EXECUTIVE COMMITTEE MEETING 7 May 2020
Update from CIOMS

Dr Lembit Rägo
Secretary-General
of CIOMS

Not everything that can be counted counts and not everything that counts can be counted

CIOMS has established itself as a forum for international, cross-sectoral consensus-building on topics related to bioethics and safety of medicines. As at 31 October 2019:

Members and alternate members from regulatory and research agencies, academia, patient organizations and biopharmaceutical companies participate in the five active CIOMS Working Groups.	**139**
Guidance documents and other publications are available through the CIOMS online bookshop (41 of them for free, including 28 free PDFs.	**56** (41 of them for free, including 28 free PDFs)
22 715 (27 per day)	**Downloads** of the 28 free CIOMS PDF publications have been metered on the CIOMS website since its launch on 12 July 2017. That is 27 downloads per day.
2016 Ethical Guidelines - 11 per day	The CIOMS International ethical guidelines for health-related research involving humans (2016) have been **downloaded** more than 9 times every day on average, or more than 11 times if translations are considered.

Special Newsletter 20 February 2020 (1)

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

This is the third of a series of special newsletters that describe the context of CIOMS activities and the work of its member organizations and partners. It explains what the World Health Organization (WHO) is doing 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.

Quick links

The problem

"Every person has the right to expect that when they use a medical product, whether

Definitions endorsed by the Seventieth World Health Assembly [2]

Substandard medical products

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."

From: The Oxford Statement [1]

All approved medical products have been scientifically proven to treat, prevent or diagnose disease. But this does not mean that all products on the market conform to approved quality standards. Substandard and falsified products are produced, distributed and sold all over the world. The problem is growing as the products themselves and their distribution chains are becoming more complex.

Definitions endorsed by the Seventieth World Health Assembly [2]

Substandard medical products

Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both.

Unregistered/unlicensed medical products

Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/ distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Falsified medical products

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

The term "counterfeit" is not used in this context. This term is usually associated with the protection of intellectual property rights, an area which is expressly excluded from the mandate of the WHO Member State Mechanism on substandard and falsified medical products.[2]

Substandard

Left: Manufacturing defect – a partially formed tablet in a blister pack.
Right: Storage – burst tablets kept unpacked at 40°C/75% relative humidity for 5 days.
(From: WHO Prequalification experience, presentation at ICDRA 2010 [3])

Unregistered

"... the above-mentioned product has not gone through the FDA Philippines registration and testing process. ... Thus, the Agency cannot guarantee its quality and safety."
(From: FDA Philippines Advisory No. 2019-468)

Falsified

A confirmed falsified pack of a product, of which falsified versions were traded globally. The tablets were found to contain paracetamol, instead of the leukaemia medicine ponatinib as stated on the label.
(From: WHO Medical Product Alert No. 2/2019)

Special Newsletter 20 February 2020 (3)

The bottom line

The Oxford statement, of which CIOMS is a signatory, calls for making access to quality medical products an immediate global priority [1]. Effective global coordination mechanisms, including the WHO Member State Mechanism, are working on many fronts to safeguard medicines quality standards. Governments and other decision-makers should sustain these efforts and resource them appropriately in the interest of public health.

- *The issue of substandard and falsified medicines is very actual during the current pandemic – an increase of incidence has been reported from many parts of the World*

References:

1. Newton PN, Bond KC. Global access to quality-assured medical products: the Oxford Statement and call to action. Lancet Global Health. 2019 Dec;7(12):e1609-e1611
2. Newton PN, Bond KC on behalf of 53 signatories from 20 countries. **COVID-19 and risks to the supply and quality of tests, drugs, and vaccines**. Lancet Glob Health, Published OnlineApril 9, 2020 https://doi.org/10.1016/S2214-109X(20)30136-4

CIOMS and COVID-19 Solidarity Fund

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

- Based on CIOMS Executive Committee (23.03.2020) decision 10 000 US $ was donated to this fund

Support to WHO

Extract from the e-mail to CIOMS:

Dear Donors,

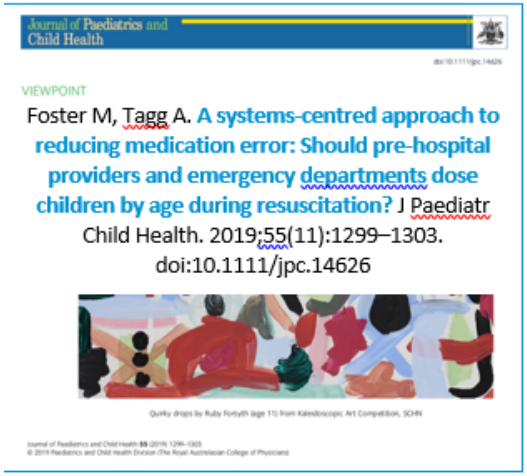
Swiss Philanthropy Foundation is grateful for your support for the COVID-19 Solidarity Response Fund for the World Health Organization (WHO). Because of your generosity, we have been able to raise more than ***$205M million*** *to support WHO and their partners in countries around the globe.*

Student awards 2019

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

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**.

CIOMS Working Groups

CIOMS Working Groups – current situatiom

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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

Clinical Research in RLSs

DILI

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

IOMS WG on Drug-Induced Liver Injury (DILI)

3

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

Working Group reflections in international meetings

- DIA Pharmacovigilance and Risk Management Strategies Conference, Washington DC, United States, 27 - 29 January 2020 – DILI WG – Prof Hervé Le Louet and other WG members

- European Medicines Agency (EMA) Patient and Consumer Working Party, Amsterdam, the Netherlands, 3 - 4 March 2020 _ WG XI – Patient – Dr Lembit Rägo and some other WG members

- And several other meetings postponed (DIA EURO) or converted into virtula (DIA Annual in US)

New Working Group in 2020 – good news!

- Real-World Data and Real-World Evidence in Regulatory Decision-Making started in end of March

In-person meetings cancelled due to COVID-19

- **Clinical Research in Resource-Limited Settings**

6th Working Group meeting , 22–23 April 2020, Geneva, Switzerland

- **Real-World Data and Real-World Evidence in Regulatory Decision-Making**, Geneva, 30-31 March 2020

- **Patient Involvement in the Development and Safe Use of Medicines**

5th Working Group meeting, 1–2 April 2020, Utrecht, the Netherlands

- **Benefit-Risk Balance for Medicinal Products**

2nd Working Group meeting, 29–30 April 2020, Peapack NJ, United States

- **MedDRA Labelling Groupings**

3rd Working Group meeting, 13–14 May 2020, Tallinn, Estonia

Discussion and Conclusions