



## NEW CIOMS WORKING GROUP

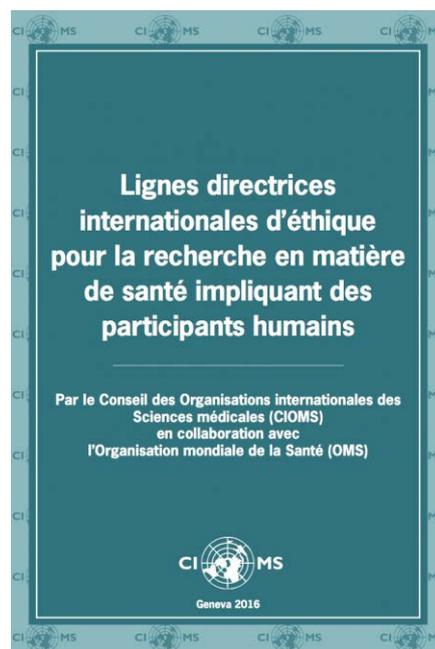
A new CIOMS Working Group (WG) on Practical Guidance to Clinical Product Development Research in Resource-Limited Settings (or Good Practices for Clinical Research in Resource-Limited Settings) will start later this year. CIOMS is organizing a working group (WG) of senior scientists from academia (including representatives of its member organizations), drug regulatory authorities, the pharmaceutical industry, public-private

partnerships for product development (PPP/PD) to analyse the situation of clinical research in resource-limited settings (RLS) with the focus on, but not limited to, randomized controlled clinical trials (RCT). The WG will develop a consensus on relevant scientific, regulatory, ethical and administrative issues and propose pragmatic recommendations for improvement of the environment and good practices for social acceptance, planning, assessing, performing and interpreting randomized controlled clinical trials.

The WG is also intended to review how to benefit more from electronic health records (EHR) and how to prevent mistakes which make the use of EHRs difficult for clinical research in RLS. As usual, it is up to the WG to decide the final scope, directions and outcome of the WG. However, it is believed that these criteria/guidelines to be created could be used by all parties involved in policy-making, planning, designing, assessing and carrying out clinical research (including but not limited to RCT in RLS, notably by Ministries of Health/regulators/health technology assessors, industry, public-private partnerships and academia worldwide)

### HIGHLIGHTS

- Public consultation on new Vaccines Communication Guide is still open
- New Working Group on Clinical Research in Resource-Limited Settings
- French translation of Ethical Guidelines now available



The French translation of *International ethical guidelines for health-related research involving humans, 2016* : is [now available in the CIOMS online bookshop](#). *Translations into other languages are also underway.*

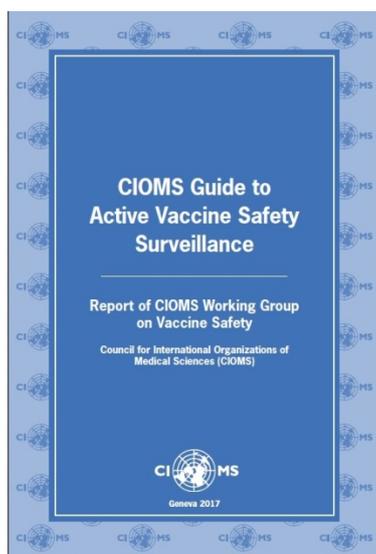
## 4th International Neonatal & Maternal Immunization Symposium.

The Secretary-General of CIOMS, Dr Lembit Rägo (LR), participated in the 4th International Neonatal & Maternal Immunization Symposium - INMIS 2017 (more at <http://www.inmis.org/>) on 10–12 September in Brussels, Belgium. INMIS is a useful forum to bring together scientists, clinicians and public health experts from all continents to present, discuss and debate the opportunities and challenges that maternal and neonatal immunization can bring.

In this sensitive area of science, ensuring safety is one of the most important issues. The new CIOMS Guide to Active Vaccines Safety Surveillance can assist in proper planning of active safety surveillance of vaccines that are to be used for neonatal and maternal immunization in resource-limited settings. Dr Steven Bailey (Pfizer) from the CIOMS Vaccines Safety Working Group that authored the mentioned guide proposed to have a presentation about the new CIOMS Guide on Active Vaccines Safety Surveillance during INMIS 2017.

A poster presentation with the heading *An Overview of the CIOMS Guide to Active Vaccine Safety Surveillance: Report of CIOMS Working Group on Vaccine Safety* authored by Steven R. Bailey<sup>a</sup>, Lembit Rägo<sup>b</sup>, Ulrich Heininger<sup>c</sup> and Irina Caplanusi<sup>d</sup> was prepared under the leadership of Dr Bailey. Unfortunately Dr Bailey was unable to attend the meeting so the poster was presented by LR on behalf of the authors. In spite of the impressive progress by various groups of stakeholders to address challenges of maternal and neonatal immunization there might be still topics for which new consensus documents could give added value. During the symposium, LR continued informal exploratory discussions about the potential to set up a CIOMS Working Group dedicated to some aspects of maternal and neonatal immunization.

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### New publication on maternal immunization safety monitoring in LMICs

Maternal immunization holds the promise of reducing the global burden of morbidity and mortality in pregnant women and newborns, particularly in low- and middle-income countries (LMICs) where there is the greatest burden of vaccine-preventable disease and the most limited access to essential health services. Global efforts are underway to develop, evaluate, and implement new vaccines targeted specifically for use in pregnant women in LMICs. In response to this development, the Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) has developed a report, with support from the Bill & Melinda Gates Foundation and input from a large, multidisciplinary group of experts, which summarizes the literature and existing programs in pharmacovigilance and maternal, newborn, and child health (MNCH) surveillance in LMICs, identifies gaps, and outlines a roadmap for program development and implementation of safety monitoring for maternal immunizations in LMICs.

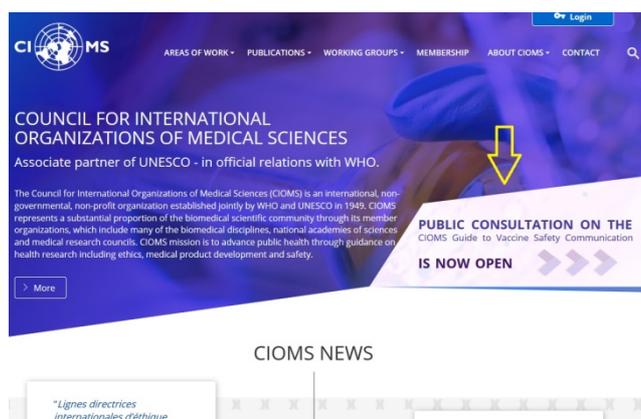
Key stakeholders such as industry, regulatory agencies, WHO, public health agencies, vaccine programs, donor organizations policy makers, epidemiologists, clinical researchers, and healthcare organizations working in vaccines, were all engaged in the development of a strategy for monitoring safety of maternal immunizations. The Secretary-General represented CIOMS in this process.

The report outlines the need for adaptation of existing pharmacovigilance programs, at both the international and country levels, to address the unique events specific to maternal immunization. The report mentions CIOMS among other international organizations important in strengthening pharmacovigilance systems in LMICs. It should be mentioned that the *CIOMS Guide to Active Vaccine Safety Surveillance (2017)* is a very timely publication that can contribute substantially to maternal immunization safety. Finally, successful implementation of maternal immunization safety monitoring programs will contribute to protecting public health and advancing vaccine programmes to reduce the global burden of maternal and newborn morbidity and mortality.

The report, "*Maternal Immunization Safety Monitoring in Low- and Middle-Income Countries: A Roadmap for Program Development*" is available for download at the following link:

<http://gapps.org/docs/MaternalImmunizationSafetyMonitoringInLMICs.pdf>

## New CIOMS Vaccine Communication Guide



CIOMS will soon make available the Guide to Vaccine Safety Communication which will be a standalone document with a focus on vaccines and tailored toward regulators, especially in Resource Limited Countries (RLC). Yet it can also be seen as essential accompaniment to the recently published CIOMS Guide to Active Vaccines Safety Surveillance (CIOMS, 2017). Moreover, the Guide could be useful to all stakeholders who have expertise or are interested in vaccine safety and have relevance for all medicinal products and applicable worldwide.

*Public consultation on the draft document was made available through our website in September and comments can still be sent in until 11 October.*

### CIOMS discusses cooperation with medical students

On 26 September, CIOMS Secretary-General Dr Lembit Rägo (LR) had a business lunch with Priit Tohver (PT), the Regional Director for Europe of the International Federation of Medical Students' Associations (IFMSA). IFMSA is currently an associate member of CIOMS. The areas of potential cooperation were discussed with an aim to strengthen links between the two organizations in a mutually beneficial manner. The potential areas of mutual interest were medicines safety and medical research ethics, as well as collaboration with, and support to the World Health Organization. After discussions and reflections on several issues LR made concrete proposals for IFMSA consideration. PT promised to give feedback from IFMSA quickly. They were optimistic that some progress will be made before the end of 2017 and that useful contacts between the two organizations will continue.

## 12th MedDRA Implementation Working Group Meeting, 27–28 September 2017



The CIOMS MedDRA\*Implementation Working Group (IWG) met in Geneva from 27–28 September 2017 and was attended by 17 representatives from regulatory and pharmaceutical organizations, as well as academia, the MedDRA Maintenance and Support Services Organization (MSSO) and the Japanese Maintenance Organization (JMO).

After an introduction by CIOMS Secretary-General Dr Lembit Rägo, the IWG discussed ongoing work on a Concept Paper that explores the feasibility of developing groupings of MedDRA terms for use in the presentation of safety information in the labelling of medicinal products. In addition, time was spent to reflect on the future of the IWG in terms of workload, potential new areas of work of interest and maintenance of SMQs. The teams charged with developing specific candidate Standardised MedDRA Queries (SMQs), e.g. SMQs for Dehydration, for Hypokalaemia, Opportunistic infections, Infusion related reactions, Hallucinations, Progressive multifocal leukoencephalopathy, Developmental disorders and Autoimmune diseases/Immune mediated medical conditions presented their test results and findings to the IWG for discussion, bringing development of these SMQs forward in a well-established process towards production. More discussion about the future of the IWG was held before the meeting closure. It was agreed that the IWG next meeting will take place in Geneva during 11 to 13 April 2018.

*\*Medical Dictionary for Regulatory Activities*

## RECENT ARTICLES ABOUT CIOMS

*Where available, articles about CIOMS can be accessed through our website at : [www.cioms.ch/cioms-in-the-media/](http://www.cioms.ch/cioms-in-the-media/)*

### CIOMS 2016

Bandewar SVS. CIOMS 2016. Indian J. Med Ethics. 2017 Jul-Sep;2(3) NS:138-40. DOI: 10.20529/IJME.2017.067

CIOMS is mentioned several times in this report available through GAPPS : **Maternal Immunization Safety Monitoring in Low- and Middle-Income Countries: A Roadmap for Program Development**

**Guide to active vaccine safety surveillance: Report of CIOMS working group on vaccine safety - executive summary.**

Heininger U, Holm K, Caplanusi I, Bailey SR; CIOMS Working Group on Vaccine Safety. Vaccine. 2017 Jul 13;35(32):3917-3921.

**CIOMS guidelines remain conservative about vulnerability and social justice**

Calvin Wai-Loon Ho. Indian J Med Ethics. 2017 published online Jun 20

**Patterns of use and impact of standardised MedDRA query analyses on the safety evaluation and review of new drug and biologics license applications.**

Chang LC, Mahmood R, Qureshi S, Breder CD. PLoS One. 2017 Jun 1;12(6):e0178104. doi: 10.1371/journal.pone.0178104.

**Critical analysis of the Council for International Organizations of Medical Sciences 2016 International Guidelines for health-related research involving humans.**

Kottow Lang MH. Medwave. 2017 May 15;17(4):e6956

### CIOMS Publications in e-bookshop

Several CIOMS publications in both hardcopy and PDF format are available for free and can be ordered or downloaded directly from the online bookshop at:

<https://cioms.ch/product-category/free-publications/>

Other titles can be purchased with discounts when you buy 2 or more hardcopies of the same title.

### CIOMS SECRETARIAT

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### UPCOMING MEETINGS

**2nd Meeting of CIOMS Working Group on Drug-induced Liver Injury (DILI), Malaga, Spain**

14–15 November 2017

**1st Meeting of CIOMS Working Group on Clinical Research in Resource Limited Settings, Geneva, Switzerland**

20–21 November 2017

**84th CIOMS Executive Committee Meeting, Geneva, Switzerland**

December 2017