ICMRA Summit October 2017
Kyoto

Key Outcomes

A summary of the key outcomes from the Summit hosted by PMDA/MHLW in Kyoto, Japan, on 25th and 26th October 2017, attended by 30 regulatory agencies.

Supply Chain Integrity

ICMRA discussed the benefits and challenges of the interoperability of Track and Trace (T&T) Systems, and agreed to adopt the Supply Chain Strategy document, setting out ICMRA's recommendations on alignment of existing and planned T&T systems to allow for interoperability. It will be published on the ICMRA website and ICMRA will work with operational bodies to take forward the strategy's recommendations.

Pharmacovigilance

Big data subproject: ICMRA agreed to post the inventory used by the Big data project - after a final phase of revision by the contributing members - on the ICMRA website, as well as to begin transitioning this work for practical implementation. This inventory reflects the data contributed at the time from participating countries.

Increasing adverse events reporting subproject: To help tackle under-reporting of suspected adverse drug reactions, the project leads discussed a detailed workplan to drive ICMRA's work in this area.

Vaccines subproject: The work project addressing Better management of the analysis and communication of vaccine adverse events following immunisation updated ICMRA on current work exploring the current situation. This group will continue with their analysis and report back to ICMRA.

Innovation

Three subprojects were agreed, with leads to co-ordinate and produce a project plan for the following areas:

1. Analysis of global best practice in horizon scanning.
2. Leveraging outcomes of horizon scanning.
3. Novel approaches to licencing/early access scheme.

The project leads will coordinate between themselves to produce joint project plans before reporting back to ICMRA.

Novel Developing Technologies
A presentation on novel developing technologies highlighted some of the regulatory challenges ICMRA members face in light of new innovative technologies. The need for new competencies for both regulators and health systems was discussed, and ICMRA was identified as an ideal body to foster the evolution of regulators to meet these new challenges.

External engagement
ICMRA agreed on a series of targeted engagement to strengthen links with other relevant bodies such as IFPMA and the WHO.

Communications
ICMRA members welcomed the launch of the new ICMRA website which is now live at www.icmra.info

ICMRA agreed to provide a public session at the DIA EuroMeeting in April 2018, and panel members were discussed.

Crisis Management
It was agreed that the Crisis Management group will work to finalize the framework for involvement of health regulatory authorities in the management of a global health crisis and present this at the ICMRA Plenary in Basel for adoption.

GMP Inspections
ICMRA agreed to transition the project considering GMP inspections to PIC/s as a more appropriate operational lead.

Future of ICMRA
Members are requested to dedicate time over the next nine months for further defining where ICMRA should focus its work to best add value internationally; a paper to lead discussions will be produced.