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Human Medicines Division

The European Medicines Regulatory Network Incident Management Plan for Medicines for Human Use

Version history:

Version Number	Description of changes
0	Original version (2009)
1	Revision 1 (2017)
2	Revision 2 (2025) includes the new process for IMP-H major event management with the involvement of the EU Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG).

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1. Introduction

Throughout the lifecycle of a medicinal product for human use various types of issues can occur, including new information in relation to the quality, safety and/or efficacy of the product, which in some cases may lead to a major event as referred to in Regulation (EU) 2022/123. The issue may have a serious impact on public health and/or could have important policy or reputational consequences for the European Medicines Regulatory Network (EMRN). This document describes the principles, framework, and management of such issues, hereafter referred to as "incidents".

To ensure efficient operation of the EMRN, the Incident Management Plan for Medicines for Human Use (IMP-H) has been set up as a framework for the identification and management of incidents. Its main aim is to prevent an incident from developing into an IMP-H major event by taking the necessary action(s) to remedy the situation and, where necessary, to escalate potential IMP-H major events to the EMA Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)[1]. Where appropriate, the MSSG may issue a positive opinion to confirm an IMP-H major event. The IMP-H is coordinated by the European Medicines Agency (EMA).

The first document outlining the management structures and procedures to be followed to deal efficiently with crisis situations related to pharmacovigilance or quality defects involving a centrally authorised product (CAP) became effective in September 1997 ('Crisis Management Plan Regarding Centrally Authorised Products')[2]. At that time, the Agency had already put in place the Pharmacovigilance Rapid Alert (RA) System for an immediate exchange of urgent information within the EMRN and opportunities for ad-hoc meetings to discuss and resolve issues, also in relation to nationally authorised products (NAP). This system is still in place today.

The subsequent updates of this document broadened its scope to include also medicinal products authorised through mutual recognition, decentralised and national procedures; introduced the term 'incident'; and enabled a European Union (EU) level approach for the management of incidents to avoid them developing into 'crisis' situations. A module was created in the European Pharmacovigilance Issues Tracking Tool (EPITT) to support rapid communication on incidents between Member States (MS) and the Agency, and for tracking of the steps taken.

This current document incorporates lessons learned from previous incidents, as well as builds on experience from the COVID-19 pandemic and reflects the changes brought by Regulation (EU) 2022/123.

2. Definitions

The below definitions are specific to the IMP-H and should be read considering its scope as described in Section 4 of this document.

- **Routine issues** – issues of a nature that can be satisfactorily addressed by the processes and procedures in place for the routine regulatory oversight of a medicinal product and do not require the initiation of the IMP-H.

[1] Executive Steering Group on Shortages and Safety of Medicinal Products
[2] Volume 9A of the Rules governing Medicinal Products in the European Union—Guidelines on Pharmacovigilance for Medicinal Products for Human Use

- **Incident** – an issue in relation to the quality, safety or efficacy of one or more medicinal product(s) that could have a serious impact on public health and/or could have important policy or reputational consequences for the EMRN.
- **IMP-H major event -** an issue which is likely to pose a serious risk to public health in relation to medicinal products in more than one MS, which concerns a serious incident that can affect the quality, safety or efficacy of medicinal products, which necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

  Note: This definition captures certain elements of the definition of major event set out in Regulation (EU) 2022/123, in line with the scope of work of the IMP-H and does not include elements related to medicine shortages, which are under the mandate of the Medicines Shortages Single Point of Contact (SPOC) Working Party. Thus, the IMP-H major event represents a subset of major events as defined in Regulation (EU) 2022/123: 'an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State, which concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin, or a serious incident that can affect the supply of or demand for medicinal products, or quality, safety or efficacy of medicinal products, which may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection'.

3. Objectives

The objectives of the IMP-H are:

1. To continuously and proactively identify and monitor incidents, and to take the necessary action(s) to remedy the situation with the main aim to prevent an incident from developing into an IMP-H major event and, where necessary, escalate a potential IMP-H major event to the MSSG.
2. In the case of an IMP-H major event confirmed by the MSSG, to ensure the urgent and coordinated action within the EMRN. This activity is referred to in this document as IMP-H major event management.

4. Scope

The following elements define the scope of the IMP-H:

1. **Type of incident**: The incident may be related to quality (including manufacturing compliance), efficacy and/or safety concerns (e.g. viral contamination of biological products [safety and quality], reduced potency [quality and efficacy], non-compliance with previous approved product manufacturing process or specifications [quality]). Of note, product quality reports, defective product reports and all reported incidents that may be caused by product quality issues should be dealt with in accordance with the EMA and national quality defect procedures. Incidents related to availability of medicinal products are dealt with in accordance with established systems and processes, with the involvement of the SPOC Working Party[3] and escalated to the MSSG, as necessary.

[3] Medicine Shortages Single Point of Contact (SPOC) Working Party | European Medicines Agency (EMA)

2. **Type of medicinal products**: The incident may be related to a single medicinal product or to several medicinal products authorised in the EU. The product(s) may have been authorised through the centralised, mutual recognition, decentralised and/or (a) national procedure(s). New safety information arising from clinical trials that may affect the safe use of medicinal products in the approved indication also falls within the scope of the IMP-H. While veterinary medicinal products are excluded from the scope of IMP-H, situations may exist when veterinary products are impacted by the issue dealt with through the IMP-H. In such a situation, collaboration will be initiated with the concerned veterinary parties.
3. **Public information**: The incident may be triggered by information in the public domain. Events in the public domain that do not seem at a first glance to have a serious impact on public health, irrespective if they are subject of media attention or not and may lead to serious public concerns about (a) product(s), otherwise meeting the criteria for an incident may also need to be considered in the scope of the IMP-H. Likewise, situations which might have a negative impact on the appropriate use of (a) medicinal product(s) (e.g. resulting in patients stop taking their medicine) falling within the definition of an incident may also be considered in the scope of the IMP-H.

5. General principles

To meet its objectives, several prerequisites need to be fulfilled:

- The IMP-H should be **flexible** enough to address the various situations which may arise in the EU regulatory framework and to take due account of their specificities.
- The IMP-H should be **able to address the incidents in a coordinated manner and within the shortest possible timeframe**. The availability of adequate mechanisms and structures to enable efficient decision-making is hereby of utmost importance.
- The IMP-H should ensure **rapid escalation** to MSSG in case of identification of a potential IMP-H major event.
- In all situations there should be **close collaboration** between National Competent Authorities (NCAs), the European Commission (EC), the Agency and other partner organisations (e.g. the European Directorate for the Quality of Medicines & HealthCare (EDQM))
- To make best use of available resources, it is of utmost importance that **clear roles and responsibilities** are allocated to the involved parties.
- It is also of key importance to ensure that all actions taken guarantee **the highest possible protection of public health**, and that any situation which could endanger public trust in the EMRN is avoided.
- For situations where access to and distribution of data held in the EudraVigilance database is deemed necessary, the principles outlined in the EudraVigilance Access Policy should be followed.
- To ensure the protection of individuals in relation to the **processing of personal data**, during the IMP-H activities and sharing of information, the EMRN should adhere to the Union personal data protection laws, particularly Regulation (EU) 2018/1725, the EU Data Protection Regulation (EU DPR), and Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR).

6. Management structures

Specific governance bodies are set up for management of incidents and IMP-H major events to provide streamlined governance, more agile and timely information sharing, decision making and implementation of actions.

6.1. Incident management structure

The Incident Review Network

The Incident Review Network (IRN) is the dedicated structure of the IMP-H in charge of reviewing, from a managerial perspective, all the information on an incident available at the current time in terms of public health impact and advising on whether (and which) processes and procedures in place for the regulatory oversight of a medicinal product are sufficient to remedy the situation, or if it could be considered as an IMP-H major event, requiring urgent escalation to the MSSG. The rules of procedure of this virtual network are provided in Annex 1.

6.2. IMP-H major event recognition and management structures

The EU Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

The MSSG was established to ensure coordinated monitoring and a robust response to IMP-H major events and public-health emergencies, including through provision of advice and recommendations on the necessary measures to safeguard the quality, safety, efficacy and supply of medicinal products and to ensure a high level of human health protection. As an EMRN-wide executive level forum, it may also provide strategic guidance on any IMP-H major event implications for the network. The MSSG evaluates all available information, considers the need for an urgent and coordinated action at EU level and provides recommendations to the EC, MSs, marketing authorisation holders and other stakeholders as necessary.

Following a positive opinion of the MSSG, the Commission may recognise an IMP-H major event.

For IMP-H major events, the work of the MSSG will be supported by EMA scientific committees, their working parties, expert groups and/or the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

Major Event Support Group

Following recognition of an IMP-H major event, a Major Event Support Group may be set-up at EU level, for tactical level coordination of activities, to act as support to the MSSG by providing administrative and scientific input (see Chapter 7.3). This group is formed on an ad-hoc and urgent basis, when the need arises. The responsibilities of the group include:

(1) implement the actions agreed by the MSSG in a timely manner,
(2) follow-up on the implementation of actions,
(3) provide status updates to the MSSG,
(4) propose to the MSSG any additional necessary remedial actions, and
(5) propose the closure of the IMP-H major event.

EMA Crisis Preparedness and Response Steering Group

The EMA Crisis Preparedness and Response Steering Group provides a strategic steer on evolving scientific and regulatory challenges, topics of political, interinstitutional, international interest and other emerging issues with high interest from stakeholders and/or the media. It is an EMA internal group

which agrees the EMA position on incident and (potential) IMP-H major event related matters for EMRN discussions. It also performs monitoring of the EMA response to crises (including IMP-H major events), ensures adaptation of EMA business continuity plan as needed and oversees the review and reporting of EMA lessons learned from crises. In the context of IMP-H major event preparedness, the group ensures exchange of information and coordination and agrees on necessary actions.

National crisis management structures

It is the responsibility of each NCA to establish a national crisis management structure which allows for adequate interaction with the management structures set up at EU level. Such national structure should operate in accordance with a national crisis management procedure and have features to facilitate collaboration within the EMRN and efficient decision-making in the context of the IMP-H (e.g. adequate communication channels, availability of back-ups).

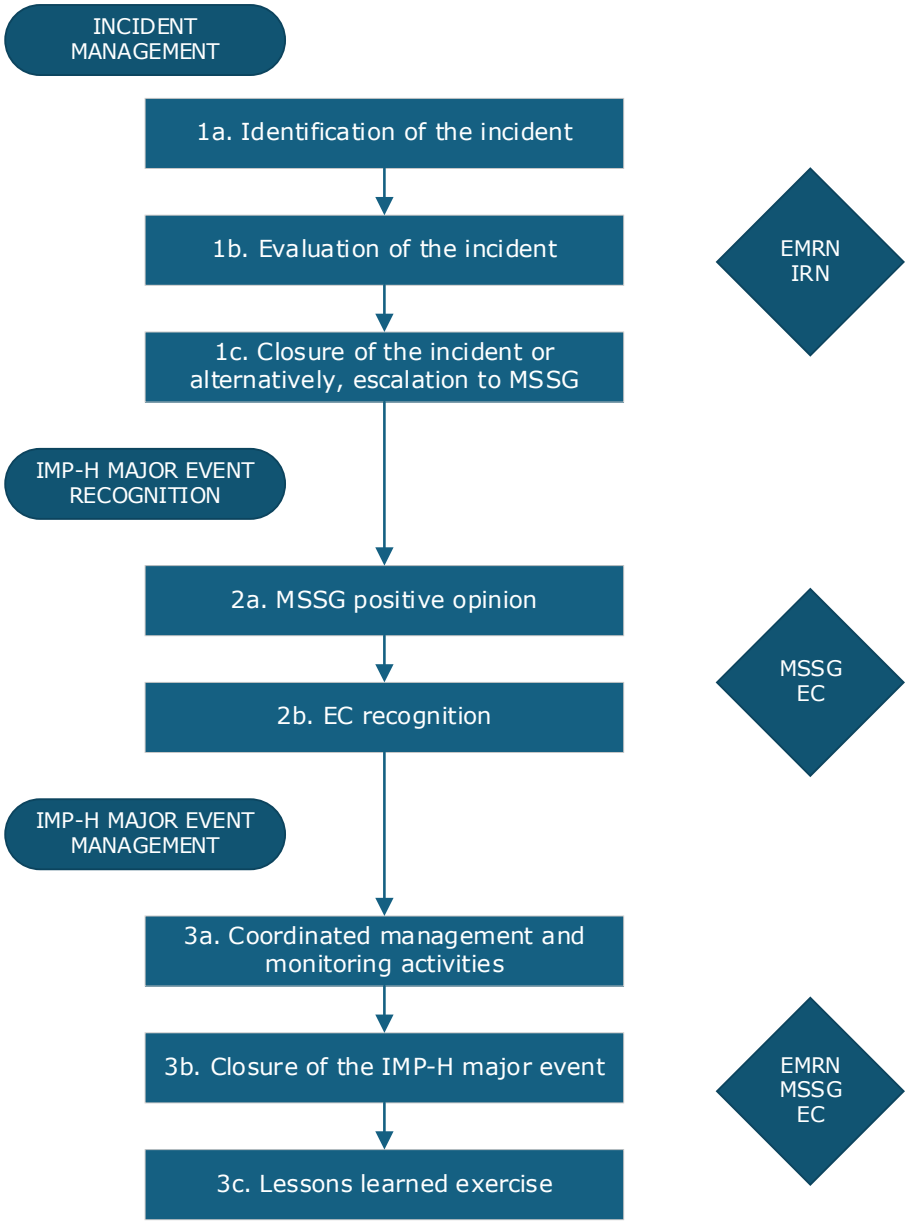
7. Steps of the EU Incident Management Plan

The steps of the IMP-H are:

1. Incident management:
    a. identification of the incident.
    b. evaluation of the incident (initiation and monitoring of the action(s) and communication strategy agreed by the IRN, identification of the need for remedial action(s), where necessary, or consideration if the incident could be considered as a potential IMP-H major event, requiring urgent escalation to MSSG).
    c. closure of the incident or alternatively, escalation to the MSSG (including the IRN request for drafting of a briefing document (BD) (which includes the background of the incident and discusses regulatory considerations, actions to date, communication aspects, as well as provides a rationale for escalation of the incident to the MSSG [template in Annex 2]), and provision of the BD to the MSSG for consideration and confirmation (or not) of an IMP-H major event).
2. IMP-H major event recognition:
    a. MSSG opinion that the incident constitutes (or not) an IMP-H major event.
    b. EC recognition of the IMP-H major event.
3. IMP-H major event management (in line with the provisions set out in Regulation (EU) 2022/123):
    a. coordinated management and monitoring activities (gathering and evaluation of information, consideration of the need for urgent and coordinated action and provision of recommendations by the MSSG, where necessary).
    b. closure of the IMP-H major event by EMA Executive Director or the EC.
    c. conduct of a "lessons learned" exercise.

In most situations only the incident management steps will need to be followed, and the complete IMP-H (including the IMP-H major event management steps) will have to be followed only in rare cases.

Fig.1 Steps of the EU Incident Management Plan



7.1. Incident management

a. Identification of the incident

Sources of information

Various sources of information might suggest an incident. Such information can be in the public domain or not and possibly be subject to media attention. In the latter case, the immediate assessment of the situation and handling of communication may become crucial especially when public confidence in the EMRN is at risk. Examples of sources of information are new safety data provided to an NCA, newly published data in scientific journals, media reports, action taken by a non-EU regulatory authority, safety signal from a database, etc.

Exchange of information

It is of utmost importance that any information suggesting an incident is shared without delay within the EMRN.

In EPITT, the Pharmacovigilance Rapid Alert (PhV RA) and Non-Urgent Information (NUI) systems allow for rapid exchange of information on safety concerns within the EMRN. A clear distinction is made between the criteria for the use of a PhV RA vis-à-vis the use of a NUI, as follows:

1. A PhV RA should be used by a MS/the EMA for notification of a safety concern in relation to one or more medicinal product(s) that could have a serious impact on public health and/or could have important policy or reputational consequences for the EMRN.
2. A NUI should be used by a MS/the EMA for information exchange in relation to safety concerns not fulfilling the criteria for a PhV RA. In practice, several incidents have been notified also through this system.

In addition, information on a possible incident can emerge from notifications to the P-PV-emerging-safety-issue@ema.europa.eu mailbox. More information on emerging safety issues can be found in Guideline on good pharmacovigilance practices (GVP) - Module IX – Signal management (Rev 1) (europa.eu).

Furthermore, a system for the management of alerts arising from quality defects risk assessment is in place to ensure that information concerning the recall of medicinal products due to quality defects, products which are falsified or when urgent action is required to protect public or animal health, is notified rapidly between the NCAs, the EMA, the EC as well as other relevant partners, competent authorities outside the EU and international organisations (e.g. Council of Europe/European Directorate for the Quality of Medicines & HealthCare, World Health Organization, Pharmaceutical Inspection Collaboration Scheme (PIC/s) authorities). The 'Compilation of Union procedures on inspections and exchange of information | European Medicines Agency (EMA)' also provides additional instructions and platforms for exchange of information concerning defective medicines (e.g. Management and classification of reports of suspected quality defects in medicinal products and risk-based decision-making performed by EU authorities).

Ultimately, an incident can be notified by any member of the EMRN to any member of the Agency. Agency staff should be aware that in rare situations, information which may possibly constitute an incident may be reported directly to them.

Filtering mechanism

Upon receipt of information potentially constituting an incident, the IRN Chair should consider the relevance for involvement of the IRN taking due account of the apparent severity and urgency of the issue. The IRN Chair may decide to provide information in writing to the IRN instead of convening a teleconference.

b. Evaluation of the incident

Involvement of the Incident Review Network

The IRN is convened as a virtual network, conform to the Rules of Procedure (Annex 1) to address incidents promptly, within a timeframe that is proportionate to the urgency of the issue raised.

c. Closure of the incident or alternatively, escalation to the MSSG

Closure of the incident at the level of IRN

Should the IRN consider that the processes and procedures in place are sufficient to address the incident (which is not considered to potentially lead to an IMP-H major event), the subsequent circulation of the IRN minutes will mark the end of the IRN involvement and the closure of the incident. The actions agreed in the IRN will be included in the IRN minutes and will be followed up by the designated responsible parties as part of the processes and procedures in place. Further communication in writing to the IRN or further IRN TCs on the same topic can be organised should the need arise.

Escalation to the MSSG by IRN

Should the IRN consider that the incident is a potential IMP-H major event, the IRN will escalate it to the MSSG. For this purpose, the IRN will request the preparation of a BD (template in Annex 2), in a very tight timeframe. The BD will provide the background of the incident and discuss regulatory considerations, actions to date, communication aspects, as well as provide a rationale for escalation of the incident to the MSSG.

The roles and responsibilities in drafting of the BD will be discussed in the IRN. In situations when CAPs are involved (or both CAPs and NAPs), the BD should be drafted by the CHMP (Co)-Rapporteur(s), PRAC (Co)-Rapporteurs, in collaboration with the EMA. When only NAPs are involved, the BD should be drafted by the Lead Member State(s) of the product(s) concerned depending on authorisation type (e.g. Reference Member State(s) or Lead Member State(s) for signal detection in EudraVigilance as appropriate), in collaboration with the EMA.

Once available, the BD will be circulated to the IRN for information and then provided by the EMA to the MSSG.

7.2 IMP-H major event recognition

a. MSSG opinion

Based on the BD the MSSG will identify whether the incident constitutes an IMP-H major event.

Should the MSSG not confirm that the incident constitutes a major event, the MSSG will recommend appropriate measures to address the incident.

b. EC recognition

Based on a positive MSSG opinion the EC may recognise the major event.

7.3 IMP-H major event management

a. Coordinated monitoring and management activities

In case of a recognised IMP-H major event, the MSSG will consider the most appropriate legal / regulatory framework to be used to address the situation.

In addition, the MSSG will agree on the approach to communication, resulting in the preparation of a communication strategy. Involvement of patients' and healthcare professionals' representatives may

be considered on communication aspects and should be favoured, whenever possible. The overall aim is to convey a unified and targeted message to the public within the shortest possible timeframe.

In accordance with the Rules of Procedure[4] of the MSSG, the MSSG may set up ad-hoc Working Groups to support the work, including to address a specific IMP-H major event. MSSG may decide to set up the Major Event Support Group as a Working Group of the MSSG. The core composition should include staff members appointed by the EMA, EC, as well as the CHMP (Co)-Rapporteur(s), the PRAC (Co)-Rapporteurs, the Reference Member State (RMS) representatives, the Lead Member State (LMS) representatives, the Supervisory Authority representatives, as applicable. This composition shall be supplemented according to the nature of the IMP-H major event.

The MSSG will provide recommendations to the EC, MSs, marketing authorisation holders and other stakeholders as necessary.

b. Closure of IMP-H major event

Once the MSSG considers that the IMP-H major event has been sufficiently addressed, the MSSG shall inform the EC and the Executive Director of the Agency. The EC or the Executive Director of the Agency may confirm that the assistance of the MSSG is no longer needed.

c. Conduct of a "lessons learned" exercise

It is of utmost importance to carefully monitor the adequacy of the provision outlined in the IMP-H. To this effect, "lessons learned'' exercises should be performed, following the closure of IMP-H major events, when sufficient evidence shows that the IMP-H major event has been resolved, and should be sent to all involved parties. The outcome of a "lessons learned" exercise may lead to a revision of the IMP-H.

Incidents managed at IRN level can be addressed by processes and procedures in place and hence "lessons learned'' exercises are not needed on a regular basis after each incident, however, they may be triggered on an ad-hoc basis, should the need arise.

[4] Executive Steering Group on Shortages and Safety of Medicinal Products

Annex 1 – Incident Review Network - Rules of procedure

The Incident Review Network (IRN) is the dedicated structure of the Incident Management Plan for Medicines for Human Use (IMP-H) in charge of reviewing, from a managerial perspective, all the information on an incident available at the current time in terms of public health impact and advising on whether (and which) processes and procedures in place are sufficient to remedy the situation, or consideration if the incident could be considered as a potential IMP-H major event, requiring urgent escalation to MSSG.

The IRN is a tactical coordination and decision-making body with a purely managerial and advisory role. Its role will not interfere with the scientific assessment of the identified concerns and the provision of recommendations for regulatory outcomes performed by the CHMP, the PRAC, the CMD(h) and other bodies (e.g. national assessments incl. for clinical trials).

Mandate

The IRN will address incidents promptly, within a timeframe that is proportionate to the urgency of the issue raised and will identify the most appropriate regulatory framework to be used to address the incident, as well as a communication strategy.

Following IRN discussion, three types of tools are at the disposal of the European Medicines Regulatory Network (EMRN), to be initiated via the usual methods: (1) pharmacovigilance and quality/manufacturing compliance monitoring tools, (2) tools available in Union legislation to take regulatory action including where necessary recommendations for product recalls and/or cessation of supply, and (3) communication tools to inform patients, healthcare professionals and the public. The actions to be taken to address the public health concerns can either consist of one type or a combination of tools, according to the severity and urgency of the issue.

Examples of tools include:

- The introduction of changes to the product information, combined or not with communication to healthcare professionals (e.g. the circulation of a Direct Healthcare Professional Communication)
- The recommendation of the Committee for Human Medicinal Products (CHMP) for a suspension of the marketing authorisation, combined with a press release and a Questions & Answers (Q&A) document, or the Coordination Group for Mutual Recognition and Decentralised Procedures – Human [CMD(h)]’s consensus view that the marketing authorisation of the concerned NAPs should be suspended.

To prepare for replies to media/public queries, the IRN can request the EMA to consider the preparation of “lines to take” within an agreed timeframe. Plans for public communications and the final communication materials should be shared with the EMRN and with international partners via the Early Notification System (ENS) under embargo ahead of publication if possible.

Should the IRN consider that the incident is a potential IMP-H major event, the IRN should take the steps necessary to escalate the issue to the MSSG.

Composition

The IRN is a virtual multidisciplinary network set up within the EMRN. It is composed of the following groups with variable composition, which are invited to IRN TCs as described below:

- Core Group: This group is invited to all IRN TCs and includes representatives of the EC, Heads of Medicines Agencies (HMA) and EMA, Chairs and vice-Chairs of the relevant EMA Committees, Medicine Shortages Single Point of Contact (SPOC) Working Party.
- Additional Members (issue specific): This group is invited to IRN TCs according to the topic discussed and includes representatives of HMA, EMA, EMA Committees, Official Medicines Control Laboratory (OMCL), Clinical Trials Coordination Group (CTCG), European Directorate for the Quality of Medicines & HealthCare (EDQM) with expertise in e.g. pharmacovigilance/pharmacoepidemiology, quality/GMP non-compliance, clinical trials, inspections, advanced therapy medicinal products.
- Additional Members (product specific): This group is invited to IRN TCs according to the product involved and includes the PRAC and CHMP Rapporteurs and Co-Rapporteurs, Reference Member State/Lead Member State, EMA representatives.

Also, a variable number of EC and EMA representatives will be additionally copied in all correspondence and follow the IRN meetings, depending on the nature of the incident.

The EMA will chair the IRN, as well as organise IRN meetings and provide administrative support, including in the case of escalation of the incident to MSSG.

Renewal of membership

The membership of the IRN members is renewed every three years. Calls for expression of interest are sent to the EC and HMA four months before the end of the mandate, for their members to continue membership for another term of 3 years, or new appointments to be made.

Operational aspects

Upon receipt of information potentially constituting an incident, the IRN Chair should consider the relevance for involvement of the IRN taking due account of the apparent severity and urgency of the issue. The IRN Chair may decide to provide information in writing to the IRN instead of convening a teleconference.

The IRN conclusion should be by consensus. Should the information be insufficient for the IRN to recommend actions or should the IRN find difficult to reach a consensus, a second IRN TC can be organised following receipt of further information.

The circulation of the IRN minutes to all IRN participants will mark the end of the IRN involvement and the closure of the incident. The actions agreed in the IRN will be included in the IRN minutes and will be followed up by the designated responsible parties as part of the processes and procedures in place. Further communication in writing to the IRN or further IRN TCs on the same topic can be organised should the need arise.

The outcome of the IRN discussions will be recorded by the EMA into the European Pharmacovigilance Issues Tracking Tool (EPITT). In addition, the outcome will be circulated to CHMP, PRAC, CMD(h), HMA, MSSG, as appropriate.

Should the IRN consider that the incident is a potential IMP-H major event, the IRN will request the lead party to draft a BD (template in Annex 2), in a very tight timeframe. The BD will provide the background of the incident and discuss regulatory considerations, actions to date, communication aspects, as well as provide a rationale for escalation of the incident to the MSSG.

The roles and responsibilities in drafting of the BD will be discussed in the IRN. In situations when CAPs are involved (or both CAPs and NAPs), the BD should be drafted by the CHMP (Co)-

Rapporteur(s), PRAC (Co)- Rapporteurs, in collaboration with the EMA. When only NAPs are involved, the BD should be drafted by the Lead Member State(s) of the product(s) concerned depending on authorisation type (e.g. Reference Member State(s) or Lead Member State(s) for signal detection in EudraVigilance as appropriate), in collaboration with the EMA.

Once available, the BD will be circulated to the IRN for information and then provided by the EMA to the MSSG.

Annex 2 – Briefing document for the MSSG

<INN - BRANDNAME> - <issue>

1. Administrative details

This Briefing Document for the MSSG was drafted following the recommendation of the IRN TC held on <DD Month YYYY> by <name of CHMP Rapp, PRAC Rapp, LMS, as applicable>.

Date of the draft BD for agreement by IRN:	DD Month YYYY
Date of the final BD for consultation of MSSG:	DD Month YYYY
Substance:	<INN (medicinal product invented name and associated names)>
Authorisation type:	<Specify 'Centralised' and/or 'Non-centralised'>
Originator:	<Specify Member State/competent authority>
Notified as (RA, ESI, EPITT signal, others):	<If available, specify the EPITT reference number>
CHMP Rapporteur(s):	<Name> <E-mail address>
CHMP Rapporteur assessor(s):	<Name> <E-mail address>
CHMP Co-Rapporteur(s)	<Name> <E-mail address>
CHMP Co-Rapporteur assessor(s):	<Name> <E-mail address>
PRAC Rapporteur(s):	<Name> <E-mail address>
PRAC Rapporteur assessor(s):	<Name> <E-mail address>
PRAC Co-Rapporteur(s)	<Name> <E-mail address>
PRAC Co-Rapporteur(s) assessors	<Name> <E-mail address>
Lead Member State representative:	<Name> <E-mail address>
Lead Member State assessor(s):	<Name> <E-mail address>
EMA team members:	<Name> <E-mail address>

2. Background information

[Includes description of the issue and available information]

3. IRN discussion and steps taken

3.1 Regulatory considerations (options, limitations).

3.2 Actions already taken (e.g. ad hoc PRAC, list of questions circulated to MAH; Contact points of EMA/ Rapp/ PRAC Rapp/ MAH already used)

3.3 Communication aspects

4. IRN considerations on potential IMP-H major event

[Consideration of IRN why the incident is a potential IMP-H major event – rationale for escalation to MSSG]