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OMCL NETWORK INCIDENT MANAGEMENT

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Concerned Network	GEON

OMCL Network Incident Management

Scope

This document focuses on incident management within the OMCL Network. It is also recommended to have an incident management plan in place at national level. The term incident is understood as defined by EU documents (see below).

Aim of the OMCL Network Incident Management Procedure

The OMCL Network Incident Management Procedure will ensure that the OMCL Network is capable of adequately responding to incidents affecting the Network in an effective, efficient and timely manner.

Definition of an incident

In the context of this Incident Management document, an incident relevant for the OMCL Network is defined as a situation where an event occurs or new information arises, irrespective of whether this is in the public domain or not, in relation to (a) medicinal product(s) authorised in the EU or an ingredient(s) thereof, and irrespective of the licensing route, which could have a serious impact on public health or animal health and

- which is not managed by another body or group [e.g. 1, 2],
- where established procedures are not deemed sufficient, and
- where OMCL involvement is considered appropriate.

Situations such as events that do not seem at a first glance to have a serious impact on public health but are in the public domain irrespective of whether they are the subject of media attention or not) and may lead to serious public concerns about (a) product(s), may also need to be considered as incidents. Likewise, situations which could have a negative impact on the appropriate use of (a) medicinal product(s) (e.g. resulting in patients stopping taking their medicine) or on the availability of medicinal product(s) fall within the definition of an incident. Other extraordinary events or needs of an OMCL, for which the OMCL Network's knowledge and capacity could be of assistance, may also be treated according to this incident management scheme.

Overall objective

An essential requirement for successful incident management is good communication between OMCLs, National Competent Authorities, the EMA and other international authorities (as necessary). The EDQM will maintain the respective information exchange tools within the Network. Communication for incident management will be facilitated by, for example, using a single points of contact (SPOC) network, comprising a team of administrative and/or scientific contact persons. Intra-GEON communication will be streamlined by using the Network's secure IT platforms.

Crucial resources, such as information, availability of analytical methods and reference standards, laboratory capacities, workload, specific samples and test results, should be shared by the OMCLs involved. A testing overview should be established in order to avoid duplicate analysis of the same products/batches, in order to further improve efficiency and expedite data generation.

Incident management

Prerequisites to Incident management

An overview of analytical techniques and capabilities within the Network should be readily accessible, in order to quickly define which OMCLs are the most suitable to provide support during an incident. OMCLs may also have some resource restrictions, if the issue causing the incident has a high political and/or national priority, which will limit their support of the Network. Early clarification of how such limitations affect their ability to support the GEON should be made.

An additional prerequisite is the capability of the OMCLs to invest early in technologies, personnel and analytical methodologies based on market developments. Rapid and easy information sharing will also help to clarify which technologies and/or new products the network should focus on.

Procedure

Identification of incidents

The OMCL that observes or is informed of a potential extraordinary situation alerts the EDQM that there is a potential incident, providing as much detail of the situation and potential impact as they have available at the time. Information on the possible incident could come from different stakeholders, such as the NCA, the EMA, the WGEO, other international regulators, or WHO, and may be distributed via the rapid alert system or by email.

Initialisation of incident management

When an incident is identified, the appropriate Advisory Group (AdG-GEON or AdG-CAP or AdG-OCABR or AdG-VBRN) and the Secretariat act as the initial management lead. If needed, they may appoint an Incident-Specific Working Group (ISWG) composed of specialised OMCLs with the technical expertise to carry out the analyses needed.

The work is co-ordinated by the Secretariat. Its duties include identifying and liaising with specialised OMCLs that are able to act in incident situations, and alert management – including the use of the various existing rapid alert networks. The Secretariat will focus on the exchange of information within the group and with external partners.

The responsible group periodically re-evaluates the situation with the OMCLs involved, the EDQM and any relevant external partners (e.g. the EMA or International regulators). The Secretariat ensures timely communication to key stakeholder groups and reporting to the relevant Advisory Group.

Network incident response

If the Advisory Group appoints an ISWG, it officially initiates the Network incident response. A member of the originating OMCL may become the scientific leader, if appropriate. The ISWG (or otherwise the appropriate Advisory Group) is responsible for and organises an adequate alert management immediately. Throughout the incident period, the Secretariat together with the responsible group co-ordinates the execution and evaluation of emergency activities, promotes and maintains situational awareness, tracks the progress of ongoing initiatives and modifies plans based on new and emerging information. An Incident Action Plan may be developed based on these actions in order to provide operational and tactical direction. The EDQM assists the responsible group and co-ordinates actions and exchange of methods, reference standards and samples, if applicable. Sampling is normally solely managed by national inspectors; however, in the case of European or international incidents, the EDQM should co-ordinate sampling with the support of the EMA and inspectors for better targeting of samples to be tested. The EDQM organises and keeps up to date all incident-related information on the appropriate EDQM IT platforms (OMCL inventory database forum, ACT platform and others) for all OMCLs concerned or interested. The regular sharing of information, organised by the EDQM, should limit the risks of duplication and maximise the efficiency of the market surveillance.

If an ISWG is established, it is composed of members of specialised OMCLs that have specific know-how, sufficient laboratory capacity, technical equipment and readily available experience. Any participation of individual OMCLs must be on a voluntary basis. The mutual recognition of test results across the OMCL Network is strongly recommended. In order to achieve that, an intra-laboratory study may be organised and performed.

OMCLs that do not have the required technology and/or experience with the matter can ask the responsible group to test samples. Centralised co-ordination of samples and results from these OMCLs will help to limit the number of single requests and efficiently cover this need. Additionally, simultaneous testing of samples from several countries will give a better oversight of the markets covered by the OMCL Network.

The end of an incident

When re-evaluation reveals that the extraordinary situation is under control, the responsible group declares the end of the incident. The group, in collaboration with the scientific project leader if defined, will provide a final report on the handling of the incident by the Network. The report will also contain proposals for further measures (e.g. continuous surveillance of a situation/product) to avoid escalation of the same or a similar situation in future.

At the end of the incident the Advisory Group concerned, together with the AdG-GEON, will review the final report and draw conclusions in a "lessons learnt" report, in order to improve procedures for tackling future incidents.

References

1. The European Union regulatory network incident management plan for medicines for human use (Inspection and Human Medicines Pharmacovigilance, EMA/351583/2012 Rev 1, August 2017).

2. The European Union regulatory network incident management plan for medicines for veterinary use (Veterinary Medicines Division, EMA/711053/2010 Rev 2, December 2017).