2019, almost certainly because activities in tissue establishments were

dramatically reduced during the lockdowns imposed by national governments during the Covid-19 pandemic and the effects are still evident almost three years after the beginning of the pandemic. When compared with 2021, the number of alerts has slightly decreased for the tissues and cells.

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 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.

The Netherlands informed Poland that, due to the withdrawal of an authorisation of a tissue establishment, stem cells from umbilical cord blood stored in that establishment were moved to another tissue establishment in Poland, but this material cannot be used for application on humans, and therefore it shall not be distributed, as its safety and quality cannot be guaranteed.

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 2022

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 12 rapid alerts were encoded in RAB, ten related to epidemiological notices, one to quality and safety defects and one was an information notice. These were issued by the following seven Member States: AT (4), DE (1), FI (1), FR (2) IT (1), PT (2) and SK (1).

Similarly to the RATC, the number of alerts submitted to the blood network almost halved compared to 2019 but slightly increased compared to 2021.

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

One alert was encoded as an Information Notice (from Finland) reporting that loose particles (later identified as polyethylene / polypropylene) were detected in used and unused blood bags for preparation of platelet products. Remaining quantities of affected lots were blocked by the manufacturer, that has however confirmed that it was safe to use products that were already on the market because the integral mesh filter used in the product would catch all of the loose particles observed in returned samples.

One alert was encoded as a Quality and Safety defect (from Germany) reporting the mislabelling of a reagent used in automats for AB0 blood group determination. Affected lots were recalled and blood establishments were invited to follow the recommendations issued by the respective competent authorities regarding potential action to be taken.

Conclusions

In comparison with 2019, the number of alerts has considerably decreased for both tissues & cells and blood & blood components. When compared with 2021, the number of alerts has slightly decreased for the tissues and cells while it has slightly increased 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 proved to be an effective tool to respond to the needs of authorities for communication and information dissemination in relation to immediate health threats.