FRAMEWORK FOR THE INVOLVEMENT OF HEALTH REGULATORY AUTHORITIES IN THE MANAGEMENT OF GLOBAL HEALTH CRISES

Version 2 – October 2022

Executive Summary

This document presents the framework for the involvement of Regulatory Authorities (RAs)[1] in the management of global health crises. The work was developed by the Crises Management Group of ICMRA, led by Anvisa (Brazilian Health Regulatory Agency - Brazil) and MHRA (Medicines and Healthcare Products Regulatory Agency - United Kingdom), who have been working together to identify opportunities and challenges that arise during the management of a global health crisis.

The Framework was previously published as the ICMRA Standard Operating Procedure (SOP) for Crisis Management, in 2019. The updated Framework provides experiences, learnings and real-life examples related to the COVID-19 pandemic. In the main body of the Framework, types of scenarios that Regulatory Authorities (RAs) may encounter during a public health scenario, the principles, roles, and responsibilities of the ICMRA Secretariat and members are described.

Finally, Annex 1 presents the operational procedures necessary to facilitate immediate collaboration between the Heads of the RAs during a global health crisis.

1. Problem Statement

Global health crises, including public health emergencies of international concern, are by nature unpredictable, multifaceted and involve multiple external stakeholders in addition to regulators.

Moreover, global health crises frequently become political priorities with multiple areas competing for limited resources. Regulatory activities are often fundamental to the management of the crisis.

1 In this document, regulatory authorities refer to national and regional regulatory authorities responsible for the regulation of medical products.

Hence, it is important to clarify the role of regulators and to open pathways for international engagement in a coordinated aligned regulatory and policy response with a collaborative communication strategy for global health crises.

There are several initiatives dealing with global health crises at an international level, such as the Global Health Security Initiative (GSHI), the Coalition for Epidemic Preparedness Innovations (CEPI), and several WHO initiatives: R&D Blueprint, the International Health Regulations (IHR), the Emergency Use Listing (EUL) and the Health Emergencies Programme. The EUL mechanism applied during the COVID-19 pandemic, especially sharing of WHO EUL dossiers and reports with National Regulatory Authorities (NRAs) under confidentiality agreements promoted implementation of reliance, facilitated timely regulatory decision-making without compromising each NRA's independent evaluation process and were adapted to increase efficiency, according to a changing pandemic environment. At the regional level, initiatives are also in place, such as the EU Incident Management Plan (IMP), which involves regulators in the continuous monitoring of incidents that may have a serious impact on public health, and the African Medicines Regulatory Harmonization (AMRH) Initiative and African Vaccine Regulatory Forum (AVAREF), in which African regulators can share information and accelerate development of medical products towards regulatory approval, including clinical trial approvals.

As regulators may not be directly involved within the initiatives listed above, this ICMRA framework was developed to meet the need to have better international coordination in the regulatory/ policy field of medicines regulators.

2. Purpose

This document is a framework for the involvement of Regulatory Authorities in the management of global health crises in a coordinated and consistent manner. It addresses the roles and responsibilities of RAs in this process and identifies the opportunities for international collaboration.

It also establishes a Standard Operating Procedure (SOP) for RAs dealing with global health crises, through a structure of communication among RA focal points, a platform/form for information exchange and roles of the secretariat for organizational support[2] (Annex 1).

Appendices A – C are supporting materials used in communications that facilitate timely collaboration among ICMRA members, in a public health emergency scenario.

The scope of this work is based on the need for a rapid and continuous process of information sharing, the strengthening of ongoing IMCRA initiatives, and for the development of specific contingency plans for each scenario defined.

2 Based on FDA paper: "ICMRA Standard Operating Procedure – Facilitating Prompt Collaboration among Heads of Regulatory Authorities".

3. Defining global health crises from a health regulator´s perspective

A Public Health Emergency of International Concern (PHEIC) is defined in the WHO International Health Regulations (IHR) (2005) as "an extraordinary event which is determined, as provided in these Regulations:

(i) to constitute a public health risk to other States through the international spread of disease; and

(ii) to potentially require a coordinated international response". This definition implies a situation that is serious, unusual, or unexpected; carries implications for public health beyond the affected State's national border; and may require immediate international action." [3]

For the purpose of this paper, and considering the RA specificities, a global health crisis is considered as an unforeseen occurrence or a combination of circumstances that poses a significant public health risk to other countries, not limited to the spread of diseases, and that involves the safety, efficacy, quality security and availability of health products. Additionally, this event should potentially require or would benefit from a coordinated international response by RAs.

After assessing related risks, if routine response procedures are not considered sufficient, urgent, and coordinated action is required to manage and control the situation. Since health crises are unpredictable, dynamic, and have the potential to escalate into a Public Health emergency, each ICMRA member should be prepared to act, preferably early at the beginning of a crisis, preventing escalation where possible.

3.1. Major scenarios of global health crisis related to RA activities

Involvement of regulators in health crises as defined above can be envisaged as three major scenarios:

Scenario 1 - Incidents of quality or safety issues for products on the market, where such quality or safety issues have a global impact on public health.

Some cases might be categorized as incidents related to quality or safety. While most of these cases would be expected to be ordinary and would be addressed with existing resources and protocols that each RA already has at its disposal, in rare circumstances, some of them may require a broader involvement and collaboration among RAs. Only those few incidents would be categorized as a potential global health crisis as per Scenario 1.

3 WHO. IHR Procedures concerning public health emergencies of international concern (PHEIC). PHEIC Procedures.

Examples might include the assessment of a worldwide incident with a medicine with potential to cause serious adverse events, which can also lead to the lack of a substitute product.

It is up to each involved RA to assess and decide if an incident would require or benefit from broader international involvement, liaising with the concerned RAs through ICMRA. On a case-by-case basis, different actions can be considered, including liaising bilaterally with RAs or their regional offices, or working through ICMRA, bringing together a group of involved RAs, national public health organizations, or experts to deal with the incident.[4]

The European Union (EU) incident management plan (IMP) contains specific measures that must be taken to allow for an efficient management of a crisis. It ensures that the concerned bodies take appropriate action whenever incidents arise concerning human medicines. The incident review network (IRN), a dedicated structure in the context of incident management, reviews incidents in terms of their impact on public health and the measures needed to address them (for example, if the identified concerns are likely to be addressed through routine measures). The IRN is also responsible for identifying the most appropriate legal/regulatory framework to be used to address the situation and deciding if an incident would require/benefit from a broader international involvement.[4]

Scenario 2 - Unavailability of products due to a crisis, where already registered products are in short supply or unavailable

Unavailability of medical products used to prevent or treat a serious or life-threatening disease, for which there is no other available source with sufficient supply of that product available, is very challenging and can easily evolve into a crisis. RAs can play an important role in minimizing negative impact on patients, healthcare facilities and clinicians. Examples in this category may include a viral pandemic where antivirals, other medicines, or vaccines are in shortage or unavailable.

In this scenario, international consultations and information exchange are of value. Besides possible actions listed under Scenario 1, different approaches could be applied, varying from ad-hoc consultations through email until it is possible to establish a mechanism for regular virtual or face-to-face meetings. During the first year of the COVID-19 pandemic, ICMRA initiated the ICMRA COVID-19 Policy calls beginning in

4 EMA. Available from: https://www.ema.europa.eu/en/documents/other/european-union-regulatory-network-incident-management-plan-medicines-human-use_en.pdf

April 2020, with the goal of sharing information about policy approaches taken in different regions in response to the COVID-19 pandemic. These calls were intended to support mutual awareness and potential alignment on policy approaches and guidance to industry, particularly related to medicines under investigation and availability of medicines.

Topics for further discussion, analysis and work up identified in the ICMRA COVID-19 Policy call were referred to a then-established ICMRA COVID-19 Working Group, split further into other groups based on different topics. These groups would relay updates on workplan items in monthly ICMRA COVID-19 Working Group meetings, and these would, in turn, be reported back to the ICMRA COVID-19 Policy teleconferences.

Additionally, regular ICMRA COVID-19 Policy calls took place. The objective of these calls was to support mutual awareness and potential alignment on policy approaches and guidance to industry, particularly related to medicines under investigation and the availability of medicines.

The above two structures are examples of where ICMRA rapidly initiated a formal mechanism for virtual meetings to discuss all aspects of a crisis, promoting international information sharing and discussions, and preparing for each stage in a pandemic. These structures could easily be adapted for use in future pandemics.

Scenario 3 - Urgent need for new treatments or vaccines in the face of an emerging health threat

This applies to situations where there are true unmet needs for medical treatments or vaccines, the demand for regulatory actions, given a lack of available treatments/ vaccines [5]. An incident is categorized as scenario 3 in the instance that the World Health Organization declares it a Public Health Emergency of International Concern (PHEIC).

In this Scenario, each Country's Ministry of Health (MoH) and the WHO will take measures using WHO-IHR mechanisms. Nationally, RAs should provide the necessary support for these mechanisms, when requested to. Additionally, in this context, it remains the responsibility of RAs to identify regularized or new medical products under

5 WHO. 2018 Annual Review of the Blueprint List of Priority Diseases: Potential to cause a public health emergency and the absence of efficacious drugs and/or vaccines, there is an urgent need for accelerated research and development for Crimean-Congo hemorrhagic fever (CCHF), Ebola virus disease and Marburg virus disease, Lassa fever, Middle East respiratory syndrome coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS), Nipah and henipaviral diseases, Rift Valley fever (RVF), Zika, Disease X. Available from: http://www.who.int/blueprint/priority-diseases/en/

assessment to participate in collaborative initiatives in the regulatory field or to facilitate development and availability of the novel technologies[6].

Scenario	Definition	ICMRA Initiative involved
1	Incidents of quality or safety issues for products on the market, where such quality or safety issues have a global impact on public health	• Communication • Supply Chain Integrity • Pharmacovigilance • GMP • Capacity Building
2	Unavailability of products due to a crisis, where already registered products are in short supply or unavailable due to stockpiling	• July 2021 ICMRA Industry Workshop on enhancing manufacturing • Communication • Supply Chain Integrity • Capacity Building
3	Urgent need for new treatments or vaccines in the face of an emerging health threat	• Clinical Trials • Communication • Antimicrobial Resistance (AMR) • Pharmacovigilance • GMP • Capacity Building • Innovation

A summary of ICMRA initiatives involved in pandemic preparedness:

- ICMRA Public Health Emergency Clinical Trials Working Group

This working group aims to increase pandemic preparedness, through facilitating the efficient approval, oversight, and start-up of clinical trials, reflecting on experiences during COVID-19 as an initial model.

The group aims to do this through developing a reflection paper that discusses the challenges/ solutions/ enablers of multi(national/regional) platform clinical trials and publishing the key considerations for protocol elements that support platform trials – both of which are set in a public health emergency context.

- ICMRA COVID-19 vaccine pharmacovigilance network (VPN):

This Working Group is an example of how an ICMRA structure was rapidly initiated to discuss novel COVID-19 vaccinations and post-marketing information, sharing best practices and early vaccine safety information. This network could be adapted for use during future pandemics, thereby increasing pandemic preparedness through forward-planning. It is important to note that the structures for international

6 World Health Organization. Emergency Use Assessment and Listing (EUAL) Procedure for medical products (candidate vaccines, In Vitro Diagnostics (IVDs), medicines, vector control and others) in the context of a public health emergency. Available from: http://www.who.int/medicines/news/public_consult_med_prods/en/

collaboration should be in place permanently – not just in declared crises – to ensure proactive and rapid action when a new crisis emerges.

The 'network' meets frequently to discuss pre-deployment issues (routine signal detection, topics of special interest e.g., vaccines in pregnancy and lactating persons) and post-deployment surveillance (information on vaccine usage, emerging safety profiles, communications).

- Digital transformation of GCP and GMP inspections

As part of the COVID-19 Working Group, this work aimed to increase pandemic preparedness by reflecting on the ways that international RAs adapted their inspection approaches during the COVID-19 pandemic, based on restrictions to protect public health.

The group produced a reflection paper, published in December 2021, on the challenges, successes, and technologies of remote and hybrid inspections. This work is useful for future pandemic preparedness as it has been made available to industry, to help move towards global harmonization.

4. Principles, Roles and Responsibilities

The principles of crisis management by ICMRA members include:

Collaboration – creating and sustaining broad and transparent relationships among stakeholders to support trust, collaboration, consensus, information exchange and rapid communication.

Communication – Timely and clear communication is critical in handling a current crisis and preparing for future crises.

Comprehension – considering all threats, phases, scenarios, stakeholders, and impact related to a global health crisis scenario.

Confidentiality – regarding restricted information and the use of secure communication channels. Depending on the type of information exchanged, ad-hoc confidentiality agreements may be established, or sponsor agreement to share information amongst RAs may be obtained.

Coordination – synchronizing the activities of all relevant stakeholders to achieve a common purpose.

Flexibility – using creative and innovative approaches in solving global health crises challenges. This includes collaborative regulatory initiatives to foster the development and availability of **new** medicines and technologies.

Integration – ensuring aligned efforts (including on aligning regulatory requirements and flexibilities) and transparency among all domestic levels of government and ICMRA members.

Patient-focus – ensuring that the safety of patients (including the welfare of 'healthy people') is the guiding principle for regulatory actions and decisions.

Professionalism – applying scientific-based approaches and engagement with education, training, experience, ethics, and feedback.

Foresight – anticipating future crises, using forward-planning, to take preventive and preparatory measures against damage in global public health.

Risk-based – using sound risk management principles (assessment, management, and communication) in assigning priorities and resources.

Transparency – conducting organizational operations and decisions with (the related principles of) accountability, trustworthiness, and transparency and the goal of building and maintaining trust among ICMRA members and partners. Use of the ICMRA website to promote information to all stakeholders.

4.1 Roles and Responsibilities

ICMRA recognizes the WHO as the international leader in global public health emergency scenarios. To improve collaboration ICMRA encourages the WHO to contact the ICMRA Chair or Secretariat where regulatory actions are required in a global health crisis.

The roles and responsibilities applicable to ICMRA members are the following:

ICMRA Secretariat

- To activate and maintain contact with the RA's designated focal points, through the appropriate channels.
- To receive, coordinate and share information and requests with all ICMRA members – assuming the necessary confidentiality agreements are in place. This includes but is not limited to analysis of specific regulatory situations, international collaboration, data access and organizational information sharing.
- To engage with the WHO and other relevant international organizations requiring or providing situational information. To facilitate information exchange through the ICMRA website.
- To accurately communicate the role of ICMRA, where agreed.

- To invite relevant non-members to participate in ICMRA discussions, where appropriate. One example of such kind of opportunity is the ICMRA Summit. This event is held annually, aiming to promote high level discussions about relevant themes of medicines and vaccines. Non-members, internal institutions, associations, as well as academy and industry specialists are routinely invited to Summit meetings.

ICMRA members

A. Actions applicable nationally by RAs, if appropriate:

- To develop and implement a national plan for health emergency situations before a crisis emerges.[7]
- To provide a dedicated incident management structure, with the necessary supporting resource.
- To collaborate closely with national authorities to support disease surveillance, risk assessment/management, public health emergency preparedness and response measures (e.g., to be represented on the national Health Emergency Committee, usually coordinated by the Ministry of Health).
- To exchange scientific information and data relating to the cause or etiology of the crisis, with a view to mitigating risks, both nationally and globally.
- To facilitate international assessment including setting up multinational expert groups.
- To coordinate inspections to provide effective oversight of pharmaceutical quality, and of clinical trials in emergency situations, as necessary.
- To implement reliance practices for the assessment of therapeutics and vaccines authorized by other RAs.
- To establish regulations and procedures to address emergency situations and provide regulatory flexibilities.
- To strengthen the post market surveillance (quality, safety, and efficacy) of health products associated with the health threat.
- To make international collaboration, co-ordination, and alignment, where possible, a priority.

7 The Strategic Framework for Emergency Preparedness published by WHO can assist the development of national plans. It is a unifying framework which identifies the principles and elements of effective country health emergency preparedness. Available from: http://apps.who.int/iris/bitstream/10665/254883/1/9789241511827-eng.pdf

- To establish systematic communication strategies to fight false allegations and misinformation related to the use of regulated products.

B. Applicable for international collaboration of RAs:

- To exchange information on actions taken nationally among RAs regarding events that could potentially escalate into a crisis.
- To support the development and availability of novel medicinal products, including vaccination strategies using novel vaccines.
- To participate in collaborative initiatives in the regulatory field, such as the WHO's R&D Blueprint.[8]
- To explore cooperation among ICMRA members on the clinical and quality evaluation of novel products, to achieve faster approval at national level.
- To notify ICMRA Secretariat of potential or ongoing national emergencies, in a timely manner especially those that may affect other countries.
- To identify alternative manufacturers for any products in shortage, and to check the manufacturer's availability to start and continue production.
- To provide regulatory assistance on technology transfer processes, to enable other manufacturers (public or private) to start production in an expedited timeframe.

5. Communications

Communications are a key part of managing a global health crisis. Communication enables international collaboration, co-ordination and alignment where possible – this is one of the key lessons that has been learnt from the COVID-19 pandemic. Through effective communication, it is possible to provide the required information and collaborate with stakeholders in a timely manner, be open and transparent about regulatory processes, ensure coordination of regulatory actions, and maintain confidence in the regulatory authorities during a crisis. These actions clearly demonstrate positive and successful international collaboration.

The following SOP provides a mechanism for ICMRA members to communicate successfully during global health crises. It is also recognized that communication with key stakeholders, such as the WHO (and its regional offices, when necessary), may also be required. With relation to the WHO, and depending on the nature of the emergency, it is recommended that, the Secretariat of the recently updated WHO Program on Health Emergencies, or the Department of Essential Medicines and Health Products or the Department of Regulation and Prequalification (Appendix A), be contacted.

8 The R&D Blueprint was developed at the World Health Assembly in May 2016. It is a global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to avert large scale crisis.

In addition, external communication via press releases or statements on the regulators' websites may also be helpful. An example of this is the ICMRA Statement on the Need for Continued Focus on COVID-19 Therapeutics. Sharing such information may be facilitated through the ICMRA secretariat in conjunction with the ICMRA communication group, as established in Appendix B and C.

The ICMRA Communications Group

The ICMRA Communications Group has been vital in increasing pandemic preparedness, especially through use of the ICMRA website to disseminate information. It has raised the awareness of important international efforts to align regulatory actions in a crisis, positively shaping the public perception of the importance of regulatory authorities, whilst also reassuring the public of the scientific basis of regulatory decision making, allowing the general population to have a better understanding of any national measures put into place.

The Group has undertaken many important activities during the COVID-19 pandemic, which can be grouped according to the following:

- Publications (press releases, ICMRA statements, reports from ICMRA Working Groups, communication plans, updating the ICMRA website).
- Organization (coordination of more frequent ICMRA Communications Group meetings during the pandemic, planning and launching ICMRA campaigns).
- Communicating with internal and external stakeholders (providing timely and targeted information, enhanced the cohesion of ICMRA by raising awareness internally, and promoting ICMRA's unique contributions externally).

These actions have supported ICMRA to deal more effectively with public health threats and, are easily adaptable for use in future pandemics.

ANNEX 1 - ICMRA Standard Operating Procedure Facilitating Prompt Collaboration among Heads of Regulatory Authorities

1. Purpose

- To provide a coordinated and consistent global approach to preparing for, preventing, protecting against, mitigating, responding to, and recovering from incidents involving or impacting products regulated by ICMRA members.

- A longer-term objective is global coordination and communication between various stakeholders to expand the global reach and leverage our individual and collective responses. Special attention will be given to the communication strategy, to ensure prompt and effective co-ordination, and contribute to the coherence of necessary measures in a crisis.

2. Definitions

- A global health crisis is considered as an unforeseen occurrence or a combination of circumstances that poses a significant public health risk to other States and that involves the safety, efficacy, security, and availability of health products, potentially requiring a coordinated international response by RAs. After assessing an event's associated risks, routine measures are found insufficient, therefore urgent and coordinated action is required to manage and control the situation. A requestor is defined as those referred to ICMRA Membership, according to definitions mentioned in ICMRA Terms of Reference, seeking to quickly bring together selected global regulatory counterparts for discussions on a public health emergency issue.

3. Communications

ICMRA members can engage in global health crisis management based on a comprehensive approach. The approach can encompass a range of preventative, preparatory, response and recovery actions, which can be applied in a broad sense to an unknown disease outbreak or, alternatively, in a narrower context - such as the response to a specific incident of product quality or safety issues.

It is encouraged that simple mechanisms of exchange of information between requestors and ICMRA Members are adopted. The ICMRA Secretariat will facilitate communication, receiving requests and forwarding to the ICMRA Emergency Contact List. However, for those cases where the ICMRA Chair and/or ICMRA Executive

Committee foresees the emergency notification or can benefit from an Emergency call among ICMRA members, the next steps below can be triggered.

The agenda for the Emergency call (Appendix A) can either accompany or be sent immediately after the emergency communication has been submitted.

The ICMRA Secretariat will subsequently assist the requestor in alerting the ICMRA Emergency Contact List and will provide logistical support, as necessary, for ensuring that prompt dialogue occurs [9]. The ICMRA members may indicate experts or a multi-disciplinary team to address specific issues, including matters related to other stakeholders, in a timely and effective manner.

Outcomes of the discussions and key decisions taken during the call can be circulated to ICMRA members using a Meeting Report (Appendix B). At any time, ICMRA may need to communicate with various stakeholders. Appendix C provides further information on guiding principles informing communication with non-RA organizations.

The ICMRA Secretariat responsibilities on these issues may include, but are not limited to, the following: i) to organize/ update the ICMRA Emergency Contact List, according to the procedures agreed in this document; ii) to support ICMRA members in summarizing meeting reports; iii) to manage the archive and distribution of meeting minutes and supporting documents, organizing them in a confidential/secure way; iv) to facilitate teleconference meetings among ICMRA members, upon request; v) to facilitate communication with the WHO, and other non-RA organizations.

<u>ICMRA Emergency Contact List and Email and Teleconferences</u>

- Each ICMRA Member should identify at least two points of contact, and this contact list should be updated regularly. The initial contact may be the Head of the Regulatory Authority, and the second one may be an institutional email. Additional contacts can be provided.
  ICMRA Emergency Contact list should include names, titles, organizations, email addresses, work telephone numbers, and mobile telephone numbers.
- Where the ICMRA Secretariat contacts ICMRA Members, requesting/providing information on a crisis, at least one of the NRA's points of contact should confirm the receipt of the email within one working day.
- ICMRA members are responsible for alerting the ICMRA Secretariat when their Emergency Contacts change.
- During emergencies, to escalate information about the incident, the requestor should send it to the email distribution list managed by ICMRA Secretariat.
- ICMRA Secretariat and the requestor will work together to organize the emergency ICMRA teleconference, unless otherwise specified.
- The teleconference developments may be forwarded to ICMRA members using Appendix C.

---

9 Whenever possible, the ICMRA Secretariat should provide a virtual communication mechanism to support the expedited share of information among ICMRA members, allowing other RAs and WHO to have access to and use information or any update as soon as it is made available.

4. APPENDIX A: Template Agenda for Emergency Calls

The 'Call leader' is either the ICMRA Chair or Vice-Chair.

Proposed time of Teleconference (and GMT designation)

1. Brief Summary of the issue and purpose of the call

2. Roundtable: Updates from other Countries *(all)*

3. Identification of:
- additional countries ICMRA may need to talk to/coordinate with; and
- external stakeholders ICMRA may need to talk to/coordinate with. *(all)*

4. Assign who will Lead the Communication Outreach the Parties Identified in Agenda Item 3, if any *(call leader)*

5. Summary of the Discussion and Action Items *(call leader)*

5. APPENDIX B: Template Meeting Report

1. Summary of the Discussion	*Call leader (The Secretariat)*
2. Main Decisions	*All*
3. Next Actions	*All*
4. Next Meeting (if it is the case)	*All*

6. APPENDIX C: Non-Regulatory Authority organizations to receive ICMRA crisis communications[10]

Principles:

It is assumed that each RA will be responsible for ensuring that ICMRA crisis communications are delivered to the relevant government agencies and health system organizations within its jurisdiction.

Based on the nature of each crisis incident, a judgement will be made with regards to which organizations, will need to be included in any communications issued.

10 This document was prepared by the ICMRA Communication Group and revised by the ICMRA Crisis Management revision Working Group of 2022.

The Secretariat will co-ordinate liaison between the relevant members to decide which non-RA organizations are to be included in the communications. This will depend on whether an incident team has been established.

- Where an incident team has been established, **the team** will work with the Chair of the ICMRA Communications Group to suggest a plan for the communications, which will then be agreed with the MC Chair and Vice Chairs.
- Where there is no incident team, the **requesting member** will work with the Chair of the Communications Group to suggest a plan for the communications which will then be agreed with the MC Chair and Vice Chairs.

The non-RA organizations should be categorized according to the following priority stakeholder groups to reflect the relevance, and perceived level of influence that the organization may hold in relation to the specific crisis incident, and the type of ICMRA communication that they should receive.

In all cases where the stakeholder is a national or regional organization, the relevant RA(s) will take the lead in the communications approach.

Type of stakeholder	**Relevance**	**Level of influence**	**IMRA communication received**
Priority 1	High	Influence the course of action taken, support ICMRA position, enable ICMRA communication to reach a wider audience.	Targeted – seeking stakeholder support. This should be reinforced, (where appropriate), by direct contact from an ICMRA member, RA, or Executive Committee representative.
Priority 2	Intermediate	Support ICMRA position, enable ICMRA communication to reach a wider audience.	Generic – seeking stakeholder support and further engagement if required.
Priority 3	Low	Enable ICMRA communication to reach a wider audience.	Generic – for information only.