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OMCL NETWORK INCIDENT MANAGEMENT
ADDENDUM: EXAMPLE OF INCIDENT ACTION PLAN IN THE EVENT OF LIMITED OMCL RESOURCES / LABORATORY CAPACITY

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OMCL Network Incident Management
Addendum: Example of Incident Action Plan in the event of limited OMCL Resources / Laboratory capacity

Introduction

This document is an addendum to the GEON document "OMCL Network Incident Management" *PA/PH/OMCL (11) 159*. The overall principles, definitions and incident management procedures defined in the main document are to be followed.

Scope

This addendum to the "OMCL Network Incident Management" *PA/PH/OMCL (11) 159* procedure contains additional points to be considered and a flowchart to be used in the event that limited resources (e.g. instruments, level of expertise, personnel) and/or a limited number of OMCLs capable of performing the necessary testing are available. One illustrative example is the "Nitrosamine-Incident", during which – given the vast number of products to be tested – a relatively small number of OMCLs were able to conduct the necessary testing.

Definition of "limited resources"

In the context of this addendum, the term "limited resources" in the OMCL Network is defined as follows:

- limited availability of knowledge/experience in a specific analytical technique (e.g., cell culture, radiopharmaceuticals, nitrosamine testing, etc.);
- limited availability of specific types of instruments (e.g., NMR, HR-MS, sequencing, etc.);
- limited availability of staff resources to perform large number of analyses;
- limited availability of reference material or very expensive reference material.

Overall objective

The overarching objective of the OMCL network is to rapidly generate enough data to cover as many countries as possible, with the ultimate goal of enabling data-driven market decisions by national authorities. It is of the utmost importance to stop the distribution of, quarantine or recall all affected products while simultaneously ensuring the continued availability of those not affected to patients.

In circumstances in which resources are limited, effective communication between OMCLs, National Competent Authorities, the EMA and other international authorities (as required) is a crucial element of successful incident management. The EDQM will maintain the relevant information exchange tools within the Network. Communication for incident management will be facilitated by, for example, the implementation of a single point of contact (SPOC) network, comprising a team of administrative and/or scientific contact persons.

To avoid unnecessary repetition of product and batch analysis, increase efficiency and expedite data generation, it is essential to implement a test overview.

Prerequisites

To ensure a rapid and effective response to any incident during which limited resources are available:

- It is essential to maintain an up-to-date list of available analytical techniques and capabilities in the OMCL-DB (database).
- It should be ensured that all OMCLs have clear procedures already in place (i.e. before a crisis) to consult reliable information sources as well as having a list of SPOC persons to be contacted in the event of an emergency.
- It is also vital to appoint a contact person (SPOC) or team to retrieve registration data and define the process for requesting and retrieving information. This should include details such as API and/or DP (drug product) suppliers and manufacturing sites, specifications, registered analytical procedures, and so on. The OMCL's contact person or team could ask for help from their inspectorate or licensing divisions, and the Rapid Alert Network (RAN) could also be involved if necessary.

- Data sharing: as per the GEON ToR, mutual recognition of results is key. This is valid for all full members of the GEON. For the associate members and observers, access to data would be granted depending on the degree of implication of each country in the emergency situation, also taking into account cases in which a laboratory had sent samples but not tested them. Access to data should thus be granted on a case-by-case basis.

Procedure

Initialisation of incident management for limited OMCL Resources/Laboratory

The Incident-Specific Working Group (ISWG), as appointed by the appropriate Advisory Group, will communicate the level of capacity available at their laboratories within the network and prepare an overview list of MAH and related products that are potentially affected. The information will be sourced from all affected countries and collated in an overview list in ACT. The ISWG will then group products by MAH, finished product manufacturing site, batch and, where available, API source and batch. The aim is for the ISWG to define a testing plan as soon as possible, covering as many products and countries as possible, given the limited testing capacity.

It is essential to ascertain whether finished product testing is sufficient or if the root cause is likely to be at the API level. This will ensure that the laboratory planning and sampling are organised accordingly. In the absence of clarity regarding the root cause, it is advisable to prioritise finished product testing, given that the end product will ultimately be used by patients.

Finished products are the quickest and easiest to retrieve (via pharmacies, wholesalers, hospitals, MAH etc.) and should be sampled at the beginning of the crisis. They might be the first in line to be tested. It is also essential to establish a sampling plan for APIs so that the member states can plan the sampling accordingly (by audits, ordering directly from the MAH, etc.).

Network incident response for limited OMCL Resources/Laboratory

Once a testing plan is available, the OMCLs involved will define who is testing what, with a view to avoiding duplicate testing and ensuring efficient planning. The product, batch number and all additional information available are updated in real time in the overview list in ACT, including the results at the end and all the additional information deemed necessary/important generated by the ISWG.

Based on the testing plan defined within the ISWG and validated by the OMCLs involved, the affected selected products will be sent to the OMCL laboratory in charge of testing from all the countries concerned, together with all the necessary information, if this has not already been entered in the overview list in ACT.

Regular teleconferences/meetings are organised between the EDQM and the ISWG with the purpose of discussing the results and of clarifying whether a root cause can be defined. The testing plan and/or parameters may also be modified based on the latest information and results generated. An update will be provided on a regular basis to other divisions/departments involved (e.g. market surveillance, licensing, inspectorate).

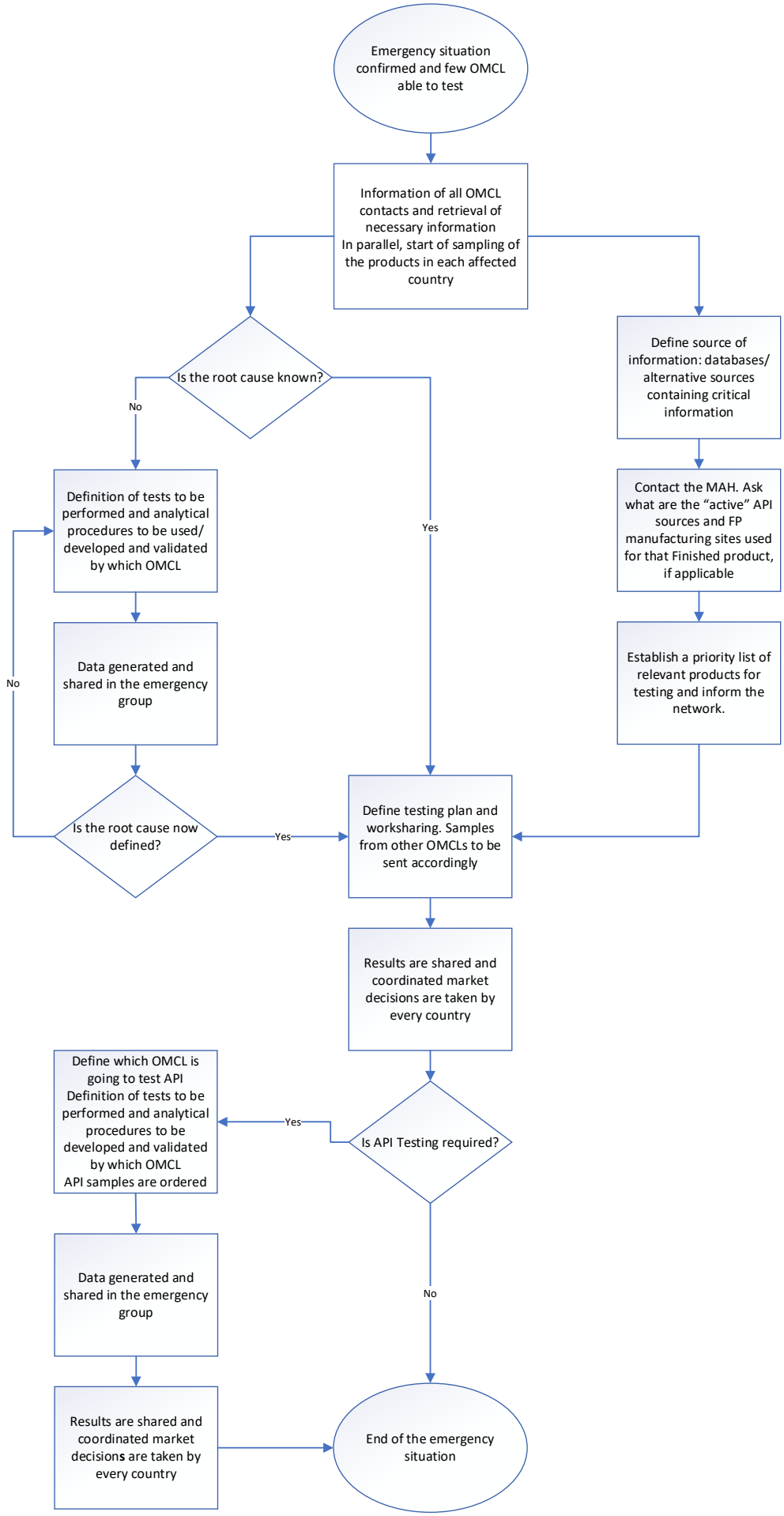
In certain instances, the ISWG may request the availability of reference standards from all OMCLs and suppliers. Additionally, the ISWG can assist testing OMCLs to ensure a sufficient supply is maintained.

The end of an incident

The incident is concluded in accordance with the procedures set forth in the main document, "OMCL Network Incident Management," *PA/PH/OMCL (11) 159*.

References

"OMCL Network Incident Management" PA/PH/OMCL (11) 159.


Emergency situation confirmed and few OMCL able to test
Information of all OMCL contacts and retrieval of necessary information
In parallel, start of sampling of the products in each affected country
Is the root cause known?
No
Yes
Definition of tests to be performed and analytical procedures to be used/ developed and validated by which OMCL
Data generated and shared in the emergency group
Is the root cause now defined?
No
Yes
Define source of information: databases/ alternative sources containing critical information
Contact the MAH. Ask what are the "active" API sources and FP manufacturing sites used for that Finished product, if applicable
Establish a priority list of relevant products for testing and inform the network.
Define testing plan and worksharing. Samples from other OMCLs to be sent accordingly
Results are shared and coordinated market decisions are taken by every country
Is API Testing required?
Yes
Define which OMCL is going to test API
Definition of tests to be performed and analytical procedures to be developed and validated by which OMCL
API samples are ordered
Data generated and shared in the emergency group
Results are shared and coordinated market decisions are taken by every country
No
End of the emergency situation