ICMRA Communications Strategy: 2018 - 2020

Introduction

The International Coalition of Medicines Regulatory Authorities (ICMRA) is a voluntary, high-level, strategic coordinating, advocacy and leadership group of medicines regulatory authorities that work together to provide direction for a range of areas and activities common to many regulatory authorities' missions and goals at the international/global level; identify areas for potential synergies to be made; and wherever possible, leverage existing efforts to maximise the global regulatory impact.

Four over-arching objectives guide ICMRA's work to reinforce global resilience and the contribution that pharmaceutical regulation makes to protecting public health:

- to protect human health throughout the life-cycle of medicinal products;
- to enable regulatory conditions which facilitate improved access to and availability of safe, efficacious and quality medicinal products. This also includes enabling innovation and advancing regulatory science as it relates to medicinal product research and development;
- to promote coherent and strategic multilateral cooperation among regulatory authorities;
- to promote the leveraging of regulatory authorities' collective resources, including knowledge and expertise.

The scope of ICMRA is medicinal products for human use (pharmaceuticals, biologics, genetic therapies, radiopharmaceuticals and "grey zone"/combination products).

ICMRA's strategic priorities are:

- Pharmacovigilance
- Supply Chain Integrity
- Innovation
- Crisis management

Over time, ICMRA will enable a global framework to support enhanced communication and information-sharing, address issues of regulatory science and facilitate the response to public health emergencies.

From informal meetings of some medicines regulatory authority (MRA) executives, held at the margins of others' events in 2012, the group has been established, formally, since 2014

and now consists of a core membership of 22 regulatory jurisdictions plus another five who are associate members; in addition, the World Health Organization (WHO) is an observer.

Following an initial three-year period, under the chairmanship of Health Canada, there is now an Executive Committee (EC) established since February 2017. The EC is composed of the UK as chair, with co-vice chairs from Australia and Mexico, plus the former Chair and co-vice chairs, respectively Canada, Japan and Ireland

In addition, there are various working groups leading on delivery of ICMRA's strategic priorities.

The first ICMRA Communications Strategy was agreed in 2015, following the establishment of a Communications Group. Subsequently we have delivered: a refreshed communications toolkit, an ICMRA public website, a process for press releases, a document management process, an internal engagement plan and an external engagement calendar; as well as dedicated ICMRA sessions at the DIA Global 2016 and 2017 annual meetings plus the DIA EuroMeeting 2017. This is therefore now a good juncture at which to bring the communications strategy up-to-date.

The aim of this Communications Strategy for 2018-20 is to:

- Build on the communication activity that has supported the initial four years of ICMRA and to support the next phase of its development: establishing its reputation as the leading strategic medicines regulatory group, able to effectively address global regulatory issues and challenges for the benefit of public health.
- Communicate the value of ICMRA to fellow regulators plus other partners, stakeholders and external audiences through:
    - Communication activities that are generated by ICMRA's Working Groups.
    - Website with content targeting outcomes of meetings and projects that require input from external stakeholders.
    - Facilitating interactions with stakeholders to understand their challenges relevant to the mandate of ICMRA.
- Improve internal communication between ICMRA members and groups, so that they can leverage each other's work rather than duplicate and to empower them to deliver on outcomes.

1. Where we are now – the current position

Considerable effort has already gone into establishing ICMRA and ensuring awareness of its existence, with particular emphasis on providing communications tools such as a factsheet and core slide deck, and on introducing ICMRA to key stakeholder organizations as well as at conferences and in journal articles. An ICMRA public website was developed by Japan in 2016 and will be further enhanced during 2017. There have been dedicated ICMRA panel sessions at both the 2016 and 2017 DIA Global Annual Meetings; as well as the 2017 DIA EuroMeeting.

A cross-ICMRA Communications Group, composed of communications representatives from the member authorities, was established in 2016 to "own" the strategy, develop relevant sub-strategies and contribute to resourcing implementation of the Communications Strategy. The group has a maximum of ten member authorities and is currently composed of representatives from: Australia (the Therapeutic Goods Administration - TGA), Canada (Health Canada), European Medicines Agency (EMA), Italy (Italian Medicines Agency - AIFA), Japan (Pharmaceuticals and Medical Devices Agency - PMDA), Sweden (Medical Products Agency - MPA), Switzerland (Swissmedic) and the UK (Medicines and Healthcare products Regulatory Agency - MHRA). It is currently chaired by the UK.

There is now a greater level of awareness of ICMRA's role, ambitions and functions amongst fellow regulators and other key stakeholder organizations. For example, an Associate category of membership has been introduced in response to growing interest from regulators keen to join since 2016. With a new governance structure, expanded membership and refreshed set of strategic priorities, ICMRA is in consequence better placed now to deliver tangible examples of the impact it can have that will enhance other global initiatives. This will help continue to demonstrate what distinguishes it from other groups and further increase external recognition of ICMRA.

The first ICMRA communications strategy was agreed in 2015 to cover the period until 2018. It has now been updated to reflect the considerable progress made and changes effected since 2015 in order that it can support the next phase of ICMRA's development through to 2020.

2. ICMRA communication activity to date

The communications activity undertaken so far has been effective in introducing ICMRA and its objectives to those key stakeholder organizations that primarily operate in the field of regulation.

- Several communication pieces have been issued, most notably a joint statement on Ebola and a press release on Zika virus.

- A set of communication tools has been developed and kept updated, including an ICMRA Fact Sheet and Power Point deck, to support members in the delivery of presentations on ICMRA to external stakeholders

- The stakeholder groups targeted to date are:
    - International Pharmaceutical Regulators Forum (IPRF).
    - International Council on the Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human use (ICH).
    - The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).
    - Drug Information Association (DIA).
    - Heads of Medicines Agencies (HMA).

- Meeting and email correspondence with the Drug Information Association (DIA) to explore the potential for collaboration, following an approach from DIA. Collaboration with the DIA has been further progressed since 2016, with ICMRA DIAmond panel sessions held at both the 2016 and 2017 Global Annual Meetings, plus also at the latter an Executive Forum session with senior representatives from industry.

- Initial work was carried out with the Secretariat, in late 2016, to explore the development of an extranet that will enable documents to be shared amongst ICMRA members. This initiative is now being progressed by the Secretariat with interested parties, including Pan American Health Organization (PAHO).

- Development of a public website built by PMDA.

- Journal articles (e.g. the WHO Drug Information journal).

- Conference presentations (e.g. 2017 DIA EuroMeeting).

3. Where we want to be – overall aim, audiences and communication objectives

ICMRA wants to be recognised as providing strategic direction, advocacy and leadership to the global medicines regulatory community, enabling key regulatory challenges to be addressed. To do this, ICMRA needs to continue to raise its profile amongst its target audiences, giving visibility to its activities and demonstrating how it adds value.

ICMRA's target audiences are:

- Medicines regulatory authorities globally, which are potential future members of ICMRA.
- The staff of those medicines regulatory authorities that already participate in ICMRA.
- International collaborative bodies for both medicines regulation and pharmaceutical industry.
- Major charitable and philanthropic organizations with an interest in medicines regulation.
- Global non-Government Organizations (NGOs).
- Pharmaceutical industry, including biotech.
- Major conference organising bodies.

These high-level target audiences are considered in more detail in the External Engagement Plan (see Annex 1). It is envisaged that communications to national level associations or stakeholders will be undertaken by the relevant national regulatory agency.

3.1 Objectives for ICMRA communications

- To continue to establish ICMRA's identity and reputation as the leading coalition of medicines regulatory authorities that provides pro-active strategic leadership, meeting the challenges posed by globalisation through the promotion of regulatory convergence, collaboration, information sharing and joint working.

- To demonstrate impact through leveraging existing initiatives and dissemination of outputs from the ICMRA working groups - information sharing in order to enable greater use of global resources and support capacity building that would not otherwise exist.

- To promote and articulate ICMRA's unique contribution, explaining why it is needed to avoid duplication of work and channel efforts towards common objectives through dialogue and collaboration with other established international initiatives.

- To facilitate ICMRA to achieve its strategic goals.

- To ensure good internal communications, particularly between the ICMRA Executive Committee and the broader membership.

3.2 How we will achieve our communications objectives – ICMRA communications strategy

As a voluntary collaborative group, ICMRA has relatively limited resources and this is reflected in the communications strategy proposed. The strategy is therefore to –

- **Promote ICMRA key messages**
    - ICMRA is an international executive-level coalition of key medicines regulators from every region in the world –
        - 22 regulatory jurisdictions in core membership, plus another five associate members.
        - Regions covered include: Pan America, Europe, Africa, Asia Pacific and members of the BRIC (Brazil, Russia, India and China) countries.
        - Value and advantages can be gained by a regulator from playing an active part in such a network.

    - ICMRA provides a global strategic focus for regulators –
        - Agreement of a Strategic Framework.
        - Setting of strategic priorities.
        - Ensure delivery of strategic priorities, leveraging existing initiatives as appropriate.

    - ICMRA gives strategic leadership on shared regulatory issues and challenges -
        - Proposal on Substandard and Falsified (SF) Medical Products for the WHO.
        - Projects on shared issues such as Supply Chain Integrity, Good Manufacturing Practice (GMP) and Crisis Management.

        - Development of capacity building work passed to the WHO.
        - GMP project work passed to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

    - ICMRA promotes regulatory convergence, collaboration and joint working –
        - Equivalency work for the Supply Chain Integrity Project, developing criteria for track and trace.
        - Development of a Unique Facility Identifier by the Supply Chain Integrity Project - to be taken forward by PIC/S.

    - ICMRA identifies areas for potential synergies among regulators –
        - Methodology for mutual reliance through the GMP project work.
        - Joint horizon-scanning and novel approaches to licensing through the Innovation projects.

    - ICMRA facilitates international leveraging and resource savings –
        - Promotion of reliance concepts in the area of GMP inspections in cooperation with PIC/S on the GMP Project.

    - ICMRA can mobilise key regulators to work together in the event of a public health emergency.

    - ICMRA is open for regulators to join on request as associate members.

- **Ensure consistent information about ICMRA is easily accessible by and widely available to members and stakeholders**
    - Update and maintain an electronic communications toolkit for use by all ICMRA members to include:
        - Key messages, slide presentations, key facts, case studies and examples of achievements to demonstrate ICMRA's achievements and added value, for incorporation in members' existing communications activities
        - Reports from those ICMRA members who have given presentations to external audiences - what were the messages they wanted to get out, what questions were raised, how receptive the audience was, anything that ICMRA might need to action / amend in its communications, anything that might influence ICMRA working groups
    - Update and maintain an ICMRA overview which can be used by all ICMRA members on their own websites
    - Further develop the public ICMRA website and digital presence (potentially to include a Facebook page and Wikipedia entry). The website should initially be in English but consideration should be given to at least introductory sections being available in other languages
    - Include a contact email address for the ICMRA Secretariat within slide presentations and other communication pieces.

- **Target an ICMRA engagement programme with key external stakeholders**
    - Seek to develop close collaborations and regular interactions with those key stakeholders that have common goals, common projects and the greatest global reach to our target audiences.
    - Identify and target ICMRA speakers and/or hold ICMRA events at a number of relevant international events and conferences each year (leveraging the likely attendance of ICMRA members at such meetings in addition to specifically targeting others).
    - Explore working with bodies such as DIA (but without exclusivity) to facilitate engagement with wider groups of stakeholders such as industry, research/academia, patients and fellow regulators.

  See the External Engagement Plan at Annex 1 and 4. below.

- **Generally raise the ICMRA profile by:**
    - Contributing to expert information that is made accessible globally, both online and offline with an ICMRA comment/viewpoint
    - Encouraging and equipping all ICMRA members to mention ICMRA and its work in their own communications and speaking engagements
    - Developing and providing articles and thought leadership/positioning pieces for relevant global press and media (e.g. 'Scrip' or 'Regulatory Rapporteur')
    - Supporting existing ICMRA members to act as informal "ambassadors" to encourage their peers/fellow regulators to join.

4. External Engagement Plan

A plan for engagement with external stakeholders is attached at Annex 1. This plan will be regularly updated by the Communications Group. It covers:

- Target audiences/key stakeholders – identification of those international representative organizations, with a broad interest in medicines regulation and the pharmaceutical industry, with whom ICMRA should build a dialogue and priorities for developing those relationships.
- External events calendar – a forward calendar of key stakeholder events that ICMRA should target for either a dedicated speaking slot or panel discussion.
- Global media – draw up a programme of content that can provide a resource for use in engaging with stakeholders and global media.

5. Develop a website and other digital tools

The public website, implemented by PMDA in 2016, is a key communication tool and resource for ICMRA and its stakeholders. During 2017-18 PMDA will further develop the website by introducing a Content Management System (CMS) that will improve its ease of use and search functionality and Swissmedic will contribute to the enhancement of the website. The improvement will help the website to consistently appear in the top ranking for results generated by relevant searches. Initially the website is provided in English only.

Key aims for the website are to:

- Act as the primary medium to convey ICMRA's Strategic Framework, Terms of Reference, mission and goals.
- Support raising ICMRA's international public profile through use of search engine optimization and other online marketing tools.
- Communicate news and views from ICMRA and its members.
- Provide a globally accessible information resource that will demonstrate the added value of ICMRA to its stakeholders.
- Promote the successes of ICMRA

ICMRA will also consider other digital tools (potentially including a Wikipedia entry and Facebook presence).

6. Internal Engagement Plan

A plan for engagement with internal stakeholders is attached at Annex 2. This plan will be regularly updated by the Communications Group. A sub-group has been formed to oversee the implementation. The plan covers:

- Objectives – to increase raise awareness, interest and knowledge of ICMRA amongst employees, external experts and other close associates at member agencies.
- Principles of internal engagement – a three-pronged approach: inform agencies' employees and experts, look for engagement and dialogue opportunities between member agencies, appoint ICMRA communication champions at each member agency.
- An action plan – actions grouped within three broader communication themes, including prioritisation for each action within the short and medium term, plus identification of responsibility for implementation.

- Future engagement opportunities – suggestions for how internal engagement might be developed in the longer-term, dependent on available resources and technical infrastructure.

7. Next steps for implementation

A Delivery Plan is attached, at Annex 3, to provide a schedule for the key practical steps to be taken in order to progress continued delivery of the strategy:

- Agree on a yearly External Engagement Plan that brings together the existing external events calendar and stakeholder mapping, sets priorities and responsibilities.

- Provide support to Secretariat to shape ICMRA's involvement in the programme of DIA annual meetings and other external event opportunities.

- Co-ordinate the implementation of the Internal Engagement Plan and review progress.

- Maintain the communications toolkit to ensure that it reflects current ICMRA accomplishments, developments and strategic direction.

- Support the next stage of development of the ICMRA public website to ensure alignment with the agreed communications messages and facilitate content that is relevant and engaging.

- Introduce a standing item whereby, at the end of each ICMRA meeting, a summary is agreed as to what the main communications messages are from that session. A short synopsis of this meeting summary is posted on the ICMRA Public Website.

8. Evaluation and review

This communication strategy will be kept updated by the Communications Group and under regular review by the Executive Committee. Appropriate evaluation mechanisms will be put into place as ICMRA continues to develop.