



## What's On @ CIOMS!

- OFFICE AFFAIRS

In February 2010, Dr Gottfried Kreuz retired from his position as Secretary-General of CIOMS. Dr Kreuz had been a valuable member of the CIOMS Secretariat since 2006 and we wish him all the best in his retirement back home in Berlin.

With this, CIOMS is pleased to introduce the new Secretary-General, Dr Gunilla Sjölin-Forsberg, joining the staff in Geneva from Sweden.



Gunilla Sjölin-Forsberg is a medical doctor trained in clinical pharmacology and dermatology at the University and University Hospital of Uppsala and the Karolinska Institute and Huddinge Hospital, Stockholm, Sweden. For several years she participated in the education of medical students parallel to conducting research in experimental and clinical skin pharmacology and training in clinical pharmacology and dermatology. She then continued as associate attending physician and consultant in dermatology at the University Hospital, Uppsala, before entering regulatory medicine in the late nineties. Her position for the last seven years has been Head of Department of Drug Safety at the Medical Products Agency (MPA) in Sweden, a position that for the last years also she combined with being a delegate of the Pharmacovigilance Working Party (PhVWP) at the European Medicines Agency (EMA), London.

Dr. Sjölin-Forsberg has been a member of the WHO Advisory Committee on Safety of Medicinal Products since 2005 and has experience of CIOMS activities having been a member of CIOMS Working Group VIII designed to focus on the lifecycle of safety signals. She is very much looking forward to her new position as Secretary-General of CIOMS.

*A note from Dr Gunilla Sjölin-Forsberg:*

"CIOMS activities have for me, through the years, always represented high quality international standards and recommendations of medical science. I am therefore very grateful for the opportunity to be engaged with CIOMS and have the possibility to take part in future developments. High profile issues of CIOMS have previously been medical research ethics and drug safety. It will be important to continue developing and maintaining the working documents already produced within these areas. In addition, new challenges will come within the medical horizon.

It is of great importance for CIOMS to identify new issues where there is need for review and adoption of common principles and standards between concerned bodies. The adopted CIOMS guidelines are intended to be supportive to decision-making concerning issues related to drug development.

Let's hope the future will be as productive as the past!"

**\*!!!! CIOMS WEBSITE !!!!!\***

We are pleased to announce the new-look CIOMS website. With a new face, the CIOMS website should now be easier for users to access all the important CIOMS information and browse CIOMS publications!

[www.cioms.ch](http://www.cioms.ch)

- NEW CIOMS PUBLICATION

The much anticipated Report of **CIOMS Working Group VIII: *Practical Aspects of Signal Detection in Pharmacovigilance***



In recent years public expectations for rapid identification and prompt management of emerging drug safety issues have grown swiftly. Over a similar timeframe, the move from paper-based adverse event reporting systems to electronic capture and rapid transmission of data has resulted in the accrual of substantial datasets capable of complex analysis and querying by industry, regulators and other public health organizations.

These two drivers have created a fertile environment for pharmacovigilance scientists, information technologists and statistical experts, working together, to deliver novel approaches to detect signals from these extensive and quickly growing datasets, and to manage them appropriately. In following this exciting story, this report looks at the practical consequences of these developments for pharmacovigilance practitioners.

The report aims primarily to provide a comprehensive resource for those considering how to strengthen their pharmacovigilance systems and practices, and to give practical advice. But the report does not specify instant solutions. These will inevitably be situation specific and require careful consideration taking into account local needs. However, CIOMS Working Group VIII is convinced that the combination of methods and a clear policy on the management of signals will strengthen current systems.

Finally, in looking ahead, the report anticipates a number of ongoing developments, including techniques with wider applicability to other data forms than individual case reports. The ultimate test for pharmacovigilance systems is the demonstration of public health benefit and it is this test which signal detection methodologies need to meet if the expectations of all stakeholders are to be fulfilled.

- CIOMS WORKING GROUPS

- **\* NEW CIOMS Working Group!**

**CIOMS Working Group IX on "Practical Considerations for Development and Application of a Toolkit for Medicinal Product Risk Management"**

The working group is composed of members from the pharmaceutical industry, regulatory agencies, governmental institutions, and academia and was created in April 2010.

The plan is to develop a pragmatic consensus guideline to be used by industry and regulators. It will contain a harmonized list of tools for managing risks of medicinal products intended for human use that can be applied globally, as well as the potential application of these tools. Main focus will be on risk minimization.

**CIOMS Working Group VIII on "Application of Signal Detection in Pharmacovigilance"**

The conclusions of this Working Group have now been finalized and are in press. See announcement under the heading: *New CIOMS publication*.

CIOMS in 2006 set up a working group of senior scientists (from drug regulatory authorities, the pharmaceutical industry, and academia) in order to develop consensus Points to Consider in the development and application of quantitative methods for signal detection using pharmacovigilance databases.

The contents of the publication focus on signal detection systems, strategies and program, stakeholder perspectives and signal management. Future directions in signal detection, evaluation and communication are elaborated. Key definitions of pharmacovigilance, taxonomy of drug safety signals and discussions on different systems of spontaneously reported data, traditional methods of signal detection and statistical data mining methods are also included.

- CIOMS EXECUTIVE COMMITTEE

The 77<sup>th</sup> CIOMS Executive Committee meeting and the XXth CIOMS General Assembly will be held during the afternoon of Tuesday, 30 November 2010 from 13:00 to 18:00 at WHO Headquarters in Geneva.

At the meeting this year we will be voting on a number of new positions on the Executive Committee, including President and Vice-President.

CIOMS will be calling for nominations for these vacant positions soon and would like encourage all CIOMS National and International Members to consider nominating.

Further details will be sent to all CIOMS Members in the near future.

- PANEL DISCUSSION

In conjunction with these meetings CIOMS will be hosting a panel discussion which will take place on Tuesday, 30 November 2010 from 09:00 to 12:00, at WHO Headquarters.

As you may know, CIOMS has promoted ethics since its creation in 1949 and this mini-symposium will focus on aspects of ethical update and more specifically the implementation of ethical principles in medical practice (from bench to bedside) with case examples.

The topic of *"Implementation of ethical principles in medicine from bench to bedside: How the physician may integrate the treatment of his patient with science"* is to be discussed by a panel of expert members, followed by a question and answer session.

This is expected to be a most interesting and informative discussion and CIOMS will forward further details, including the announcement of Panel Members, in the near future.

- UPCOMING TRAVEL/MEETINGS

**28-29 June 2010** CIOMS WG IX (2<sup>nd</sup> meeting)  
Leuven, Belgium  
(Dr G. Sjölin-Forsberg attending)

**19-22 Aug 2010** ISPE, Brighton, UK  
(Dr G. Sjölin-Forsberg attending)

**16-18 Sept 2010** EACME, Oslo, Norway  
(Prof. M.B. Vallotton attending)

**28-29 Sept 2010** MedDRA 5<sup>th</sup> Core Group Mtg  
Bayer Schering, Berlin  
(Dr G. Sjölin-Forsberg attending)

- CIOMS Secretariat

**Secretary-General**

Dr Gunilla Sjölin-Forsberg  
Tel: 041 22 791 3406

**Administrative Officer**

Ms. Amanda Owden  
Tel: +41 22 791 3467

**Secretary**

Ms. Lisa Hodson  
Tel: +41 22 791 3413

**Senior Advisers**

Prof. Juhana E. Idänpään-Heikkilä

Mr Sev Fluss

Dr Jan Venulet

**c/o World Health Organization**

Avenue Appia  
CH - 1211 Geneva 27  
SWITZERLAND

Fax: +41 22 791 4286

Email: [cioms@who.int](mailto:cioms@who.int)

**WEBSITE:** [WWW.CIOMS.CH](http://WWW.CIOMS.CH)