Pharmacovigilance – an ICMRA strategic initiative

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Purpose and structure

Purpose of our pharmacovigilance work

- To inform, share and strengthen collaboration
- Not to establish new systems, but to assist policy discussion
- The transfer of skills and knowledge between member countries of ICMRA
- To contribute to international convergence in pharmacovigilance
- To guide future policy direction
- To guide future investment priorities and programs

Structure

An overarching leadership team with key work being undertaken through three subproject areas:

- Big data
- Increasing adverse event reporting
- Better management of the analysis and communication of vaccine adverse events following immunisation (Vaccines)

1. Big data

What is big data?

Includes:

- Structured: Examples include electronic health records and administrative health data
- Unstructured: Examples include social media such as Twitter and Facebook, and patient forums

What outcomes are ICMRA seeking through this subproject's work?

- While spontaneous reporting systems (SSR) are crucial and essential, they never give a complete picture of patient safety information
- We are looking at new ways to enhance the quality and quantity of adverse drug reaction reports. We consider this has the potential to supplement traditional SSR
- We are using the subproject as a forum to share and facilitate knowledge transfer on the use of big data analytics

Big data – deliverables and achievements

Key messages from our work to date

- Different agencies are at different stages of systematic use of large data sets.
- A rapidly moving, shifting landscape
- Our work must align with the work of others to be of value
- Privacy concerns for data sharing will need to be overcome
- Technical issues in compatibility of data models and coding

What have we considered this week?

- How to progress our work to a practical implementation stage
- Publication of our findings - in the interests of global knowledge sharing and transparency

Big data – deliverables and achievements

- Series of webinars
  - 1 per month starting in November 2018 (nine planned so far)
  - Each webinar will deal with a particular agency's experiences in dealing with analysis of large data sets to enhance pharmacovigilance.

- Subject to final checks we also plan to publish a policy paper, dated mid 2016, and noting that it reflects thinking up to that point

- We will also consider closing the project next year and moving the technical implementation to another group

- We also discussed the role of RWD/RWE and use of big data for purposes other than pharmacovigilance.

2. Increasing adverse event reporting

What outcomes are ICMRA seeking through this subproject's work?

Setting the scene: Some medicines regulatory authorities have adopted strategies to increase reporting

- we are considering the different approaches being taken and where these approaches may have had the greatest impact
- Learning forum
- Consideration of quality, and impact of reporting in terms of patient safety and public health

Increasing adverse event reporting – deliverables and achievements

Key messages from our work to date

- Underreporting of suspected Adverse Drug Reactions (ADR) is a problem globally
- Need to focus on quality of ADR as well as the number of reports; and the impact of reporting in terms of patient safety and public health
- Recognise the role of other players for example World Health Organization.

Increasing adverse event reporting – deliverables and achievements

What have we considered this week?

- Refocussing our efforts to ensure the proposed work is achievable and continues to value add.
- Broadening our membership base.
- Agree to start an information gathering exercise from participating countries abut their work on increasing ADR reports.
- Analysis of this will inform next steps.

3. Vaccines

What outcomes are ICMRA seeking through this subproject's work?

Initially:

- Exploring which countries actively collect surveillance information and which passively
- Determining what expertise is currently available for ICMRA to draw on and what can it potentially have access to
- What success stories are out there already?

Then:

- From the collated information a workplan will be determined

Vaccines - deliverables and achievements

Key messages from our work to date

- Need to be careful through our work not to draw more attention to negative reactions detected, than to the wider benefits of vaccines
- Regulations regarding adverse reactions vary by country
- Avoiding duplication of effort

Vaccines - deliverables and achievements

What have we considered this week?

- We are on track to inform ourselves of current work being undertaken in this field.
- Progression to identifying a valuable niche for any future work.
- Baseline information has been sought from participating members. For example, where the reporting of AEFI is mandatory or not.
- We will analyse the responses and propose next steps.
- We will also look closely at other international programs in this area to see where ICMRA can add value.

To conclude

- **Clear benefits to continuing ICMRA's pharmacovigilance strategic initiative**
- **Thank you to my international counterparts participating in this work**

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