ICMRA meeting: COVID-19 Real-World Evidence and Observational studies

19 April 2020

Chairs: Marc Mes (Health Canada), Peter Arlett (European Medicines Agency)

1. Welcome and introduction – Guido Rasi (EMA Executive Director and Chair of ICMRA)

Guido Rasi thanked everyone for their time and dedication to the protection of public health, especially during the pandemic. RWE can play an important role in the evaluation of the disease epidemiology and in the monitoring of medicinal products used in Covid-19 infected patients. This meeting is an essential step to explore ways and agree on how to collaborate on topics such as pregnancy research, building international cohorts and prepare for vaccines monitoring. Guido also encouraged the international partners to publish on their website as much information as possible on their Covid-19 related activities, including on observational studies to increase transparency and foster collaboration.

2. Introduction and overview of the Agenda – Marc Mes (Health Canada)

Marc Mes welcomed participants to the meeting. He shared the main objective of the meeting which was to discuss specific proposals on observational studies that addressed knowledge gaps and which would benefit from collaboration with regulatory partners through ICMRA.

3. Summary of ICMRA meeting of 6 April 2020 – Peter Arlett (EMA)

Peter Arlett briefly summarised the meeting where colleagues shared their plans or ongoing activities. The outcome was to encourage the sharing of information including methods on observational studies to increase collaboration and have a positive impact on responding to this pandemic.

4. Sharing experiences of work on observational studies including specific proposals for collaboration – All

a) Pregnancy research

- Corinne De Vries presented the EMA's planned phased initiative that aims at 1/ better understanding the natural history of Covid-19 in pregnancy, pregnancy outcomes and babies, and 2/ monitoring the treatments currently used off label during pregnancy.

  The idea of the project is to establish global collaboration between regulators to establish a network of data sources worldwide (that will help estimate background rates), and to agree on

common protocol / common data model. IMI ConcePTION project was cited as an example of consortium that could provide data as they already have established cohorts.

A representative of WHO expressed interest in collaborating.

- Nathalie Broutet presented the WHO's plan for a prospective longitudinal cohort study. The objectives are to analyse if SARS-CoV-2 infection in pregnant women increases the risk of adverse outcomes compared to non-exposed pregnant women, to estimate the risk of mother-to-child-transmission of the virus during and after pregnancy, to describe the viral presence and persistence in biological samples including placenta etc, and to characterise the clinical course and disease spectrum of Covid-19 during pregnancy. The protocol will be published and shared widely among various networks. Colleagues are more than welcome to participate through a common protocol, or share data of their own studies, and join the Covid19 pregnancy cohort study working group. This WG will discuss the study but also other aspects such as research gaps and pooled analyses of pregnancy cohort data.

  It was noted that the 2 projects planned by the EMA and WHO are complementary with one looking more at medicines monitoring and the other at disease epidemiology.

- Representatives from CBG-MEB, FDA and Health Canada expressed the interest of their agencies in further cooperation.

b) Building international cohorts

Gaya Jayaraman (Health Canada) presented on work underway through the drug safety and effectiveness research network in Canada, with reference to the CNODES distributed network of research sites. They have established a core data model across 6 provinces in Canada, that allows the data to be meta-analysed to produce pooled results. They can easily add new sites over time. The cohort can facilitate the identification of knowledge gaps and respond to priorities related to use/safety/effectiveness of medicines and Covid-19 disease.

Xavier Kurz informed about the EMA's plan to launch a procurement call to establish a multicentres' cohort and expressed interest in further collaboration, including on the drafting of research questions.

The FDA is also supportive of further collaboration on the topic.

c) Preparation for vaccine monitoring

Xavier Kurz presented the EMA's project for vaccines effectiveness and safety monitoring to be in place by December 2020 when vaccines start to be introduced on the market.

The idea is to have a system ready to:

- ✓ Access up to date data rapidly on vaccination coverage per vaccine brand (through the establishment of a Europe-wide network of data sources)
- ✓ Define adverse events of special interest and related background rates
- ✓ Have an expedited reporting of spontaneous ADRs
- ✓ Have rapid signal detection methods
- ✓ Quickly perform studies
- ✓ Ensure appropriate communication.

FDA, MHRA and Health Canada expressed their interest to further collaborate.

Finally, a representative of WHO indicated that the GACVS (WHO) will further discuss vaccines monitoring next week, and that he will share the outcome of the discussion with ICMRA.

Next steps:

Peter Arlett proposed to have another ICMRA general TC on Covid-19 and to establish technical working groups on the three topics for collaboration (pregnancy research, building international cohorts and preparing for vaccine monitoring).

The Co-Chairs, through the ICMRA Secretariat, will issue a call for additional members interesting in participating in the technical working groups for the three proposed collaborative projects on pregnancy research, building international cohorts and preparing for vaccine monitoring.