What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

WWW.CIOMS.CH March 2020 | **Newsletter** # 29

Quick links

COVID-19

As this newsletter is published, the COVID-19 pandemic dominates not only the news, but everyone's lives and outlook for the future. CIOMS is no exception. All face-to-face meetings have been postponed until at least end of August, the Working Groups are meeting on virtual platforms, and the CIOMS Secretariat staff are working from home.

The outbreak has disrupted all plans for 2020. Many CIOMS Working Group members are at the frontlines of combating the virus in hospitals, government and research institutions. Still, telework continues within the groups, and news and good wishes pass between the members and the continents.

At its teleconference held on 23 March 2020 the CIOMS Executive Committee discussed the situation. The COVID-19 pandemic is a stark reminder of how vulnerable our globalized world is. New thinking is needed to protect people's lives and health. CIOMS has an important function in documenting science and sharing lessons learned in times of crisis, to help avoid past mistakes and create a better future.

The World Health Organization (WHO) is doing its best in leading the fight against COVID-19. To express its solidarity with all medical professionals fighting COVID-19, CIOMS has donated US$ 10 000 to the WHO COVID-19 Solidarity Response Fund.

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/donate

International events

*CIOMS DILI Working Group members **Dr Mark Avigan**, U.S. FDA (standing), **Dr Arie Regev**, Eli Lilly (seated, middle) and **Professor Hervé Le Louët**, CIOMS President (seated, right) were the speakers at Session 3, Drug-Induced Liver Injury (DILI) at the DIA Pharmacovigilance meeting in Washington DC. The session was chaired by **Lesley Wise PhD**, Wise Pharmaco-vigilance and Risk Management Ltd, UK (seated, left).*

DIA Pharmacovigilance and Risk Management Strategies Conference

Washington DC, United States, 27 - 29 January 2020

One of the topics at this year's Drug Information Association (DIA) Pharmacovigilance and Risk Management Strategies Conference was the experts' current thinking on drug-induced liver injury (DILI). CIOMS President Hervé Le Louët spoke about the CIOMS DILI Working Group (WG), while WG members Mark Avigan and Arie Regev addressed DILI risk assessment and stratification, and the principles of detection and characterization of DILI respectively.

It was a successful session that generated considerable interest and excellent feedback. Consequently, the speakers have been invited to write an article in the DIA journal *Therapeutic innovation and regulatory science*. The CIOMS DILI Working Group will also be represented at the DIA 2020 Global Annual Meeting, to be held in Washington DC on 14-18 June 2020.

EMA Patient and Consumer Working Party

Amsterdam, the Netherlands, 3 - 4 March 2020

An update about the draft CIOMS guidelines on patient involvement was presented on the second day of the Joint meeting of the European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties. CIOMS Secretary-General Lembit Rägo spoke about CIOMS and its draft Global guidance on patient involvement, and CIOMS Working Group XI member François Houÿez from EURORDIS gave a presentation about Incorporating the EMA and patient organisations' experience. François was also one of the speakers in the next afternoon session on the topic of medicines shortages.

The EMA PCWP and HCPWP are platforms for information exchange and discussion with patients and consumers and with health care professionals on topics of common interest.

All the presentations are found on the meeting webpage.

DIA Europe 2020: Postponed to June 30 - July 3

As a direct result of the outbreak of the coronavirus disease (COVID-19), DIA has decided to postpone DIA Europe 2020 in Brussels, to June 30 - July 3, 2020.

CIOMS Secretary-General Lembit Rägo will be a speaker at the session on Patient Involvement in the Development and Safe Use of Medicines.

https://www.diaglobal.org/Flagship/DIA-Europe-2020

Update on CIOMS Working Groups

5

CIOMS Working Group XII on Benefit-Risk Balance for Medicinal Products

4

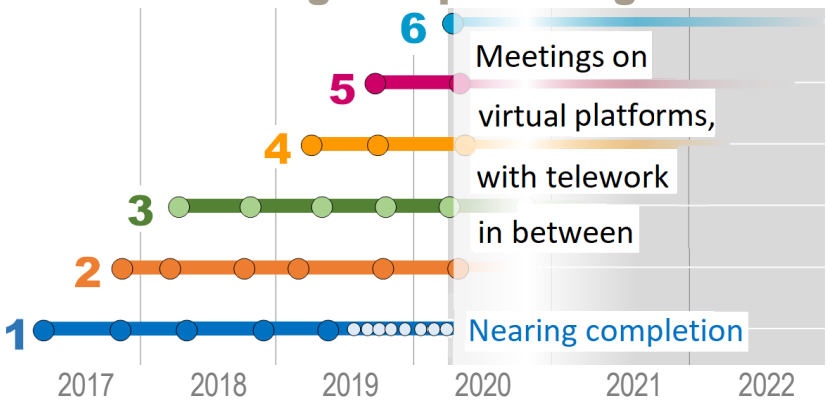
CIOMS Working Group on MedDRA Labelling Groupings

New group

6

Working Group XIII on Real-World Data and Evidence in Regulatory Decision-Making

Working Group meetings



○ = Face-to-face meeting. ○ = Editorial team teleconference

CIOMS Working Groups usually take two to four years to finalize their guidance and recommendations. Most groups have been holding two in-person meetings per year, with telework in between. The groups make use of collaborative efforts and capitalize on existing initiatives in order to provide output that is as comprehensive as possible, does not duplicate other efforts and has added value. The minutes of Working Group meetings are available on the CIOMS website.

1

CIOMS WG on Drug-Induced Liver Injury (DILI)

3

CIOMS Working Group XI on Patient Involvement in Development and Safe Use of Medicines

2

CIOMS WG on Clinical Research in Resource-Limited Settings

***Clinical research to fight COVID-19** is under way at high speed. Nobel Peace Laureate Ellen Johnson Sirleaf reflects on lessons learned from the Ebola crisis, and stresses the importance of sharing knowledge, expertise and resources worldwide.*
Read her open letter here.

CIOMS and WHO

WHO activities to combat substandard and falsified medical products

Special CIOMS Newsletter

The third CIOMS Special newsletter describes the work that the World Health Organization (WHO) is doing with Member States to ensure that all medicines, vaccines and other medical products circulating on the markets of WHO Member States meet the norms and standards that have been agreed as part of their marketing authorization.

CIOMS thanks the WHO Incidents and Substandard/Falsified Medical Products Team for their support and review of this newsletter. For more information please contact the WHO Team at: rapidalert@who.int.


What's on @ CIOMS
COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

WWW.CIOMS.CH Special Newsletter | 20 February 2020

World Health Organization (WHO)
Combating substandard and falsified medical products

Quick links
The problem 1
The WHO response 3
Member State Mechanism 3
Global surveillance and monitoring 4
Strengthening regulatory bodies 5

The problem

"Every person has the right to expect that when they use a medical product, whether medicine, vaccine or diagnostic kit, it works. But too often, that is not the case."

Definitions endorsed by the Seventieth World Health Assembly [2]
Substandard medical products
Unregistered/unlicensed medical products
Falsified medical products

Substandard
Unregistered
Falsified

Comments:

"This is a very helpful overview of the WHO's work on S&F medicines. Sharing with our team for upload onto the resources section of our campaign website."

"Very good and useful! Any chance to have it in other languages, e.g. Spanish?"

The COVID pandemic increases the risk of substandard and falsified medicines.

Here are 27 reasons why.

ICMR Bioethics Unit becomes WHO Collaborating Centre

The ICMR Bioethics Unit, located at the National Centre for Disease Informatics and Research (NCDIR) in Bengaluru, India, has been designated as the WHO Collaborating Centre for Strengthening Ethics in Biomedical and Health Research. It is the first WHO Collaborating Centre on ethics in the WHO South East Asia Region.

***Dr Roli Mathur**, Head of the ICMR Bioethics Unit, is a member of the CIOMS Executive Committee and the CIOMS Working Group on Clinical Research in Resource-Limited Settings.*

The Indian Council of Medical Research (ICMR), a CIOMS member, is the apex body in India for the formulation, coordination and promotion of bio-medical research.

WHO Paediatric Regulatory Network (PRN)

WHO Headquarters, Geneva, 5-6 December 2019

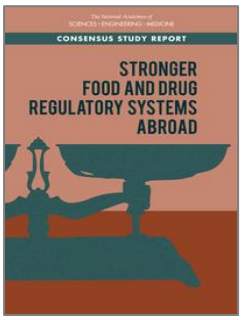
Access to good quality children's medicines can only be sustained in global collaboration. CIOMS is supporting the WHO PRN network, which aims to address the challenges of fragmented markets, frequent off-label use of medicines in children, questions on regulation of gene and cell therapies for children, as well as vaccine scepticism.

***Participants at the WHO-PRN meeting** included representatives from CIOMS, the European Medicines Agency (EMA), the U.S. Clinton Health Access Initiative (CHAI), the Drugs for Neglected Diseases initiative (DNDi), the National Agency for Food and Drug Administration and Control (NAFDAC) of Nigeria and the U.S. FDA.*

CIOMS working with others

NASEM

Report on regulatory capacity-building



CIOMS Secretary-General Lembit Rägo was a panel member in one of the three public workshops held to collect information for the report.

Ensuring medicines quality and safety is an important role of government and essential for public health. The U.S. FDA has commissioned the **National Academies of Science, Engineering and Medicine (NASEM)** to outline a strategy and recommend actions to strengthen food and medical products regulatory systems in low- and middle-income countries.

The full report can be downloaded for free through the NASEM website; a condensed table of recommendations is available here.

Regulatory reliance

The authors of the "First Opinion" article, Katherine C. Bond of Network Strategies for Health, Gavin Huntley-Fenner of Huntley-Fenner Advisors, and CIOMS Secretary-General Lembit Rägo served on the NASEM Committee on Mutual Recognition Agreements and Reliance in the Regulation of Medicines.

In a "First Opinion" article published on STAT, the authors reflect on an earlier NASEM report titled *Regulating Medicines in a Globalized World.* That report explored how countries can work together to oversee the regulation of medicines. The authors of the article argue that sharing of regulatory information should not be viewed as a burden, but as a provision of public good.

STAT is a U.S. news site focusing on topical stories about health, medicine, and scientific discovery.

DIA

Pharmacovigilance and Risk Management in 2020: A Global Perspective

The **Drug Information Association (DIA)** has published an e-book describing the landscape and developments in the rapidly evolving field of pharmacovigilance, and providing a wealth of links to relevant information and initiatives. A download link can be requested on the DIA website.

The CIOMS Working Groups are featured prominently in the DIA e-book.

IFPMA

Five questions to …

The **International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)** has posted an interview with Dr. Lembit Rägo in which the CIOMS Secretary-General describes the activities of CIOMS and his vision for more regulatory collaboration through smart reliance networks, to which both large and small regulatory authorities contribute from their specific areas of expertise.

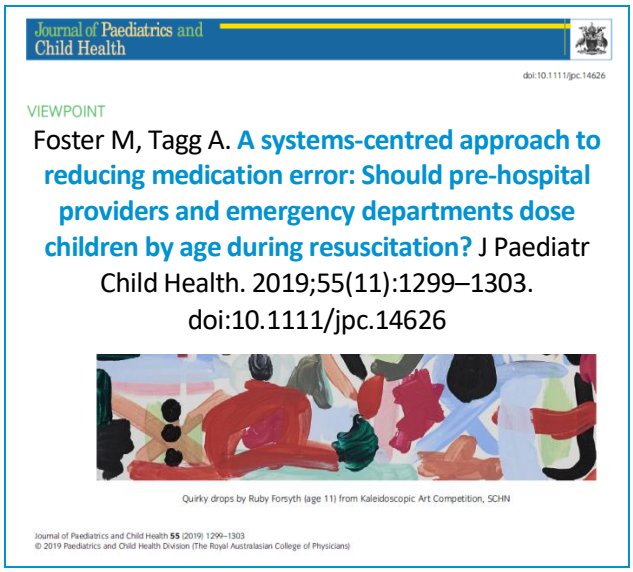
The interview was conducted in the lead-up to the 10th Asia Regulatory Conference (ARC2020) in Kuala Lumpur. CIOMS is represented in the conference Advisory Board by its Secretary-General.

The ARC2020 Conference has been postponed until 4-5 November 2020 due to the COVID-19 outbreak.

2019 CIOMS award for best student paper

The 2019 CIOMS award of US-$ 1500 for the best scientific article published by a medical student in the areas of pharmacovigilance or research ethics goes to Mieke Foster from Deakin University in Australia. In her paper, Mieke is proposing a simpler and safer approach to calculating medication doses for children with cardiac arrest.

In the high-risk, high-stress and high-stakes environment of emergency resuscitation of children, there is a risk of medication errors. From crafting and completing an elegantly simple research project, Mieke went on to communicate with world experts in the field and writing an opinion piece that challenges the current paradigm of weight-based dosing in paediatric resuscitation.


Journal of Paediatrics and Child Health

doi:10.1111/jpc.14626

VIEWPOINT

Foster M, Tagg A. **A systems-centred approach to reducing medication error: Should pre-hospital providers and emergency departments dose children by age during resuscitation?** J Paediatr Child Health. 2019;55(11):1299–1303. doi:10.1111/jpc.14626

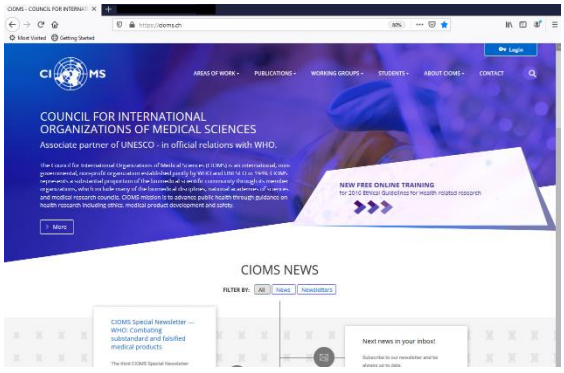
***Mieke Foster, winner of the 2019 CIOMS award**, is in her final year of a Doctor of Medicine at Deakin University in Australia. She has worked with the Joseph Epstein Centre for Emergency Medicine Research team at Western Health, and has recently completed an elective clerkship at Stanford University in the United States.*

Mieke has a keen interest in women's and children's health. She is also a great networker: She led a hugely successful "Teddy Bear hospital" event—aiming to reduce children's fears of hospitals, doctors and dentists— not as the usual school visit but in the hospital foyer, engaging local students from all health-related fields and creating key relationships between the health service and the local community. In the future, Mieke would like to continue to help design safer systems that improve patient outcomes and the healthcare environment.

Submissions are welcome for the 2020 CIOMS award for medical students. Details are found **here**.

News from the CIOMS Secretariat

Find us online: https://cioms.ch 1 Jan–18 Feb 2020: 10 152 visitors 24 759 page views



Top 10 countries:	Top 10 pages:
1. U.S.	Home page
2. India	CIOMS I form
3. UK	Pharmacovigilance
4. Japan	2016 Ethical Guidelines (English)
5. China	Publications
6. Germany	About CIOMS
7. Canada	2002 Ethical Guidelines
8. France	Four new CIOMS publications (news)
9. Switzerland	Practical aspects of signal detection
10. Mexico	2016 Ethical Guidelines (Spanish)

CIOMS in the media

Berlin J, Fang X, Zhang Y. A Summary of Report of the Council for International Organizations of Medical Sciences (CIOMS) Working Group X on Evidence Synthesis and Meta-Analysis for Drug Safety. Chinese Journal of Pharmacovigilance. 2020; 17(2): 121-125. DOI:10.19803/j.1672-8629.2020.02.12. (In Mandarin)

Ivashkin VT, Baranovsky AY, Raikhelson KL, *et al.* Drug-Induced Liver Injuries (Clinical Guidelines for Physicians). Russian Journal of Gastroenterology, Hepatology, Coloproctology. 2019;29(1):101-131. (In Russian, with English abstract)

Research in global health emergencies: ethical issues. London: Nuffield Council on Bioethics; 2020.

Pacheco VM. La comisión nacional de bioética en salud en Ecuador. La utopía de la defensa de la dignidad, la integridad y los derechos de las personas y comunidades (The national commission of bioethics in health in Ecuador. The utopia of defending the dignity, integrity and rights of people and communities). Práctica familiar rural 2019;4(3): 37-46. (In Spanish)

Prado NML, Messias GC, Santos Junior GO *et al.* Prospective monitoring of drug use: drug-induced liver injury in a primary healthcare center. Arquivos de Gastroenterologia, 56(4), 390-393. Epub November 07, 2019.

Proceedings of the VIth Congress of the Asociación Nacional de Comités de Ética de la Investigación (ANCEI), Tarragona, 30-31 May 2019. (In Spanish). *CIOMS guidance was discussed under Topics 2 – The i-Consent Project), 10 – Evaluation of Big Data research, and 14 – Perspective of the research ethics committee.*

Romanov BK, Zykova NI, Alyautdin YV, Olefir YV. Identification and Evaluation of Safety Signals of Drugs Currently under Development Using a Limited Data Set. Safety and Risk of Pharmacotherapy. 2019;7(4):216-20. (In Russian, with English abstract).

van Hunsel F, van de Koppel S, Skalli S, *et al.* Analysis of Hepatobiliary Disorder Reports Associated With the Use of Herbal Medicines in the Global Suspected ADR Database Vigibase. Front Pharmacol. 2019;10:1326. Published 2019 Nov 6. doi:10.3389/fphar.2019.01326.

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* Our offices are not currently staffed due to the COVID-19 outbreak. Please contact us by e-mail.

Upcoming meetings

Working Group XIII: Real-World Data & Evidence in Regulatory Decision-Making
1st Working Group Meeting, 30 March 2020, virtual platform

Patient Involvement in the Development and Safe Use of Medicines
5th Working Group meeting, dates and format under review

Clinical Research in Resource-Limited Settings
6th Working Group meeting , 22 April 2020, virtual platform

CIOMS Executive Committee
87th Meeting, 7 May, virtual meeting

Benefit-Risk Balance for Medicinal Products
2nd Working Group meeting, dates and format under review

MedDRA Labelling Groupings
3rd Working Group meeting, dates and format under review