What's On @ CIOMS!

The April 2014 Newsletter presents reports from the Working Groups on Vaccine Safety, MedDRA, and WHO's MIM, and also introduces the Acting Secretary-General.

CIOMS Working Group on Vaccine Safety

The 3rd meeting of the CIOMS Working Group (WG) on Vaccine Safety was held at the Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA on 5-6 February. Dr Denise Cardo, Director of CDC's Division of Healthcare Quality Promotion, opened the meeting and welcomed the participants. She explained that this Working Group mirrors CDC's priorities in vaccine-preventable diseases and global health because health issues, including concerns about the safety of vaccines, are not limited by borders. She noted how adverse effects following immunizations (AEFIs) can be rare meaning that, therefore, there is an even greater need for partnership and collaboration across sectors. A great thanks to our host! The background for this WG was presented in the CIOMS Newsletter of June 2013.

The formation of this WG is linked to the activities of the Global Vaccine Safety Blueprint of WHO and its implementation plan: the Global Vaccine Safety Initiative (GVSI). It is a global strategic plan that aims at assisting low and middle-income countries (LMICs) in their work on vaccine safety surveillance. This WG was initiated by CIOMS together with colleagues from WHO at its first meeting in London in May 2013.

The participants at the Atlanta meeting included 20 senior scientists from regulatory authorities, biopharmaceutical industry, public health authorities and other stakeholders from around the world.

Dr Ulf Bergman (see below), Acting Secretary-General of CIOMS, gave a presentation which summarized the mission and history of CIOMS and also on the progress to date on the WG on Vaccine Safety. Since the first meeting when numerous topics were discussed, the WG consists of the following three topic groups:

1. Dossier for Pre- and Post-Licensing Vaccine Safety Information
2. Active Surveillance Strategy
3. Crisis Communication Management

Plenary and break-out sessions took place over the 2-day meeting which allowed robust dialogue and debate in a multi-stakeholder format, leading to mutually agreed upon directions. Attention was focused on soliciting LMIC perspectives and input.

The primary consensus goals are to produce a dossier, guides, and additional deliverables in approximately two years with a draft business plan (work plan for deliverables and methods) to be presented at the 4th meeting in May 2014, hosted by the Uppsala Monitoring Centre (UMC), the WHO Collaborating Centre in Uppsala, Sweden.

The CIOMS WG on Vaccine Safety Website:

https://workspace.who.int/sites/CIOMS-WG-vaccine-safety/

Participants in the CIOMS WG on Vaccine Safety at CDC in Atlanta, February 2014

CIOMS IWG on MedDRA SMQ

CIOMS Implementation Working Group (IWG) on Standardised MedDRA Queries (SMQs) had its 5th meeting at ICH/IFPMA in Geneva 9 - 10 April 2014. A great thanks to our host!

The objective of the IWG is to continue the work together with the MSSO to review SMQs in production as well as new ones and to evaluate home grown queries. The IWG has also decided to update the CIOMS "Red book" of SMQs. Some SMQs discussed during the meeting in April were: pulmonary hypertension, blood premalignant disorders, acute renal failure, SMQs that are already in production and are now subject to revision while others are in development, e.g. respiratory failure, tendinopathies and ligament disorders, hypoglycaemia, tubulointerstitial disorders, proteinuria and dehydration.

The final draft of the second edition of the SMQs "Red book" is expected to be completed this year. The next meeting will take place in Geneva in September.

Participants in the CIOMS IWG on MedDRA SMQ at the meeting at ICH/IFPMA in Geneva, April 2014

MIM Meeting at WHO/HQ

CIOMS took part in a WHO informal consultation on MINIMAL INFORMATION MODEL (MIM) for reporting and vigilance for safety in health care

This was a meeting at WHO with global representation headed by Dr Itziar Larizgoitia, Technical Officer, Service Delivery and Safety, WHO, on behalf of a WHO wide Task Force involving technical areas concerned with reporting and vigilance for safety in health care, on 1-2 April 2014.

The main objectives were to facilitate an international and interdisciplinary discussion concerning reporting and vigilance systems for safety in health care among different areas of health care. Experiences in reporting systems of adverse events were presented from Haemovigilance and Blood Safety by Drs Jo Wiersum, the Netherlands and Erica Wood, Australia; Vigilance of Medical Devices by Drs Adriana Velazquez Berumen, WHO; Andrea Hanson, Ireland and Jitendra Kumar Sharma, India; Occupational Health and Injection Safety by Dr Ahmed Gomaa, CDC, USA; Radiation Safety by Drs Mary Coffey, Ireland and Ola Holmberg, Austria; *in vitro* diagnostic medical devices by Dr Anita Sands, WHO; and Patient Safety by Dr Joergen Hansen, Denmark.

Ulf Bergman, Acting Secretary-General at CIOMS, presented "The CIOMS reporting form" in the session: Reporting systems for Pharmacovigilance and Vaccine Safety and he also chaired the final general discussion. Other presenters in the Pharmacovigilance and Vaccine Safety session were Drs Shanti Pal, WHO; Priya Bahri, European Medicines Agency, United Kingdom; Alexander Dodoo, Ghana; Rachida Soulaymani, Morocco and Zhang Qi for Traditional Medicines.

One important point raised by Rachida Soulaymani was that we cannot have several parallel reporting systems if we want to make progress in vigilance and safety in health care.

Participants at WHO's MIM meeting at WHO in April 2014

In this Newsletter we have the pleasure to introduce Ulf Bergman who is serving as Acting Secretary-General of CIOMS until 1 August 2014.

He obtained an MD and PhD in clinical pharmacology at the Karolinska Institutet in Stockholm, Sweden.

He has 40 years of experience in clinical pharmacology, as outlined in the recent CIOMS/IUPHAR/WHO report "Clinical Pharmacology in Health Care, Teaching and Research" (Figure, see also the CIOMS website, from which it can be downloaded).

His research was initially related to the WHO Symposium on "Consumption of drugs in Oslo 1969" and his PhD in 1978 was on "*Studies of Drug Utilization. Clinical Pharmacological and Epidemiological Aspects*".

The Defined Daily Dose (DDD) combined with the Anatomical Therapeutic Chemical (ATC) classification system was later approved by WHO and is now being used all over the world. The Adverse Drug Reaction (ADR) monitoring system run by the WHO Collaborating Centre for International Drug Monitoring – the Uppsala Monitoring Centre (UMC) - classifies all drugs according to the ATC, and the volume unit DDDs provides a useful but rough denominator in quantification of population drug use in ADR monitoring in many countries. Ulf spent a Fellowship year in Epidemiology at the University of Pennsylvania, and at Merck, Sharp & Dohme in 1984-1985.

Until recently, Ulf served as a Professor at the Karolinska Institutet in Clinical Pharmacology and Pharmacoepidemiology, with focus on research, supervision of PhD students, postdocs and senior researchers; international collaboration in Asia, Europe, Canada and the USA with focus on pharmacovigilance and pharmacoepidemiology, quality of drug prescribing, drug use in the elderly, quality indicators, and "rational use of drugs"; and with corresponding clinical responsibilities as a Senior Medical Officer at the County Council in Stockholm.

Ulf is also one of the founders of the European Drug Utilization Research Group (EuroDURG, originally WHO-DURG); its next meeting will be in Groningen, the Netherlands on 27-29 August 2014 (www.EuroDURG2014.com), and the International Society for Pharmacoepidemiology (ISPE). Its 30th International Conference on Pharmacoepidemiology & Therapeutic Risk Management will be held in Taipei, Taiwan on 24-27 October 2014 (www.pharmacoepi.org/meetings/30ICPE/index.cfm).

Ulf has been a temporary adviser to the WHO Regional Office in Europe in Copenhagen since1976 and to WHO Headquarters in Geneva since 2000. Since 1998, he has been a permanent observer at the WHO International Working Group for Drug Statistics Methodology in Oslo.

He was a Deputy Member of the UMC from 2000-2009. The Clinical Pharmacology Department at Karolinska Huddinge also harboured a Regional Adverse Drug Reaction centre where he was active. This centre supported the national centre at the Medical Products Agency in Uppsala and thus indirectly contributed to the UMC in the field of pharmacovigilance.

Based on the epidemiological studies of ADRs causing hospitalizations, the focus has recently been on drug use in the elderly. The CIOMS/IUPHAR/WHO report on "Clinical Pharmacology in Health Care, Teaching and Research" states "The concept of personalised medicine is one where drug therapy can be based on the pharmacogenetic or *other characteristics of a particular patient*."

The *characteristic* his research group has focused on is reduced renal function in the elderly. This has not been taken into account when prescribing many

drugs dependent on renal function for their elimination.

Since 2013 he has been a Senior Professor at the Karolinska Institutet. Ulf is also a member of: the Steering Board of the Centre for Gender Medicine, Karolinska Institutet; WHO Collaborating Centre in Oslo: the International Working Group for Drug Statistics Methodology (ATC/DDD); and the European Network of Centres for Pharmacovigilance and Pharmacoepidemiology (ENCePP) of the European Medicines Agency (EMA), London.

He is very much enjoying his current work at CIOMS in Geneva.

The Secretary-General of CIOMS, Dr Gunilla Sjölin-Forsberg passing on the baton to the Acting Secretary-General, Dr Ulf Bergman, at the office in February 2014

UPCOMING CIOMS MEETINGS IN 2014

5th Working Group on MedDRA, ICH, Geneva, Switzerland, 9-10 April 2014

4th Vaccine Safety Working Group, UMC, Uppsala, Sweden, 20-21 May 2014

6th Working Group on Revision of CIOMS International Ethical Guidelines, Geneva, Switzerland, 21-23 May 2014

5th Vaccine Safety Working Group, Rabat, Morocco, 24-25 September 2014

8th Working Group X on Meta-analysis, Basel, Switzerland, 30 September – 1 October 2014

7th Working Group on Revision of CIOMS International Ethical Guidelines, Geneva, Switzerland, 12-14 November 2014

81st CIOMS Executive Committee Meeting, Geneva, Switzerland, 18 November 2014

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