

ICMRA Strategic Priority on Innovation

Concept Notes
October 10, 2017

1. Summary of ICMRA's discussions on Innovation to date

ICMRA, as an organization comprised of the heads of the world's medical product regulators, is ideally positioned to take the lead in facilitating interagency cooperation and collective engagement with stakeholder groups. Fostering collaboration between regulators, industry, and academia will ensure optimal positioning to meet the challenges described above.

ICMRA has been discussing innovation as a possible new project focus since the ICMRA meeting in Interlaken, Switzerland in November 2016. To help clarify the topics of greatest interest and necessity, ICMRA conducted a survey of its members in early 2017 to identify specific project focus areas. The members have agreed the content, including concrete themes, of the ICMRA Strategic Priority on Innovation (hereinafter, the "SPI"). The launch of the current SPI was formally approved by ICMRA at its October 2017 meeting held in Kyoto, Japan. This meeting immediately followed the 11th Summit of the Heads of Medicines Regulatory Agencies (HMRA), which also included comprehensive discussions regarding innovation.

2. Purpose

This document was prepared to provide a brief overview of

- (a) the issues the ICMRA SPI aims to address,
- (b) the rationale for why ICMRA should address these issues and how ICMRA plans to add value, and
- (c) the concrete work plan for the SPI.

This document will be made available to the public for the purpose of maintaining the transparency of ICMRA's activities.

Disclaimer: This document has been endorsed as a formal ICMRA document by ICMRA members.

3. Importance of innovation in medical product regulation

One of the key challenges facing medical product regulators today is the rapidly deepening complexity of these products. As increasingly transformative innovations continue to come under regulatory scrutiny, regulators need to be open to innovation and also be able to adapt as needed. Preparedness will enable regulators to fulfill their statutory duties, while mitigating any stifling effect regulatory procedures may have on future research and development (R&D) or impediments to swift patient access.

What is “innovation”, in the context of the SPI?

SPI focuses on R&D of novel and/or disruptive medical products, techniques, and technologies. Innovative technologies include newly devised concepts that may lead to the development of new categories of therapeutics (e.g. cancer immunotherapy), and new methods of drug development and regulation (e.g. use of real world data in pre- and post-marketing evidence generation, risk-based approach in inspections, etc.).

Many of the challenges posed by the emergence of such innovations will be common throughout the global regulatory community. This presents an ideal opportunity for ICMRA to provide strategic leadership and direction to avoid duplication of work by multiple regulators and to harmonize regulatory procedures pertaining to medical innovation.

4. Horizon Scanning: perceived issues and ICMRA’s role

To ensure the timely completion of regulatory activities and that patients gain swift access to innovative and complex medical products, regulators must cultivate the ability to forecast and identify innovative developments with implications for current regulatory practices in their earliest stages. To this end, regulators across the world are conducting “horizon scanning”. Horizon scanning refers to broad-reaching information-gathering and monitoring activities to anticipate emerging products and technologies and potentially disruptive research avenues.

Currently, however, these activities are being conducted independently by regulators with limited collaboration or sharing of methodologies, findings, or results of data analysis. It can be safely assumed that there is considerable duplication of work, and that the current lack of collaboration and information sharing will lead to missed opportunities for improving the overall effectiveness of these measures.

ICMRA can exercise leadership to promote regulatory cooperation regarding horizon scanning, especially in the following areas;

- a) compiling each regulator's scanning methods to identify best practices;
- b) identifying and sharing frequently-encountered difficulties and broadly applicable know-how;
- c) encouraging exchange of scanning findings between regulators, such as providing a secure IT platform where regulators can share potentially confidential information obtained through their respective scanning activities;
- d) encouraging regulatory scientific studies to determine the most appropriate appraisals and responses to emerging products and technologies
- e) identifying globally important trends in medical product innovation and proposing harmonized measures to appropriately adapt to such trends; and
- f) cultivating/recruiting the necessary expertise and sharing it among the ICMRA members.

5. Novel approach to licensing -perceived problem and ICMRA's role

Regulators must respect patients' wishes to attempt to benefit from the use of innovative medical products as quickly as possible. Currently, several regulatory authorities already offer accelerated or streamlined product approval pathways and related auxiliary mechanism (e.g. prioritized consultation) for promising medicines that are distinct from the standard review pathways.

To date, there have been few interagency efforts to identify best practices for ensuring that various types of innovative products reach patients as quickly as possible. Approval pathways for gene therapies, for example, are different in almost every country. Additionally, innovative products frequently come from small companies or the entrepreneurial pursuits of members of academia, both of which often lack the resources or the capability to obtain regulatory approval for their products. Such resource difficulties coupled with differences in regulatory pathways can both confuse and discourage stakeholders, particularly the drug development industry, stifling novel product development and ultimately becoming an obstacle to patient access.

The development and implementation of novel regulatory approaches face various barriers and difficulties. Coordination with stakeholders such as health technology assessment (HTA) bodies is among these difficulties. Yet another challenge is determining how regulators can best use regulatory scientific principles to achieve a balance between

swift patient access and strong efficacy and safety evidence. Outreach to stakeholders, including related industries and members of academia, is essential to finding the solutions to these issues. Although these obstacles are faced by regulators around the world, currently, many agencies are needlessly attempting to overcome them on their own.

ICMRA's global membership leaves it well-suited to assume a leadership role in building connections between regulators and catalyzing progress towards overcoming each of these obstacles.

6. SPI structure and concrete measures

An appropriate governance structure will be established and will be coordinated by the ICMRA secretariat.

The current SPI includes three discrete workstreams, which will be led and delivered by ICMRA members, covering the following topics:

- Horizon scanning: methodologies and best practice
- Horizon scanning outcomes: products; technologies; regulatory science approaches and expertise
- Novel approaches to licensing, identification of barriers and methods to address these.

Immediate subgroup work plans

The activities of the SPI and its subgroups are of an evolving nature.

Updates will be provided as the ICMRA SPI workstreams develop further and key milestones are reached.

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