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2013 Report
on the Rapid Alert system for human Tissues and Cells (RATC)

Background

Article 8 of Directive 2006/86/EC[1] requires the 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 system for human Tissues and Cells (RATC) was initiated in 2009 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 transferred across borders. The system aims at allowing Member States to take 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. The Rapid Alert system aims to allow also notifications in such situations. A report of the initial RATC system hosted by the Commission CIRCA/CIRCABC platforms from 2010 to 2012 was published last year.[2]

In February 2013 an upgraded Rapid Alert platform was launched by the European Commission. While the purpose of the platform did not change, additional functions were included allowing for an improved communication between the Member States Competent Authorities and the European Commission:

- 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 (e.g. “bilateral inquiry”).

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

[2] http://ec.europa.eu/health/blood_tissues_organs/docs/ratc_report_2008_2012_en.pdf

- Competent Authorities receiving the alert can acknowledge whether they are concerned or not, thus allowing to define the magnitude of the problem.

- The alerted Competent Authorities 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).

For instance in case of an outbreak of a communicable disease with potential impact on the tissue and cell transplantation sector, following an alert launched by a Member State, the Competent Authorities in other Member States may confirm whether they are concerned or not, may inform about the number of confirmed cases at national level and provide additional information (including uploading relevant documentation) on the progress of the outbreak until its closure.

RATC alerts

The criteria established earlier by the Member States and the European Commission for encoding rapid alerts in the RATC system remained unchanged (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 alerts and one bilateral communication were defined:

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 field corrective actions performed by the medical device sector, medicinal products sector or other sector(s), which were of significance 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 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.

5) 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 set out the details when and how Member States should inform each other. The first version was finalised in 2013 and will be constantly updated and improved.

Rapid alerts reported in RATC during 2013

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.

During the first year of the new RATC platform there have been 13 alerts and 2 inquiries related to tissues and cells. These were issued by the following 4 Member States: DK (11), FR (1), NL (2), UK (1). Of the 13 alerts:

- 12 were quality and safety defects,
- 1 was an information notice regarding a tissue establishment located in another Member State, and
- 2 were bilateral inquiries concerning the authorization status of a tissue establishment.

Concerning the 12 alerts related to Quality and Safety Defects, 1 referred to a replacement tissue, a cardiac valve to be recalled from the market, while 11 were related to sperm donors who transmitted genetic diseases (autosomal recessive genetic disorders). In the latter case, authorities limited further distribution and use of the concerned substances.

The aforementioned 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 inspection of the tissue establishment by the national Competent Authorities in the Member State where the tissue establishment was located.

  Risk analysis and appropriate recommendations for the further use of the gametes from the donors diagnosed with genetic diseases.

Conclusions

Taking into account the increase in the exchange of tissues and cells among Member States, and internationally, and the activities registered in RATC in 2013, all involved parties have appreciated the new web-based platform for the exchange of information and urgent measures.

Compared to previous systems, this new platform is more adapted to the needs of Competent Authorities for Tissues and Cells and the European Commission and provides wider possibilities of communication and information dissemination with the choice of contacting single or groups of national competent authorities.

In June-July 2013 the Commission ran a first analysis of the platform in cooperation with the National Competent Authority users which led to a revision of the SOP and user manual at the beginning of 2014.