EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate D - Health systems and products
B4 – Medical Products : quality, safety, innovation

Brussels,
SANTE B4/PC/ ARES(2016)

Rapid Alert system for human Tissues and Cells (RATC)
Summary of 2015 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 substances of human origin (SoHO) was launched in 2013 with the first module covering human tissues and cells (RATC). This platform was initiated 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.

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.

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. Competent authorities receiving the alert can acknowledge whether they are concerned or not, thus allowing for the magnitude of the problem to be defined. They can provide comments or additional information (where available and relevant), and may forward the alert to other competent authorities in the RATC system (in case not all relevant authorities have been notified).

[1] http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_294/l_29420061025en00320050.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 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. The second version was finalised at the end of 2014 and will be further updated and improved.

Rapid alerts reported in RATC during 2015

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 32 alerts were initiated in 2015: 30 alerts were encoded in relation to quality and safety defects of tissues and cells and were issued by Denmark, and one alert was encoded as

Epidemiological Notice, (FR) and one Enquiry concerning a Tissue Establishment licence (NL).

Concerning the 30 alerts related to quality and safety defects, they were related to sperm donors who may transmit genetic diseases. In the latter case, authorities limited further distribution and use of the concerned substances.

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.

- Follow-up by the national Competent Authorities in the Member State where the cells were distributed, in accordance with their national requirements.

Rapid alerts status

During the three years of activity a total of 102 alerts have been encoded. Most of them are now closed and measures have been implemented to solve the reported issues.

The rapid alerts still open were followed up by the national competent authorities with the necessary preventive/corrective actions.

Conclusions

The activities of the Member States in the rapid alert over the three years have been concentrated on the monitoring of the movement of tissues and cells in Europe and to assess the various exchanges of information and urgent measures.

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

In June 2015 the Commission organized a meeting of the RATC expert sub-group to refine some system features on the basis of the acquired experience. This meeting has produced a list of changes and improvements that will be implemented in the first half of 2016.