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Rapid Alert system for human Tissues and Cells (RATC)
Summary of 2016 activities

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.*"

The rapid alert platform for human tissues and cells (RATC) was initiated three years ago to provide the Member States' competent authorities for tissues and cells 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 and cells distributed across borders.

Under the RATC system Member States have the possibility to launch alerts to all competent authorities or to notify only the competent authorities for which the alert is relevant or to request information from another competent authority in case of specific information needs. The system aims to facilitate the communication of information needed to allow competent authorities in other Member States to assess the need for urgent measures. The system has been used in parallel with existing national vigilance systems which collect and manage alerts on human tissues and cells donated and used within a Member State. Additionally, information stemming from related sectors (e.g. human or veterinary medicinal products, blood and blood components, human organs intended for transplantation or medical devices) might suggest that the quality and safety of tissues and cells is also at risk.

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).

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

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 impacting 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) and User Manual provide guidance on when and how Member States' competent authorities should inform each other.

Rapid alerts reported in RATC during 2016

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 nine alerts were initiated in 2016: seven alerts were encoded in relation to quality and safety defects of tissues and cells and were issued by Denmark, and two alerts were encoded as Information Notices (FR, IE).

The seven alerts related to quality and safety defects concerned sperm donors identified as posing a risk for transmission of genetic disease. Authorities limited further distribution and use of the donations concerned.

The information notice issued by France concerned preventive measures applicable to tissues and cells in relation to the Zika virus outbreak. The one issued by Ireland concerned a defective *in vitro* diagnostic medical device kit used for syphilis screening in donors.

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

- Quarantine and/or recall of tissues and cells with quality and/or safety defects.

- Definition by national Competent Authorities in the Member State of preventive and corrective measures to be taken to address the device defect and voluntary withdrawal of the test kit from the market by the manufacturer.

Conclusions

The activities of the Member States in the RATC have focused on issues concerning tissues and cells that are distributed between Member States in Europe and on exchanges of information and description of urgent measures to be taken.

As a result of the number of alerts encoded, the platform has proved itself to be an effective tool to respond to the needs for communication and information dissemination in relation to rapid alerts.

A series of changes and improvements, proposed by the RATC expert sub-group in June 2015, have been implemented in RATC in the second half of 2016, enhancing the functionality of the system. These have also contributed to the improvement of the rapid alert for blood and blood component platform.