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

WWW.CIOMS.CH March 2017 | **Newsletter #** **17**

HIGHLIGHTS

1) New CIOMS Working Group on Drug- Induced Liver Injury (DILI)

2) New CIOMS publications

3) New e-shop on CIOMS website

IMPROVING ACCESS TO CIOMS PUBLICATIONS

New e-shop on CIOMS Website

CIOMS publications can now be obtained more easily through the new e-shop module of the CIOMS website at the following link: http://cioms.ch/shop/

The free publications can be downloaded and priced publications purchased online with a credit card. There is also immediate delivery of electronic versions of publications following the payment of an order.

CIOMS offers special discounts on a selection of the most recent publications which only applies to an order **of the same publication**:

Discount for 2 or more hardcopies

- 2 -5 copies 10% discount
- 6 -10 copies 20% discount
- 11 -20 copies 30% discount
- 21 -50 copies 40% discount
- 51 -50 copies 50% discount
- More than 50 – usually 50%, but contact CIOMS for further possible discount.

Several free publications are also available in both electronic and hard copy forms (with posting cost to be paid) at: http://cioms.ch/shop/product-category/free-publications/

Availability of CIOMS guidelines in other languages on increase

CIOMS has always had a limited budget for translations but the translations into other languages gather momentum. The most favoured CIOMS publication for translations into other languages is the recent 2016 International Ethical Guidelines for Health-related Research Involving Humans.

CIOMS is in the final stage of concluding a special agreement with the Pan American Health

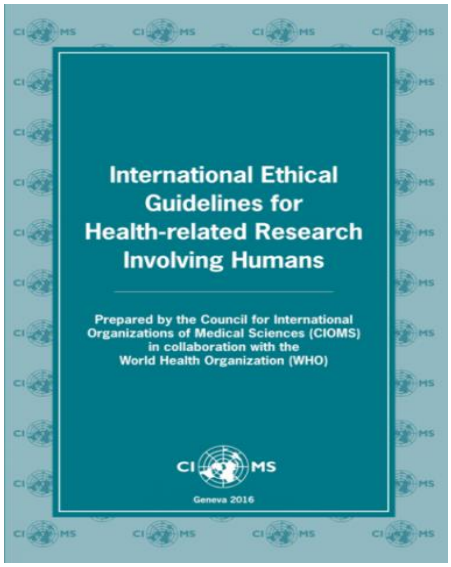
Organization (PAHO)[1] for translating these international ethical guidelines into Spanish. The translation work has already started. CIOMS gratefully acknowledges the generous support from the Brazilian Federal Council of Medicine[2] for translating these important guidelines also into Portuguese. In addition to Spanish and Portuguese translations, the translation into Japanese is also secured. At present negotiations are ongoing to translate these guidelines in addition to the three mentioned languages into Chinese, French and Russian.

The CIOMS Secretariat is also in the process of arranging Chinese translations of several CIOMS guidelines in the area of pharmacovigilance. CIOMS also wishes to acknowledge the generous offer from the Mexican regulator COFEPRIS to help CIOMS to translate the CIOMS Guide to Active Vaccine Safety Surveillance into Spanish. The CIOMS Secretariat is also working on translating some more important CIOMS pharmacovigilance guidelines into Russian.

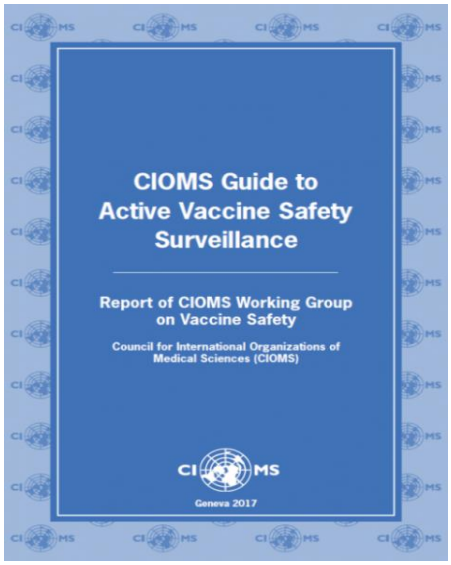
CIOMS is exploring further opportunities for translations, including potential acceptable sponsors and skilful translators willing to work for free.

New CIOMS Publications

CIOMS published the following two new publications, and they can be purchased from our e-shop at http://cioms.ch/shop/product-category/recently-published/



The electronic version of this publication is available for **free** download.



NEW CIOMS WORKING GROUP

CIOMS launches a new Working Group on Drug-Induced Liver Injury (DILI). The incidence of drug-induced liver injury (DILI) is a growing challenge because of the ever-increasing number of drugs used in medical care. It is responsible for more than 10% of all cases of acute liver failure, posing a major clinical and regulatory challenge. In a recent and well-executed population-based study, the crude annual incidence of DILI was 19.1 cases per 100,000 persons (95% CI, 1.54-23.3). In many instances, the hepatotoxic potential of a drug can only be recognized post-

[1] PAHO has two institutional hats: it is the specialized health agency of the Inter-American System and also serves as Regional Office for the Americas (AMRO) of the World Health Organization (WHO), the specialized health agency of the United Nations.

[2] The Conselho Federal de Medicina (CFM, Portuguese for *Federal Council of Medicine*) is the Brazilian public agency officially in charge of professional regulation and medical licensing in the area of medicine in the country. It is headquartered in Brasília, in the federal district. The CFM is represented by a regional council in each Brazilian State.

marketing, and DILI is one of the most frequent reasons for marketed drug withdrawal and modification of labelling. The clinical pattern of DILI is diverse and can mimic almost any form of liver disease, ranging from asymptomatic elevation in aminotransferases to severe diseases such as cirrhosis or acute hepatitis leading to acute liver failure, making it difficult for an easy and early diagnosis. It remains largely unpredictable and is not amenable to efficient preventive measures. Being an important cause of mortality and liver transplantation, and a leading cause of attrition in drug development, DILI remains a public health issue of great importance which needs additional international consensus guidance. After exploring interest among key stakeholders, CIOMS has decided to launch a new Working Group (WG) composed of academia, industry and regulatory partners to address the present knowledge and practice gaps related to DILI in order to formulate pragmatic consensus-based recommendations to address the major outstanding issues. Furthermore, collaborative efforts aimed at capitalizing on existing initiatives will also be a part of the WG in order to provide output that is as comprehensive as possible. The first meeting of this WG is scheduled for 27-28 April 2017 in Geneva.

UPDATE ON CIOMS WORKING GROUP

MedDRA Working Group Meeting: 22-23 March 2017, Geneva

The CIOMS MedDRA*Implementation Working Group (IWG) met in Geneva from 22-23 March 2017 and was attended by 18 representatives from regulatory and pharmaceutical organizations, as well as academia, the MedDRA Maintenance and Support Services Organization (MSSO) and the Japanese Maintenance Organization (JMO).

The teams charged with developing specific Candidate Standardised MedDRA Queries (SMQs), e.g. SMQs for Dehydration, for Hypokalaemia and for Hallucinations, presented their test results and findings to the IWG for discussion, bringing these SMQs forward in a well-established process towards production. In parallel, the IWG continued to tackle two extremely challenging topics by further testing and refining Candidate SMQs for Opportunistic infections and for Infusion related reactions.

In addition, the IWG discussed ongoing work on a Concept Paper that explores the feasibility of developing groupings of MedDRA terms for use in presentation of safety information in the labelling of medicinal products.
*Medical Dictionary for Regulatory Activities

Meeting with WHO, ISoP and CIOMS

CIOMS hosted the meeting between WHO, International Society of Pharmacovigilance (ISoP) and CIOMS on 28 February 2017 in Geneva. WHO was represented by Dr Clive Ondari, Coordinator for the Safety and Vigilance (SAV) team and Dr Shanthi Pal, Group Lead for Medicines Safety in the SAV team in the Regulatory Unit of the Essential Medicines and Health Products (EMP) Department. ISoP was represented by its new President, Mr Sten Olsson, and CIOMS was represented by the President of CIOMS, Professor Hervé Le Louet and Secretary-General, Dr Lembit Rägo. The meeting was opened by Dr Rägo who emphasized the common interests and shared values of the three organizations in protecting public health with the need for effective collaboration. Updates from WHO, ISoP and CIOMS followed. Further, the challenges and opportunities for strengthening pharmacovigilance systems globally were briefly discussed with the focus on complimentary synergies and the added value of working together.

It was decided to share the short and longer team events calendar of the WHO Pharmacovigilance (PV) Programme where CIOMS, ISoP and WHO

could work together. Identified events included the WHO PV National Centers meeting in Uganda (tentative dates for pre-meeting joint activities include 5-6 November 2017, Kampala, PV Inspection Training Course in China (Q4 of 2017) and the pre-meeting workshop on pharmacovigilance to precede the WHO International Conference of Drug Regulatory Authorities (ICDRA) pre-meeting workshop on PV (2018). It was also decided that the two Presidents will cooperate to set up a roster of PV experts for WHO to be used in training and other activities. As follow-up also continuation of discussions on the topics of mutual interest for the new potential CIOMS Working Groups was considered. WHO colleagues informed ISoP and CIOMS about the new WHO initiative in the area of regulatory systems strengthening - Coalition of Interested Parties (CIP) who would like to work with WHO in the area of regulatory systems strengthening. It was envisaged that the CIP Strategic Advisory Group (SAG) for PV should include CIOMS and ISoP participation.

Left to right: Clive Ondari, Lembit Rägo, Hervé Le Louet, Shanthi Pal, Sten Olsson

Maternal Immunization Safety Meeting

During 23-24 January 2017, the Secretary-General of CIOMS, Dr Lembit Rägo (LR) represented CIOMS in the Maternal Immunization Safety Monitoring in Low- and Middle Income Countries meeting organized in Seattle by Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) and Bill & Melinda Gates Foundation (BMGF). The meeting was well attended by senior staff from BMGF and GAPPS, governmental institutions and regulators, WHO, pharmaceutical industry and academic research institutions. Several speakers referred to CIOMS as a source of authoritative guidance in the area of pharmacovigilance. LR provided all participants with information about the new CIOMS Guide to Active Vaccine Safety Surveillance. This was very well received. LR also participated in group discussions and after-meeting discussions at the BMGF. He emphasized that CIOMS can take on board additional new topics of interest provided there is enough support from CIOMS core stakeholders. Most important among several informal discussions was a short meeting with Dr Jan Bonhoeffer, President of Brighton Collaboration Foundation. It was agreed to explore opportunities to continue good collaboration by drafting a concept note about a new mutually interesting CIOMS Working Group.

CIRS Workshop in Sao Paulo

The Secretary-General of CIOMS, Dr Lembit Rägo (LR), was invited to participate in the Centre for Innovation in Regulatory Science (CIRS, more at http://www.cirsci.org/) Workshop entitled Facilitating the review of new medicines through risk-based evaluations: How can a stratification process be utilized to achieve an effective use of resources. The workshop took place in Sao Paulo Airport Marriott Hotel in Brazil from 8-9 March 2017. The workshop was attended by well-established regulators from the developed world and also regulators from the emerging economies both inside and outside of the region. It was also attended by international pharmaceutical industry representatives, mostly from the region. The workshop had presentations aiming to explore models and approaches to risk-based reviews and decision making, including advantages and barriers to risk-based stratification. The opening presentation was given (via Skype) by Mr Mike Ward, Coordinator for Regulatory Systems Strengthening in the World Health Organization Headquarters in Geneva, Switzerland. Mr Ward gave WHO's views on what implementation of risk-based approaches mean in drug reviews and why countries should consider such an approach. A number of interesting presentations from CIRS staff, regulators and industry followed. LR gave a

presentation on managing medicines safety during the post-approval phase. LR pointed out that many CIOMS publications are very relevant to all concerned parties in managing post-approval safety risks. He also actively participated in a roundtable discussion focusing on managing risks during the post-approval phase, clarifying the roles and responsibilities of the company, regulator and other stakeholders.

CIOMS Ethical Guidelines symposium in Peru

On 30 March 2017 a special symposium dedicated to new CIOMS International Ethical Guidelines for Health-related Research Involving Humans took place in Peru. During the day CIOMS immediate past President Professor Johannes J.M. van Delden delivered several presentations about new important features of the guidelines. The symposium was co-sponsored by the Pan American Health Organization and World Health Organization. There is more information about the symposium "International Symposium: New CIOMS Guidelines on human research" on the website of the Peruvian NIH, there is information about

http://www.portal.ins.gob.pe/es/cursos-y-eventos/1375-simposio-internacional-nuevas-pautas-del-cioms-sobre-investigacion-con-seres-humanos

This information is also in Facebook of the Peruvian NIH.
https://www.facebook.com/INSPeruOficial/photos/a.416080468523998.1073741828.415512341914144/985342394931133/?type=3&theater

DIA EMEA Outstanding Contribution to Health Award

CIOMS is delighted to announce that Dr Lembit Rägo, Secretary-General of CIOMS, has been selected as the 2017 DIA Inspire Awards winner for the Drug Information Association (DIA) Europe, Middle East & Africa (EMEA) Regional Outstanding Contribution to Health Award, for his significant and innovative contributions to advancing global health.

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UPCOMING MEETINGS

1st Meeting of CIOMS Working Group on Drug-induced Liver Injury (DILI), Geneva, Switzerland
27-28 April 2017

12th Meeting of MedDRA Implementation Working Group, Geneva, Switzerland
20-21 September 2017

84th CIOMS Executive Committee Meeting, Geneva, Switzerland
28 November 2017