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

WWW.CIOMS.CH | September 2018 | **Newsletter #** 23

**HIGHLIGHTS**



# International events

## 18th WHO ICDRA conference

The 18th International Conference of Drug Regulatory Authorities (ICDRA) was hosted by the Irish Health Products Regulatory Authority (HPRA) in Dublin, Ireland, on 3-7 September 2018. This biennial conference has been organized by the World Health Organization (WHO) since 1980, and since 2004 it is preceded by a two-day pre-ICDRA meeting open to all interested parties. In Dublin, several hundred regulators discussed current issues under the theme of "Smart Safety surveillance: A life-cycle approach to promoting safety of medical products". CIOMS Secretary-General Dr Lembit Rägo participated in both the pre-meeting and the main event. On the margins of pre-ICDRA, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) organized a panel discussion on the topic

*Delegates at the opening of the 18th ICDRA conference. (Source: Conference website for participants)*

"Importance of Patient Involvement in Regulatory Decision-making: Lessons Learned". Dr Rägo briefly spoke about the new CIOMS Working Group XI on Patient involvement in the development and safe use of medicines. Dr Rägo also participated in the pre-ICDRA side meeting organized by United States Pharmacopoeia (USP), dedicated to a new initiative: the Medicines We Can Trust Campaign.

The main event of the 18th ICDRA included discussions on quality issues, regulatory reform and

*From left to right: Greg Perry (IFPMA Assistant Director-General), Lembit Rägo (Secretary-General of CIOMS); Emer Cooke (Head, WHO Regulation of Medicines and other Health Technologies) and Andrew Spiegel (CEO, Global Colon Cancer Association), at the IFPMA panel discussion.*

strengthening regulatory systems, safety of medical products, substandard and falsified products, access, regulation of clinical trials, regulatory collaboration, harmonization, convergence and reliance, new technologies, and regulation of herbal medicines.

Dr Rägo gave presentations during two ICDRA events: Workshop 5: "Regulation of clinical trials: focus on patient safety", and Plenary 5: "Safety of medical products throughout the product life cycle: moderated panel discussion". On both occasions he gave a short introduction to CIOMS and its activities.

*Dr Lembit Rägo at the ICDRA Workshop 5.*

In Workshop 5 he focused on the 2016 **CIOMS/WHO International Ethical Guidelines for Health-related Research Involving Humans** and the role of patients in the development and safe use of medicines (the topic of a new CIOMS working Group). In Plenary 5 he introduced the basic principles of the 2018 **CIOMS Guide to Vaccine Safety Communication**, a follow-on publication to the 2017 **CIOMS Guide to Active Vaccine Safety Surveillance**, which was referred to in several presentations by participating regulators.

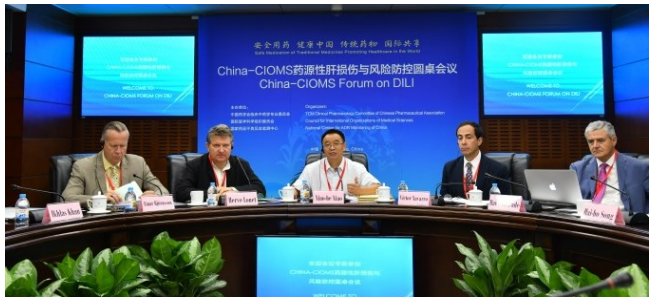
*(From left to right): Dr Sejeng Dorah Diale (South Africa), Dr Agnes Saint Raymond (EMA) and Dr Gopa Raychaudhuri (US FDA/CBER) at the ICDRA Workshop 5.*

## IUPHAR World Congress

In July 2018, IUPHAR organized its **18th World Congress of Basic and Clinical Pharmacology** (WCP2018) in Kyoto, Japan. The theme for WCP2018 was *Pharmacology for the Future – Science, Drug Development and Therapeutics*. Over 4 500 participants from 83 countries were present at the event. The main areas of the meeting matched the spectrum of CIOMS initiatives and Working Groups on clinical trials in resource-limited settings, patient involvement for the safe and effective use of medicines, vaccine safety and communication, but also on therapeutic issues, notably drug-induced liver injury (DILI). The event provided an opportunity for Professor Hervé Le Louet, President of CIOMS, to discuss two new strategic initiatives with Professor Maribel Lucena, treasurer of the **IUPHAR Clinical Division**. Firstly, IUPHAR and CIOMS intend to strengthen their collaboration in the area of pharmacovigilance, where several shared activities may be undertaken. Secondly, CIOMS reaffirmed its interest in participating in the **IUPHAR Subcommittee for Clinical Pharmacology in Developing Countries**, led by Dr Lars Gustafsson and Dr Olayinka Ogunleye. A meeting to be held in January 2019 in Stockholm could lead to the creation of a new CIOMS Working Group, capitalizing on the Council's extensive experience in this field and its great power of circulating recommendations. These two proposals will be submitted to the CIOMS Board with a view to take decisions during the Executive Committee meeting in December 2018.

## China–CIOMS Forum on Drug-Induced Liver Injury (DILI)

In September 2018, CIOMS experts participated in two academic conferences on drug-induced liver injury (DILI) held in Beijing and in Chongqing, China. The Beijing conference was held under the leadership of Professor Wang Jiabo on the theme of liver injury induced by herbs and dietary supplements; the meeting in Chongqing was organized by Professor Haibo Song. Senior experts reported on research progress in the field of DILI in China, including a large study on DILI and drug-induced kidney damage based on electronic medical data.




*(From left to right:) Professor Einar Björnsson, Professor Hervé Le Louet, Professor Xiao-He Xiao, Dr Victor Navarro and Professor Raul Andrade at the China–CIOMS Forum on Drug-Induced Liver Injury (DILI).*

# News from CIOMS partners

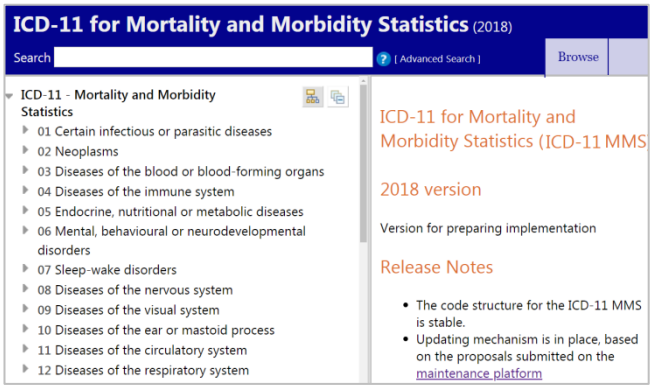
## WHO ICD-11 released

WHO has released the 11th version of its International Classification of Diseases (ICD) terminology. The ICD-11 release is a beta testing version for Member States and other stakeholders to prepare for implementation. ICD-11 took almost 20 years to design, with more than ten thousand comments received during the update process. Among its many new features are a new chapter on traditional medicines conditions, as well as coding for bacteria that have developed antimicrobial resistance (AMR), enabling ICD-11 to support WHO's AMR surveillance programme.

The ICD provides a common global terminology for diseases, disorders, injuries and other related health events, and is thus fundamental for the health community. Interestingly, experience from a joint CIOMS/WHO initiative—the International Nomenclature of Diseases (IND) project, which was active from 1975 to 1992—was used in preparing the previous version, ICD-10.

Today ICD is used in more than 100 countries, is cited in tens of thousands of scientific articles, and is used to allocate the majority of global health resources. It is linked to other terminologies such as the international non-proprietary names (INN) and the Anatomical-Therapeutic-Clinical classification and defined daily doses (ATC/DDD) for medicines.

The new ICD-11 version will be submitted to the WHO Executive Board Meeting in January 2019 and to the Seventy-second World Health Assembly in May 2019 for endorsement. WHO Member States will start using ICD-11 on 1 January 2022.




*ICD-11 can be viewed at:*
***https://icd.who.int/browse11/l-m/en***

## EU information on biosimilars

The European Medicines Agency (EMA) and the European Commission have announced the publication of new information materials on biosimilar medicines. Firstly, an animated video for patients explains key facts on biosimilar medicines and how EMA works to ensure that they are equally safe and effective as their reference biological medicines. The video is available in eight European languages. Secondly, the 2017 guidance titled "Biosimilars in the EU: Information guide for healthcare professionals" is now available in seven languages, providing comprehensive and easily understandable information on both the science and the regulation underpinning the use of biosimilars. The materials are available on the EMA website.

## U.S. FDA guidance on electronic health records

The U.S. Food and Drug Administration (FDA) has published a Guidance for Industry on the Use of Electronic Health Record Data in Clinical Investigations regulated by the FDA. The text replaces the draft guidance issued in May 2016.

*"Every clinical use of a product produces data that can help better inform us about its safety and efficacy,"* said Jacqueline Corrigan-Curay, Director of the Office of Medical Policy in FDA's Center for Drug Evaluation and Research (CDER). The guidance aims to make electronic systems more suitable for use and information exchange by different parties, such as clinicians and researchers.

This guidance will be considered by the CIOMS Working Group on Clinical Research in Resource-Limited Settings. An open session will be held on the first day of the group's upcoming 3rd Meeting in Tallinn, Estonia, to discuss how countries can learn from each other's experience in making electronic health records useful for both clinicians and researchers. As many resource-limited countries are now setting up such systems for the first time, they have the unique chance to consider lessons learned by other countries so as to avoid repeating past mistakes. Pragmatic CIOMS guidance on setting up efficient electronic health records will be of great value for countries wishing to create an enabling environment for the conduct of clinical trials.

# CIOMS Working Groups

*The CIOMS MedDRA Implementation working group*

## 14th MedDRA Implementation Working Group Meeting

The MedDRA Implementation Working Group held its 14th Meeting on 11–12 September 2018 in Geneva. The Medical Dictionary for Regulatory Activities (MedDRA) has been developed by the International Council of Harmonization (ICH) and is widely used for registration, documentation and safety monitoring of medical products.

CIOMS became involved with MedDRA in 2003, when it became clear that there was a need to harmonize the database search strategies used to extract safety information for clinical terms such as "hepatic disorders". Since then, CIOMS Working Groups have developed over one hundred Standardised MedDRA Queries (SMQs). At its 14th Meeting the Working Group reviewed the status of SMQs in production and in development.

Similar harmonization is now needed on how to group MedDRA Preferred Terms (PTs) in the section on adverse events in the approved product information (labelling). MedDRA has almost 23 000 PTs for adverse events, and the MedDRA hierarchy is not always appropriate for grouping them in labelling. Ad hoc groupings are therefore being developed by pharmaceutical companies in consultation with regulators. These groupings have implications for clinical practice as they affect not only the clarity of communication, but also the calculated frequency of the labelled adverse events.

The CIOMS MedDRA IWG is willing to lend its unique expertise to the development of consensus principles for a consistent approach to MedDRA Labelling Groupings (MLGs). The ICH MedDRA Management Committee will discuss this proposal during the next ICH Week, which will take place on 10–15 November 2018 in Charlotte (U.S.).

## Minutes of CIOMS Working Group meetings now on the web

The CIOMS website is being updated constantly to make the Council's activities transparent to the public. The minutes of some recent Working Group Meetings are now available on the CIOMS website. Meeting minutes have been posted on the web pages of the following Working Groups:

- Working group XI on Patient Involvement in Development and Safe Use of Medicines
- Working Group on Clinical Research in Resource-Limited Settings
- Working Group on Drug-Induced Liver Injury (DILI)

## Proposal for new Working Group: Protecting healthy volunteers in clinical trials

Every year, tens of thousands of volunteers participate in safety studies on new medicines or in bioequivalence studies required for marketing authorization of generics. Increasingly these studies are organized in emerging and developing countries, where costs are low. In these settings especially, many people may be in no position to refuse financial incentives offered for study participation. At the same time they may not be able to fully appreciate the risks they are taking. Some volunteers reportedly depend on compensation from studies as a source of income. They may even develop strategies to participate in multiple trials, a practice that is likely to affect their health as well as the study outcomes.

More must be done to ensure that the rights and obligations of healthy volunteers in clinical trials are respected. It is proposed that a new CIOMS Working Group will encourage research into this poorly documented field and make recommendations.

### Do you have an idea for a new Working Group topic?

The mission of CIOMS is to advance public health through guidance on health research including ethics, medical product development and safety. To propose a new topic for CIOMS, contact us at: info@cioms.ch.

# News from the CIOMS Secretariat

## CIOMS supports WHO interns in Geneva

CIOMS is pleased to announce that, based on an agreement with the International Federation of Medical Students' Associations (IFMSA), the first two students has received a grant to support his internship at WHO in Geneva.

*(Right:) Dr Lembit Rägo with Mr **Christos Samaras** from Greece. Christos is a fifth-year medical student at Sofia University in Bulgaria, and has partici–pated in many national and international events and campaigns.*

*(Left:) Dr Rägo with Ms **Rose Adjei Bempah**. Rose is a medical student at the University of Ghana and holds a Master's degree in Public Health from the Ecole des Hautes Etudes en Santé Publique in Paris, France.*

The two interns will spend three months each at the WHO Essential Medicines and Health Products (EMP) Department to assist the Medicines Safety Team. Among other things, this team manages the WHO global pharmacovigilance database of reports on adverse effects of medicines, and maintains information on pharmaceuticals that are not currently approved by governments.

CIOMS created this grant opportunity in February 2018 to contribute to the living costs of one or two IFMSA students per year undertaking a WHO internship in medical research ethics, pharmacovigilance or safety vigilance of medical devices. The aim is to enable the next generation of medical doctors to participate effectively in WHO's technical work. Click **here** for more information.

### Reminder: Award for best scientific paper

CIOMS is offering an award of US$ 1 500 for the best scientific paper written by a medical student on a topic of pharmacovigilance or research ethics. The Selection Committee can approve up to three such awards each year. Click **here** for more information.

## New translations coming soon

The following translations of CIOMS publications are at an advanced stage of production and will be available soon:

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|---|---|
| **International ethical guidelines for health-related research involving humans** (2016) | Russian, Ukrainian, Portuguese |
| **Development and Rational Use of Standardized MedDRA Queries (SMQs): Retrieving Adverse Drug Reactions with MedDRA** (Second Edition 2016) | Japanese |

## WHO INN Programme: Special CIOMS Newsletter

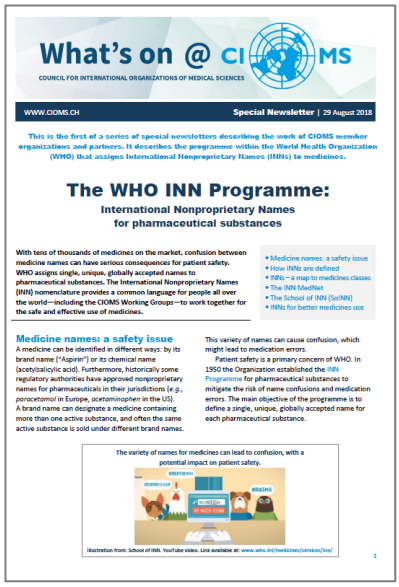
CIOMS has published a special Newsletter on the subject of WHO International Nonproprietary Names (INN). The WHO INN Programme assigns single, unique, globally accepted names to pharmaceutical substances. This nomenclature provides a common language for people all over the world—including the CIOMS Working Groups—to work together for the safe and effective use of medicines.

This is the first of a series of special newsletters describing the work of CIOMS member organizations and partners. It has been very well received:

*"This CIOMS newsflash is excellent and brings to our attention an important topic not only for physicians but for medical students. I am going to upload it in our Clinical Pharmacology signature virtual campus so that they can read it and learn."*

*"I will check if the Indian Journal of Pharmacology can put it in the upcoming issue."*

*"I will refer to this initiative next week in my hospital's drugs & therapeutics committee. We are struggling with using generic names, because antibodies etc. are so difficult."*



What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

WWW.CIOMS.CH Special Newsletter | 29 August 2018

This is the first of a series of special newsletters describing the work of CIOMS member organizations and partners. It describes the programme within the World Health Organization (WHO) that assigns International Nonproprietary Names (INNs) to medicines.

**The WHO INN Programme:**
**International Nonproprietary Names for pharmaceutical substances**

With tens of thousands of medicines on the market, confusion between medicine names can have serious consequences for patient safety. WHO assigns single, unique, globally accepted names to pharmaceutical substances. The International Nonproprietary Names (INN) nomenclature provides a common language for people all over the world—including the CIOMS Working Groups—to work together for the safe and effective use of medicines.

- Medicine names: a safety issue
- How INNs are defined
- INNs—a map to medicines classes
- The INN MedNet
- The School of INN (SoINN)
- INNs for better medicines use

**Medicine names: a safety issue**

A medicine can be identified in different ways: by its brand name ("Aspirin") or its chemical name (acetylsalicylic acid). Furthermore, historically some regulatory authorities have approved nonproprietary names for pharmaceuticals in their jurisdictions (*e.g., paracetamol* in Europe, *acetaminophen* in the US). A brand name can designate a medicine containing more than one active substance, and often the same active substance is sold under different brand names.

This variety of names can cause confusion, which might lead to medication errors.

Patient safety is a primary concern of WHO. In 1950 the Organization established the INN Programme for pharmaceutical substances to mitigate the risk of name confusions and medication errors. The main objective of the programme is to define a single, unique, globally accepted name for each pharmaceutical substance.

The variety of names for medicines can lead to confusion, with a potential impact on patient safety.

Illustration from: School of INN. YouTube video. Link available at: www.who.int/medicines/services/inn/

## CIOMS IN THE MEDIA

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

Bloomsmith MA, Perlman JE, Hutchinson E, Sharpless M. Behavioral Management Programs to Promote Laboratory Animal Welfare. In: Weichbrod RH, Thompson GAH, Norton JN, editors. Management of Animal Care and Use Programs in Research, Education, and Testing. 2nd edition. Boca Raton (FL): CRC Press/Taylor & Francis; 2018. Chapter 5.

Borgeat Meza M, Luengo-Charath X, Arancibia M, Madrid E. Council for International Organizations of Medical Sciences (CIOMS) Ethical Guidelines: advancements and unsolved topics in 2016 upgrade. Medwave. 2018 Apr 25;18(2):e7208. DOI: 10.5867/medwave.2018.02.7208.

London AJ. Social value, clinical equipoise, and research in a public health emergency. Bioethics. 2018;1–9. DOI: 10.1111/bioe.12467.

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Ravinetto R, Pinxten W, Rägo L. Quality of medicines in resource-limited settings: need for ethical guidance. Global Bioethics. 2018; 29 (1); 81-94.

Smith MJ, Weinstock D. Political legitimacy and research ethics. Bioethics. 2018;1–7. DOI: 10.1111/bioe.12489.

Tieu C, Breder CD. A Critical Evaluation of Safety Signal Analysis Using Algorithmic Standardised MedDRA Queries. Drug Safety. 2018 16 August; 1-11. DOI: 10.1007/s40264-018-0706-7.

Wiktorowicz M, Moscou K, Lexchin J. Transnational pharmacogovernance: emergent patterns in the jazz of pharmaceutical policy convergence. Globalization and Health. 2018; 14: 86.

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**Monika joined CIOMS on 1st July 2018.**

## UPCOMING MEETINGS

**3rd Meeting of CIOMS Working Group on Clinical Research in Resource-limited Settings**
8–9 October 2018, Tallinn, Estonia

**2nd Meeting of CIOMS Working Group XI: Patient Involvement in Development and Safe Use of Medicines**
23–24 October 2018, Berlin, Germany

**4th Meeting of CIOMS Working Group on Drug-Induced Liver Injury (DILI)**
27–28 November 2018, Aix-en-Provence, France