

# MUR50



**Uppsala Reports half-century celebration**

**The Global Fund | West Africa Health Organization**

**Three UMC publications | ISoP is 10**



Marie Lindquist  
Director  
the Uppsala Monitoring  
Centre

## **Yes, it's a birthday!**

Many readers have expressed their appreciation of Uppsala Reports and the important role it has played in the establishment of UMC's presence round the world in the last decade. I hope it will continue to document the development of the young and expanding field of pharmacovigilance: we need now, as much as ever, confidence and a strong voice to call for the commitment and resources which will improve the welfare and safety of patients in every country of the world.

## **What's in a name?**

It is very encouraging to see the steps that are now taken by major regulators and industry to upgrade their pharmacovigilance systems, including concerted efforts to apply the principles and practice of risk management, to be more proactive, and to use new methods and data sources.

I agree whole-heartedly with a life-cycle risk management approach: to plan one's safety monitoring activities based on all available pre-marketing information, including the pharmacological properties of a drug substance; to detect, assess, communicate and minimise risks; and to evaluate continuously and put into context the accumulating knowledge of perceived and real benefits, weighed against potential and real harm. To me, this is what pharmacovigilance practitioners ideally should be doing.

However, pharmacovigilance is a concept not well known beyond a quite small group of specialists, and if one considers the ever-increasing number of guidelines, regulations, conferences and articles referring to 'risk management', it is not immediately apparent to the newcomer in the field that risk management in this instance is a component of pharmacovigilance, and not a separate discipline.

So what's the problem, apart from a possible over-use of the buzzwords of the day? My concern is that people will underestimate the depth and scope of pharmacovigilance, or perhaps more to the point, what it should be. When we seek to engage with new partners, we must make it clear, in words and action, that pharmacovigilance is not a mostly bureaucratic exercise concerned with shuffling case reports in and out of databases, with a focus on processes and procedures and fulfilling regulatory requirements. This could have been the case, had it not been for persistent efforts over many years by dedicated colleagues in the pharmacovigilance community to progress the science and practice. Not only have we pushed back the boundaries and made better use of existing data, but also developed, refined and extended methods and data sources, all with the safety of patients and the needs of healthcare providers as the top priority. Where we may have been less than successful, is in explaining and promoting the scope and importance of what we do.

Today there seems to be general agreement that the focus should be on patient safety (maximising the benefit of drug treatment and protecting patients from harm) rather than drug monitoring (what's wrong with the drug), and that we need to use new methods and data sources as a complement to, but not replacing, adverse event/reaction reporting schemes. Good communication practices are essential, as are evaluation and impact assessment. The introduction of more systematic, active, planned safety surveillance following general risk management principles is another step forward.

This is all great – and my hope is that these improvements are seen as a natural and essential development of pharmacovigilance, taking it into the future. It is only with an integrated approach, bringing together all the available information, tools and techniques, that pharmacovigilance can continue to play a key role in ensuring patient safety.

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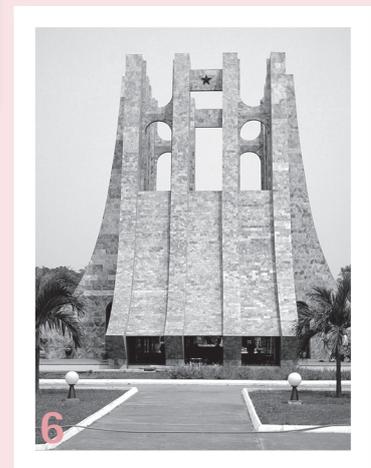
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UMC staff have been out and about

taking part in training activities and conferences; we report from some of these events.



Who cares?

The UMC do – getting out from their desks to support sponsored activities in Uppsala.



# Kenya joins the Programme

*Dr Jayesh M Pandit, Head, Department of Pharmacovigilance*

On the 4<sup>th</sup> of May 2010, Kenya became the 98<sup>th</sup> full member of the WHO International Drug Monitoring Programme. Following a focused VigiFlow training organized by UMC-Africa in collaboration with WHO and UMC Headquarters from 21<sup>st</sup>-23<sup>rd</sup> April 2010 in Accra, Ghana, Kenya submitted the required minimum number of ADR reports.

Located on the eastern coast of Africa, with a population of around 38 million, Kenya initiated formal pharmacovigilance activities in late 2004. Since then, formal mechanisms have been put in place and the department

Dr K C Koskei, the Registrar, adds "I am most impressed with the training curriculum that the Department of Pharmacovigilance has developed and the passion they have shown in conducting the trainings. It is really helping to sensitize and train all health professionals in Kenya in the area of pharmacovigilance. I have heard from many sources that they are benefitting properly from the training we are providing and are regaining the faith in the Drug Regulatory Authority in addressing issues pertaining to patient safety", he said in one of the provincial trainings held.

Mr G Muthuri and Dr E Abwao, officers in the department of pharmacovigilance remind me, "we are doing very well since we are focused, – patient safety is the goal we strive towards. But we need to scale up our activities now and involve the public even more to keep this success on."

## Training programme

Since the 2009 launch, we have trained over 350 health workers in formal five-day pharmacovigilance courses and sensitized over 1,100 Kenyans, public and private, on pharmacovigilance. We acknowledge the wonderful support from WHO, UMC, UMC-Africa and MSH-SPS toward strengthening the pharmacovigilance system in Kenya and look forward to greater inter-country working relationships, especially from Africa, towards enhancing patient safety through the medicines they consume.

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*Kenyan pharmacovigilance team at the Pharmacy and Poisons Board (from left) Dr Edward Abwao, Dr FM Siyoi (Deputy Registrar), Dr K C Koskei (Registrar), Dr Jayesh Pandit and Mr G Muthuri*

is gradually gaining the strength and capacity to ensure safety of patients in Kenya. The formal launch of the National Pharmacovigilance System only took place on 9th June 2009 (see UR47, p11). "We have come a long way" the Deputy Registrar Dr F M Siyoi said, "reflecting from the initial days when the National Vision for Pharmacovigilance was being detailed to me by Jayesh. We have since developed very well designed national guidelines and reporting tools, and have already disseminated them across the country, with focused trainings that are well accepted by all health providers and by the public health programmes too" he added, during a meeting with stakeholders in Kenya.

## Reporting quality issues

The Department has also managed to incorporate very well the issue of reporting poor quality medicines into the otherwise well known, routine system of detecting, reporting and managing Adverse Drug Reactions (ADRs). To date, the department has received 72 poor quality medicinal product complaints. This has brought the department to work very closely with other departments within the Drug Regulatory Authority such as the Pharmaceutical Inspectorate, Drug Registration and Good Manufacturing Practice departments. It truly helps us work together as one team, one Regulator, which may not necessarily be the case otherwise.

# Zambia – a toast to full membership!

*Oscar Simooya*

For most people in this part of the world, the year 2010 will be remembered as the year when the soccer World Cup was held for the first time on the African continent. However, for us at the Regional Pharmacovigilance Centre in Kitwe, Zambia, 2010 shall best be remembered as the most significant year in the development of pharmacovigilance in Zambia.

After years of associate membership, the country was in March this year finally accorded full membership of the WHO Programme for International Drug Monitoring. Our thrill and excitement after receiving this news will certainly rival that expected from the Lionel Messi, Wayne Rooney and other megastars at the football extravaganza in South Africa!

## Preparation for membership

Zambia's initial contact with the WHO programme was made in 2001 when I attended the international pharmacovigilance course in Uppsala. This was followed by a proposal to the Ministry of Health (MOH) recommending the establishment of pharmacovigilance in Zambia.

## New structures

In October 2004 the Pharmaceutical Regulatory Authority (PRA) was established to replace the Pharmacy and Poisons Board (PPB). The PRA is an autonomous body under the MOH with the responsibility of among other things, monitoring drug safety. Later in 2006 the National Pharmacovigilance Unit (NPVU) was set up within the PRA to coordinate pharmacovigilance in the country. In view of an increasing work load at the NPVU, the PRA in April 2008 designated the Copperbelt University Health Services as a Regional Centre for coordinating pharmacovigilance in the northern part of the country comprising five provinces – Copperbelt, Luapula, Northern, North Western and Western. The Regional Centre would later be given the mandate to represent the NPVU/PRA in all pharmacovigilance matters.

## First reports

The process of promoting adverse drug reaction (ADR) reporting began immediately after our appointment and by March this year we had collected 550 ADR reports.

## VigiFlow boost

From last November we started using VigiFlow culminating in our recognition as the 97<sup>th</sup> full member of the WHO Programme. Our vision is to be an excellent centre of pharmacovigilance.

The Regional Centre is manned by three people; Oscar Simooya, Physician/ Clinical Pharmacologist; Boyd Lunshano, Pharmacist and Kaselekela Poshano, Senior Pharmacy Technologist.

Finally, as we toast our new status, special thanks go to colleagues at the WHO, UMC and in Vigimed for having encouraged and motivated us in our work.

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*The Regional Pharmacovigilance Centre team in Kitwe, Zambia working on VigiFlow. Oscar Simooya (seated), with Kaselekela Poshano (left) and Boyd Lunshano*

Further impetus to the programme was made in 2004 when the WHO held a regional meeting in Lusaka, Zambia to promote pharmacovigilance, in particular that of artemisinin-based combination therapies (ACTs) for malaria. Following this meeting Zambia attained associate membership of the WHO programme.

These reports are mainly due to anti-retrovirals, anti-malarials and product quality problems. In addition, the NPVU has received 295 ADR reports, mainly from clinical trials, the Tropical Disease Research Centre and pharmaceutical manufacturers.

# Ghana – the 2010 centre of pharmacovigilance

Alex Dodoo



*The meeting venue*

Crossed by both the equator and the Greenwich meridian, Ghana will become the heart of pharmacovigilance later this year. The 33<sup>rd</sup> Annual Meeting of countries participating in the WHO Programme for International Drug Monitoring will take place in its capital, Accra, from 31<sup>st</sup> October 2010 to 3<sup>rd</sup> November 2010. That will be followed by the 10th Annual Meeting of the International Society of Pharmacovigilance (ISoP), and there will be a joint WHO-ISoP Symposium on 3<sup>rd</sup> November 2010 which promises to be extremely exciting. All the major players in pharmacovigilance have confirmed their participation in the joint symposium which is expected to be a Global Health Initiative event with donors, international organizations, non-governmental agencies and pharmacovigilance technical service providers all expected to attend.

Ghana is a good choice for this first ever meeting of National Centres in sub-Saharan Africa. It was the first country in the region to obtain independence and has, since joining the WHO Programme in 2001 contributed actively and passionately to the work of the Programme. Ghana was the first West African country to join the WHO Programme and has been involved and supportive of the establishment of National Centres in five other countries in the region including Nigeria, Togo, Sierra Leone and Senegal. Currently, the WHO has designated the University of Ghana Medical School as a WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance. The Uppsala Monitoring Centre also has its Africa

operations coordinated from Accra with the UMC-Africa offices located in Accra (see page 16).

There is so much to look forward to in Ghana – 555 km of golden sandy beaches, historic forts and castles dating back centuries, a rich cultural tradition and very safe cities and communities. The UK magazine *Time Out* puts it nicely when it describes Ghana as “Africa for beginners”. It is Africa not like you would probably expect – safe, relaxed, friendly and efficient. Join your colleagues and friends in Ghana to network and also to enjoy this truly wonderful destination which has affordable accommodation, good inexpensive restaurants and a buzzing night life. Oh, of course, and a future World Cup winning football team!



*The many sides of Ghana*

# The Global Fund and drug safety

*Serge Xueref*

The Global Fund to fight AIDS, TB and Malaria (GFATM, or 'the GF') has provided a unique support to countries in scaling up access to medicines critical for the treatment of HIV, malaria and TB. However, concerns remain regarding the safety and safe use of these medicines in low and middle income countries with a high prevalence of co-morbidities and inadequate systems to monitor the quality as well as the adverse events linked to these medicines.



*Serge Xueref*

## Pharmacovigilance within emerging health systems

Increasingly, pharmacovigilance (PV) is regarded as a cross-cutting area, calling for innovative strategies to be built in the perspective of strengthening health systems. To date, countries applying for GF grants have not systematically included a description of their PV systems and/or a plan to strengthen PV in their programmes; the GF, WHO and partners have not yet taken a pro-active role to thoroughly enforce the implementation of PV systems through GF grants.

## Strategy to help countries

The GF and WHO are now addressing this issue by developing a strategy for integrating PV into treatment programmes as a (core) component of a health system, as a standard of care and as a key component to ensure health program effectiveness. One of the key objectives is to ensure that all grants implement PV, based on minimum requirements, before moving on to more mature PV systems. WHO, with financial support from the GF and in collaboration with technical partners such as UMC, its

collaborating centre in Ghana and the USAID-funded SPS program (MSH), is now developing such PV minimum requirements (see page 22). WHO and partners are also developing with GF support the PV toolkit, a practical set of PV tools and processes gathered into a user-friendly toolkit to be offered to countries.

The rolling-out of the GF PV strategy will follow a phased approach, with a 18-month first phase of "proof of principle" starting in the fall 2010 in 10-20 invited countries that will aim at documenting cost-effective PV approaches for low and middle-income countries, reflecting on their past PV activities (what has worked, what has not worked and why?), and field testing the PV minimum standards, the PV toolkit as well as new PV techniques. Based on lessons learned, the future GF strategy on PV will be finalized and proposed to the GF Board to decide whether it should be globally rolled-out in all countries receiving GF resources.

visible and consistent with WHO definitions. Applicant Countries are invited to describe their national pharmacovigilance systems, to propose a plan to strengthen them as appropriate and request for GF resources as needed.

Finally, the GF pharmacovigilance strategy is designed in a way so it will not be limited to the GF grants, as national PV activities shall not be specific to GF monies invested in the countries: other Global Health Initiatives are invited to participate and to co-own the strategy. UNITAID and the World Bank already expressed their interest in joining this initiative.



*Offices of the Global Fund to fight AIDS, TB and Malaria are located in Geneva*

## Updating application forms

In the meantime, as a concrete and immediate measure, the GF has updated its application and proposal forms in April 2010 for Round 10 (deadline for submission of proposals: 20 August 2010), so pharmacovigilance is more

# FP7 updates

## Uppsala meeting for PROTECT

Ennita Nilsson

WP3 and prepared for the upcoming interim report for the first 12 months of this 5-year project. The full-day meeting allowed for discussions regarding the coordination roles and responsibilities, a further update on the current sub-project status reports, and identifying early deliverables to include in the first year report.

## Monitoring Medicines launches new website

Ennita Nilsson

The Monitoring Medicines project officially launched its website on the 8<sup>th</sup> of June 2010. The website will serve as a communication platform to all partners. A partners' forum site is being created and by end of July we hope to have this up and running. Project materials will be posted, and a discussion forum will facilitate communication to all participants.

Patient safety is very much the focus of this project. Importantly, the project will also strive to advance consumer involvement in reporting of ADRs, and to mobilize and sustain political commitment to working on drug safety issues. "The issues are not national, they are international and to solve them, you have to have a global approach," writes Sten Olsson, the Project Coordinator, in the 'Science, Technology and Innovation Projects magazine' [www.projects.eu.com/](http://www.projects.eu.com/).

The project is now in the tenth month of its 3½-year period, funded by the Seventh Framework Programme (FP-7) of the Research Directorate of the European Commission (EC). The agreement between the EC and the Uppsala Monitoring Centre came into force on 1 September 2009. To follow the progress, updates on the work packages and news, visit the project website [www.monitoringmedicines.org](http://www.monitoringmedicines.org); for more information contact the Project Manager, Ennita Nilsson, at e-mail: [ennita.nilsson@who-umc.org](mailto:ennita.nilsson@who-umc.org) or telephone +46 18 651657



Michael Kayser, Jim Slattery, Annette Prella, Niklas Norén and Ennita Nilsson during the June meeting

On the 15<sup>th</sup> June 2010 the PROTECT\* project coordination team met in Uppsala. The project is receiving funding from the European Commission's Seventh Framework Programme (FP7/2007-2013) for the Innovative Medicines Initiative. The project aims to strengthen the monitoring of the benefit-risk of medicines in Europe by developing innovative methods. The objectives are to enhance early detection and assessment of adverse drug reactions from different data sources (clinical trials, spontaneous reporting and observational studies) and to enable the integration and presentation of data on benefits and risks.

Niklas Norén, Research Manager at UMC, is co-leading the Work Package 3 (WP3) together with Michael Kayser (Bayer-Schering), Jim Slattery (EMA), and Bharat Thakrar (Roche) (who unfortunately could not participate in this meeting). Annette Prella (Bayer-Schering) and Ennita Nilsson (UMC) joined the coordination team recently. WP3 is looking at the methods for signal detection, aiming to develop new methods, and assess existing ones, for signal detection from spontaneous reports, electronic health records and clinical trials. The meeting reviewed recent progress in

\*PROTECT stands for *Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium*.

### Monitoring Medicines

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#### News Bulletin

Abstract accepted for a major international conference  
An abstract, titled "Early Indicators of Drug Dependence"...  
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Optimizing drug safety monitoring to enhance patient safety and achieve better health outcomes.

#### About the Monitoring Medicines

'Monitoring Medicines' is a project, running for 42 months, funded by the Seventh Framework Programme (FP-7) of the Research Directorate of the European Commission (EC). The agreement between the EC and the Uppsala Monitoring Centre came into force on 1 September 2009.

#### What is Monitoring Medicines?

- The four themes are:
- Strengthening consumer reporting
  - Pharmacovigilance centres collecting problems related to inappropriate drug use
  - Better use of existing global pharmacovigilance data
  - Developing active and focussed pharmacovigilance systems.

The Monitoring Medicines website <http://www.monitoringmedicines.org/>

# Singapore hosts ASEAN pharmacovigilance training

*Sten Olsson*

The Health Sciences Authority (HSA) in Singapore invited delegates from all member countries of ASEAN (Association of South East Asian Nations) for a five-day basic pharmacovigilance training course, on 29 May–4 June, 2010. The training, supported by WHO and the UMC, was arranged in response to a recommendation from the ASEAN Working Group for Pharmaceutical Development, which had identified the need to build pharmacovigilance capacity in the region. The programme offered was an adaptation of the basic pharmacovigilance course given biannually by the UMC. Course participants came from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Thailand, Vietnam and Singapore. They represented countries with very different levels of development in pharmacovigilance. Systems in Malaysia,



*Course participants and lecturers in Singapore (Singapore photos credit: James Chan)*



*John McEwen speaking at the Singapore course*

Thailand and Singapore are well established while pharmacovigilance activities have only just recently been initiated in Cambodia and Lao PDR.

Delegates were welcomed by Division Director of HSA, Dr Christina Lim. Lectures were given by HSA staff (Chan Cheng Leng, Belinda Tam), by senior clinical experts from Singapore (Chng Hiok Hee, Chow Wan Cheng), and were brought in from WHO-HQ (Shanthi Pal), UMC (Sten Olsson, Monica Plöen) and Australia (John McEwen). Lectures were intermingled with working

group discussions and 'hands-on' computer sessions. The focus of the deliberations was on how to build capacity, including human, technical and financial resources, for further development of pharmacovigilance activities and regulatory systems to ensure that patients in all ASEAN countries can benefit from the availability of only efficacious, safe and high quality medicines.

Before the course was closed by HSO chief executive officer John Lim, each country presented a pharmacovigilance action plan for the coming year.

## 4<sup>th</sup> Rabat course

*Cecilia Biriell*

Following on from the success of previous courses, the 4<sup>th</sup> 'Cours Francophone Inter pays de Pharmacovigilance' was held in Rabat from 21 to 25 June 2010 with 28 participants. These French-language courses, run by the Moroccan national centre and WHO, have offered pharmacovigilance training for the national centre staff in many countries over the years.

The 2010 cohort came from Burkina Faso, Burundi, the Central African Republic, Democratic Republic of Congo, France, the Republic of Guinea, Senegal, and Morocco itself. Senior staff from the Moroccan centre shared the teaching alongside Shanthi Pal from WHO.



*Rabat participants in the Moroccan sunshine*

## Causality workshop in Ankara

*Ronald Meyboom*

A workshop on causality assessment in pharmacovigilance was held in Ankara, Turkey on 30<sup>th</sup> September and 1<sup>st</sup> October last year. It was organised by the Technical Assistance Information Exchange Instrument (TAIEX) of the European Commission, in co-operation with the Turkish Pharmacovigilance Centre (TUFAM), General Directorate of Pharmaceuticals and Pharmacy, and aimed to develop TUFAM personnel in the various skills needed in pharmacovigilance. The meeting took place at the beautiful premises of the Turkish Pharmacists' Association.



*Guest speakers in Ankara: Thomas Goedecke, Ronald Meyboom, Ulf Bergman, Nicholas Moore*

Twenty-five people attended; in addition to the TUFAM group, Professor Semra Şardaş, chair of the Pharmacovigilance Committee of the Turkish Ministry of Health's Advisory Board, and a few other members of this committee and related scientists took part. There were speakers from four European countries. After an opening statement from former Director General Dr Mahmut Tokaç, TUFAM, Chief Pharmacist Demet Aydınkarahaliloglu gave a presentation of TUFAM's activities. Dr Ronald Meyboom (The Netherlands) focussed on the principles underlying pharmacovigilance and 'spontaneous reporting', such as the classification of adverse reactions and other drug-related problems, case report assessment, signal detection, and causality assessment. Professor Nicholas Moore (France) reviewed pharmacovigilance and risk management from the perspective of pharmacoepidemiology, and Mr Thomas Goedecke (London) discussed the design of pharmacovigilance plans and the use of the EU Risk Management Plan Template (EMA/192632/2006). On the second day, Professor Ulf Bergman (Sweden) covered drug utilisation studies and presented recent experiences at the regional pharmacovigilance centre in Stockholm.



*Semra Şardaş, chair of the Turkish Pharmacovigilance Committee*

Ronald Meyboom and TUFAM staff also had a meeting to discuss a selection of real-life adverse reaction reports received at the Turkish centre. One of the observations was that there may be an amount of subjectivity and personal experience involved in the assessments and that in a given report somewhat different outcomes may be 'good'.

Thanks to the great hospitality of TUFAM and its team everyone had a very pleasant stay in Turkey's capital Ankara, with its rich history rooted in antiquity.

## Lithuania

*Helena Wilmar and Magnus Wallberg*

In mid-June, Helena Wilmar and Magnus Wallberg from the pharmacovigilance services department at the UMC spent 1½ days at the State Medicines Control Agency (SMCA) in Vilnius.

The purpose of the visit was to meet and to establish extended collaboration with the Medicines Safety and Information Unit, the



*Staff working at the Medicines Safety and Information Unit at SMCA:*

*Justina Penkauskaitė, Virginija Zilenaite-Puodziuvienė, Helena Wilmar (UMC), Lina Kaminskyte and Rita Kalvelyte*

unit where pharmacovigilance issues are handled. On the first day the Deputy Director of SMCA, Dr Rimantas Jankunas, attended, and topics such as 'How to encourage ADR reporting in the country' and 'How to avoid duplication of work when submitting ICSRs to EudraVigilance and to the UMC' were discussed.

On the second day, a demonstration of the search tool VigiSearch was performed. Some specific modules in VigiFlow, with relevance for European Union countries dealing with EudraVigilance, were also demonstrated and discussed. The input from staff at the unit will be valuable for the ongoing Gateway project that will enable VigiFlow users within the EU to easily connect to EudraVigilance system.

## Communications about patient safety in pharmacotherapy

*M. Kriška, D. Sedláková (on behalf of Scientific Committee, Smolenice Castle Symposia)*

Dating from 1985, scientific meetings have been held in Smolenice Castle in western Slovakia, with clinical-pharmacological topics becoming a tradition. The very first one was a WHO symposium entitled 'The proper use of drugs in infancy', and others followed even during the years of limited East-West communications. This period was fruitful not only for purely scientific meetings, but important as a means of communications for enthusiastic and creative participants, building a modern framework of pharmaco-therapeutic care in this region.

Thus, under the auspices of Richard Raši, Minister of Health of the Slovak Republic, an international symposium entitled 'Communications about Drug Safety' was held at Smolenice Castle on 21<sup>st</sup> and 22<sup>nd</sup> May 2010 to mark the quarter century of meetings. Organized by the Medical Faculty of the Comenius University, in collaboration with the WHO Country Office in Slovakia, and with support from the Slovak Academy of Sciences and the Medical Faculty of the Košice University, the symposium presented perspectives on one of the major challenges in public health today. Representatives of regulators, academia, patient organizations and the pharmaceutical industry reviewed



*Symposium participants line up in Smolenice*

the alternatives for an effective system of pharmacovigilance.

After an opening lecture from P. Gibala 'Communication in drug safety – approach of State Institute of drug control (SDI Slovakia)', giving the Slovak system of pharmacovigilance within the EU system, the programme continued with 'Communication and patient safety with medicines' (R. Edwards, UMC) which critically described the current status of patient safety systems, while setting out further visions of how they could be improved. The EMA's approach to patients' safety (H. Fitt) highlighted the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), an excellent system of independent science-oriented institutions; and A. Carvajal from Valladolid University in Spain spoke on the position of universities in this network. Other sessions during the day included 'ADRs in real-life practice: pharmacovigilance, pharmacoepidemiology and the role of ISoP' (N. Moore), 'The impact of adverse effects of medicines on public health' (J. R. Laporte) – with real case scenarios showing goals to minimizing risk, J. Vlček's 'How to start with teaching communicative skills with patients' from the Pharmaceutical Faculty of Hradec Králové, and V. Rusnakova described a pilot hospital survey in 'Patient safety culture in Slovakia'.

The following day included a lecture on 'Spontaneous Reporting – lessons from the past and uses for the future' (R. Meyboom), and 'How does modified PEM support risk management?' (S. Shakir), pointing out the specialized methods in the British system of proactive pharmacovigilance. The role of clinical pharmacology in pharmacovigilance was examined (F. Sjöquist), patient safety during pharmacotherapy was reviewed using case examples (M. Grundmann) and 'Patient and industry in pharmacovigilance' (A. Czarnecky) prepared a good platform for discussions among industry, academia,

regulators and patient community. J. Petrenko covered 'Proper communication with patient'; and J. Sikač defined 'The role of generic industry in patient safety communications'. 'What constitutes a successful patient organization for allergy and airways disease' was discussed by G. Čapova-Chovanova. The meeting concluded with J. Bacou on the European Union Network for Patient Safety, and 'Risk of drug perception and patient safety' (M. Kriška). Selective topics were presented as posters.

Communication about patient safety in pharmacotherapy represents a key element not only in risk assessment but leads to the final success of therapy. We are again appreciative that presented papers are to be published in the *Bratislava Medical Journal*.

## Focus on risk communication

*Bruce Hugman*

The Thai FDA's Health Product Vigilance Centre (HPVC) held its annual meeting in Bangkok, 28–29 June.

Around four hundred physicians, pharmacists, academics and officials from across the country gathered to address the meeting's theme, Risk awareness and communication for consumer safety. The topics included current research topics in health product vigilance; the pan-Asian problem of hazardous skin-whitening products; the role of community pharmacies in risk communication and patient safety; medication error; misleading health product advertising; medication error; and developments in pharmacovigilance planning and drug registration in Thailand.

Running through much of the discussion was the challenge of transforming risk communication into safe action by

physicians, pharmacists and patients – moving beyond transmitting messages to changing behaviour, and how effectiveness could be measured. There was an impressive range of research posters, including several by HPVC staff.

Wimon Suwankesawong, Head of HPVC, and her team managed the meeting with their usual hospitable efficiency.

## Spanish centre

*Elki Sollenbring*

On June 16–18 I took part in an Analysis and Risk Management course of the 'Escuela Nacional de Sanidad' in Madrid, Spain. I took the opportunity to visit Spain's National Centre, AEMPS (Agencia Española de Medicamentos y Productos Sanitarios).



*Mariano Madurga, Elki Sollenbring and Raquel Granados*

Mariano Madurga and Raquel Granados showed me various aspects of their daily work. Among other things we went through their database 'Fedra', and had a discussion about how to improve the duplicate detection of ICSRs in collaboration with the UMC. It's very exciting to see the hard work the National Centre does to improve and maintain their pharmacovigilance.

# WHAT YOU MIGHT HAVE M

International, serious and sometimes humorous, occasionally controversial, *Uppsala Reports* has reached its half-century. This 50th edition of *Uppsala Reports* is different from the very first one in April 1996; as well as having changed its appearance, the aims of *Uppsala Reports* have also evolved – from raising awareness of the existence of the WHO Collaborating Centre, to covering activities of other groups and offering perspectives not otherwise available, as well as some glances at pharmacovigilance history.

The first edition of *Uppsala Reports* in 1996 set out the reasons the UMC was launching its newsletter:

- to explain the Centre's work regularly and clearly to member countries and to our wider audience
- to report and examine significant current issues in drug safety
- to share useful developments and discoveries from around the world
- to keep up-to-date with more personal and informal news

Although it has expanded in size, *Uppsala Reports* continues the early editions' remit to reflect the concerns of the

Centre and of the WHO Programme. UR2 explained what happened to signals; there was also a report from Japan, and Ambrose Isah wrote about the 1996 pharmacovigilance training course in Uppsala.

The third issue focussed on the important topic of IT, along with a report from the Programme meeting in Lisbon (driven by concerns over the ICH), the first of regular full reports from annual WHO Programme meetings. UR4 asked "Why do doctors report?", and noted the setting up of Vigimed.

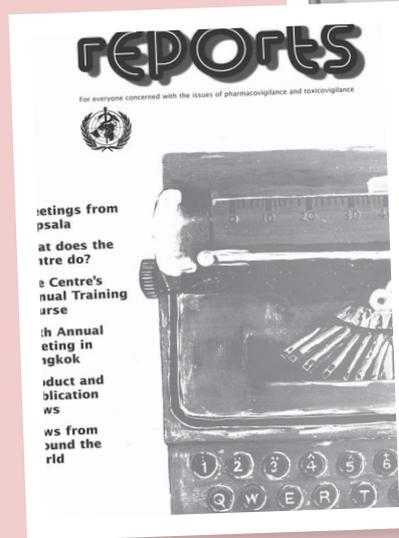
*Uppsala Reports* 5 in 1997 covered the UMC's move to new premises in central Uppsala. Updates from 'big' countries looked at pharmacovigilance in Russia and relations with regional centres in India.

In issue 6 the Erice Declaration was in the spotlight, and the 30<sup>th</sup> anniversary of the WHO Programme was reviewed. The editor noted the death of Garth McQueen, and introduced the herbals work of the Centre. UR10 examined internet learning, and revealed, not for the last time, the sporty side of UMC staff – dressed as Robin Hood and his merry men.

A summary of the 1999 Signal Review panel meeting featured, along with Ralph Edwards's description of a recent work trip – to Prague, London, Mexico, Brazil, Denmark, and South Africa! *Uppsala Reports* 12 announced the ADRespherics data-mining service for commercial customers; and appealed for sharing of promotional materials.

The next issue reported on a UMC visit to China, and had a long list of new publications; by UR15 it was time to attempt to answer the question "What does the UMC actually do?"

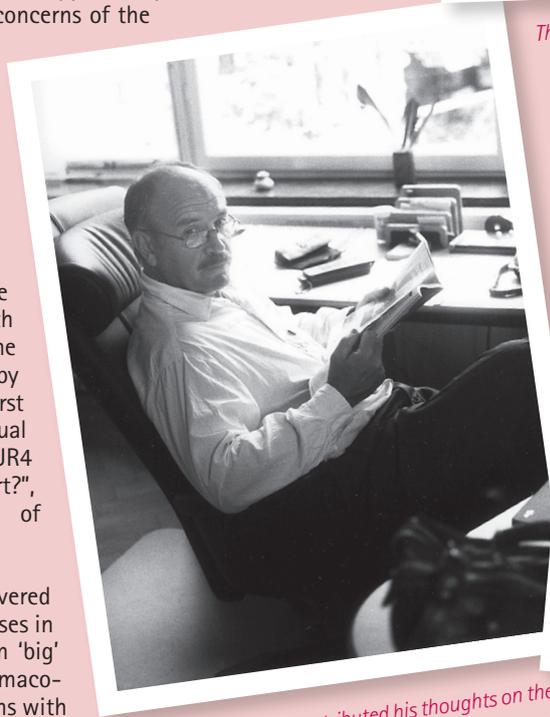
UR18 initiated regular summaries on the status of the WHO ICSR database, as well as having a 'big country' report from Brazil.



The very first issue



We report on research at the Centre: Marie Andrew Bate celebrated their PhDs



Ralph Edwards contributed his thoughts on the progress – or otherwise – of pharmacovigilance in his Director's Messages, from the first issue until his retirement



*Uppsala Reports* has profiled key pioneers in pharmacovigilance, including Bill Inman



The UMC moved to an office in the square of the city in 1997 and stayed there until 2008



The Signal Review Panel in 1999 in Uppsala – their vital work is



UMC staff often participate in sporting and cultural activities in Uppsala, including this fancy-dress boat race in 1999



Controversies have found

# ISSUED IN THE FIRST 50 ISSUES



Marie Lindquist and  
in 2003



Woodcut Erice Peter Falb

We've followed the formative meetings of drug safety experts in the Sicilian town of Erice, whose skyline was drawn by Peter Falb in 1997



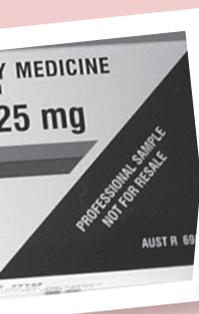
Erice in the central  
and remained there



Ralph Edwards and Mohamed Farah picking *Camellia sinensis* in China in April 2000



9 during their meeting in  
reported in our pages



their way into our pages



Björn Håkansson, keynote speaker at the anniversary meeting of the WHO Programme in 2008

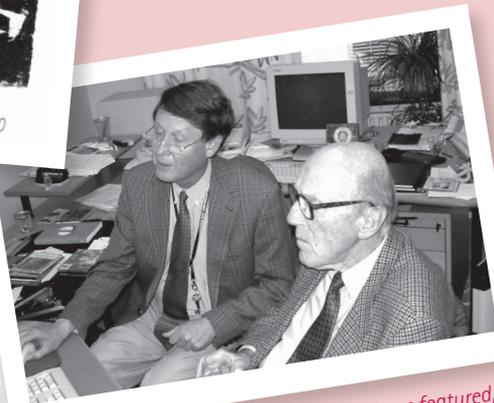


Västgöta student club male voice choir in Uppsala Castle during the 2008 Annual Meeting gala dinner

*Uppsala Reports* increased to 20 pages, with longer, more detailed articles, while still keeping news snippets in 'News from Around the World'. 'Drug Advertising to Consumers' and 'Behind the Scenes at Reactions Weekly' were featured in UR19, and an interview with Roland Orre about data-mining.

UR21 in January 2003 had a major re-design, and included the first of our occasional series of 'profiles' – David Finney, who was followed in later editions by profiles of Jan Venulet and Ed Napke.

The Information Component was explained in UR23, and we celebrated recent staff PhDs. Marie Lindquist described the new UMC database in UR24 – comparing the work to changing a car engine while on the road. As well as new Associates of the WHO Programme being introduced (eight in that issue), we present all our new permanent staff when they join us.



Our welcome visitors have featured, such as Jan Venulet (right) who visited us in 2004

WHO Drug Dictionary and UMC products and services news featured prominently in the 25<sup>th</sup> edition, while number 26 covered training on immunization safety, Burundi's sentinel sites, and visitors, including Jan Venulet.

Another breakthrough – 'Vigibase on Line' (now VigiFlow) was presented, as well as the opening of a web-shop for UMC products; Bill Inman was interviewed.

The Vioxx controversy was fully covered, and we launched the Drug Dictionary Enhanced – which reached one million entries three issues later. Consensus meetings on youth and medicines and medicinal plant safety standards were reported.

Each *Uppsala Reports* has a 'Director's message' editorial, on major issues in drug safety; Ralph Edwards concluded his directorship with a piece entitled 'Alice in Vigiland' – and in UR31 we printed some views on the just-released film *The Constant Gardener*, while in UR43 a 'personal view' asked awkward questions about the safety of medicines in developing countries, following a challenging article in UR36 which discussed 'are PSURs worthwhile?'

Over the last few years *Uppsala Reports* has looked at the UMC's collaboration with Utrecht University, at training in the Drug Dictionary, had an in-depth update from the FDA, and announced the latest versions of VigiFlow.

The 2008 anniversary meetings in Uppsala were covered in word and image in UR44.

Our aim to be as international as possible can be seen from UR47, with reports from Senegal, Denmark, Mozambique, Kenya, Panama, Sri Lanka, Croatia, USA, Ghana, Czech Republic...

UR48 focused on the theme of openness: from the Director's message, reporting from within the EU, and usage of search tools by national pharmacovigilance centres. The Centre's scientific collaboration – with journals, professionals, advanced students – was strongly featured in the next issue.

# 7th ACSoMP

Sten Olsson

The WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) was convened for its 7<sup>th</sup> annual meeting in Geneva from 26–28 April, 2010. Two of the regular members were unable to participate as a consequence of the volcanic ashes spread over the European air space last April. On the other hand two members were welcomed to ACSoMP for the first time; Dr Alejandra Rosete from Mexico and Dr Yogendra K Gupta from India. The meeting was chaired in rotation by June Raine, UK, and Alex Dodoo, Ghana.

On the first day the committee members heard brief progress reports from the Quality and Safety of Medicines team at WHO and from UMC. An update regarding WHO/UMC activities for post-marketing surveillance of pre-qualified vaccines was provided by the WHO department for Immunization, Vaccines and Biologicals. The update reports were followed by deliberations on many recent medicine safety initiatives e.g.:

- Developing a WHO strategy for promoting best pharmacovigilance practices
- A draft guideline on assuring safety of preventive chemotherapy for the control of neglected tropical diseases

- A joint Global Fund/WHO initiative for building minimum pharmacovigilance capacity in countries including a tool kit for resource limited settings
- Progress on suggested pharmacovigilance indicators.

On the second day, ACSoMP discussed committee operational procedures and how to improve and document them. The consequences of ACSoMP becoming a formal WHO Expert Committee were also considered. Additional topics on the agenda for the second day included:

- A discussion on guidelines for assessment of safety of medicines proposed for the WHO Essential Medicines List
- Access to signals produced by the UMC
- Progress regarding application and support systems for cohort event monitoring
- Progress in pharmacovigilance activities in WHO disease programmes (HIV/AIDS, malaria, tuberculosis, Chagas disease).

The third day was devoted to discussions regarding safety issues with specific

medicines. Updates were given on projects of particular interest e.g.

- Safety monitoring of A/H1N1 vaccines and the use of PaniFlow
- The Monitoring Medicines project coordinated by UMC/WHO and supported by the European Commission
- Safety monitoring of traditional medicines and a new initiative to integrate classification of Chinese Traditional Medicines with ICD
- The pharmacovigilance situation in India and in Africa and the new WHO Collaborating Centre in Ghana.

The main recommendations of the 7th ACSoMP meeting will be published in the next issue of WHO Pharmaceutical Newsletter.

Before the meeting was formally closed, David Coulter from New Zealand, who has served on the committee since it was established and who has now decided to retire, was warmly thanked for his commitment and hard work in support of WHO both by WHO representatives and all fellow committee members.



(from left) June Raine\*, Gunilla Sjölin-Forsberg\*, Sten Olsson, David Coulter\*, Cecilia Biriell, Alejandra Rosete\*, Ambrose Isah\*, Adwoa Bentsi-Enchill, Alex Dodoo\* (behind sculpture), Yogendra K Gupta\*, Shanthy Pal (seated), Marie Lindquist, Jürgen Beckmann\*, Ralph Edwards\*, Kenneth Hartigan-Go\*, Mitsuko Imai – in the grounds of the WHO HQ building in Geneva.

\* Appointed members of ACSoMP

# The first decade of ISoP

Ralph Edwards

ISoP held its first annual meeting in Tunisia a month after the 9/11 disaster. There had been concerns that a meeting in Africa after such an event would have insufficient attendance for a neonatal organisation with limited funding. When I arrived at what was a new conference venue, two days before the meeting started, I found to my horror that the electrical wiring was still being completed! I was assured that it would all be finished in time, but I confess to being even more edgy than ever at that point! But I needn't have worried, the conference room looked pristine and beautiful and the equipment worked perfectly. Indeed, 2001 was a splendid meeting, enjoyed by a substantial audience, and launched ISoP into its future as the only international, multi-disciplinary society with a determination to improve all aspects of safe therapy with medication.

## Origins

I was delighted that Professor René Royer, and a small group of us, initiated the European Society (ESOP, forerunner of ISoP) in 1992. Its aims were influenced by the French regionalised system of pharmacovigilance, which encompassed a collegiate approach allowing for interaction between pharmacological, clinical and epidemiological disciplines. We thought much more than just regulation was needed to support safe therapeutics. Education was a major preoccupation, particularly of young health professionals. But the global need was for an even broader consideration of pharmacovigilance. ISoP is unique in having a committed international approach, with involvement of all stakeholders with a real interest in medicines safety, and a critical approach to all disciplines that further its objectives:

*'The International Society of Pharmacovigilance (ISoP) is an international non-profit scientific organisation, which aims to foster pharmacovigilance both scientifically and educationally, and enhance all aspects of the safe and proper use of medicines, in all countries...'* (see ISoP website)

## International activity

International means just that: members of ISoP come from over 50 countries, and the membership grows progressively. So far, annual meetings have been held in Tunisia, Netherlands, Morocco, Ireland, Philippines, Belgium, UK, Argentina, France, and this year's venue will be Ghana. Chapters catering for more local activity have been created in Italy, the Western Pacific region, Mexico, Latin America and Switzerland. Wherever possible,

meetings have been held to allow members of the WHO Programme for International Drug Monitoring to attend before their own annual meeting. This has encouraged those in national regulatory pharmacovigilance to participate in scientific meetings.

## Development

ESOP provided a wonderful basis to build from, and ISoP has continued to both broaden and deepen the scope of pharmacovigilance, including topics in its meetings such as communication skills, risk-benefit analysis, risk perception, pharmacogenomics, ecopharmacology, medicine quality issues and counterfeiting, misuse and medical error relating to medicines, herbal medicines, and more. Education has been evolving to the extent of not only running training courses around the world, but also to an almost completed comprehensive course for pharmacovigilance.

ISoP has relationships with scientific societies and groups that have international interests that overlap with its own. ISoP has played its part in developing regulatory pharmacovigilance, such as giving scientific advice to the EU, the American Institute of Medicine, the Canadian Government, and others, on the future development of pharmacovigilance.

ISoP has an international journal, (Drug Safety) (Adis Press), chosen for its broad approach to publication and coverage of drug safety concerns.

Its user-friendly website, [www.isoponline.org](http://www.isoponline.org), gives details of its activities and has many links with other organisations with an interest in pharmacovigilance, as well as job adverts.

## What of the future?

The main challenge of pharmacovigilance is the oft-repeated cliché, 'One size does not fit all': a toolbox of methodologies and an understanding of when to use what tools are needed. Our secondary challenge is getting patients, health professionals, and other specific stakeholders in safety matters (eg, the media; the law; the public) to accept and be on the look-out for the inevitable harms that medicines can cause. The third challenge, with all other stakeholders, is to be able to minimise risk and therefore harm. Our final challenge is to be able to measure our successes.

Enquiries about membership should be made to: [administration@isoponline.org](mailto:administration@isoponline.org)



## ISoP first sub-saharan African meeting

10<sup>th</sup> Annual Meeting of the International Society of Pharmacovigilance (ISoP 2010) - Accra, Ghana from 3 to 6 November 2010  
[www.isop2010.org](http://www.isop2010.org)

Ghana is a welcoming and stable country with the capital and meeting city Accra acknowledged as one of Africa's safest cities.

The organizers of ISoP 2010 are promising a memorable conference:

- ♦ a panel of distinguished international experts in pharmacovigilance
- ♦ a joint session with the WHO Annual National Centres Meeting on 3 November (afternoon)
- ♦ post conference training at different levels (both in English and French)
- ♦ Celebration of the 10th anniversary of ISoP with a wonderful social programme (all in the registration fee)
- ♦ A simplified conference fee which includes access to all social functions and gala dinner

Gone are the days when each country or organisation has tried to work out pharmacovigilance on its own. In keeping with the Annual Meeting's theme 'Pharmacovigilance in a Global Village', ISoP believes international collaboration and team-working is key in tackling strategically the many challenges we face but that the local needs of each country can be taken into account when it comes to implementation and tactics.

Full details at: [www.isop2010.org](http://www.isop2010.org)

## WAHO and drug safety

Alex Dodoo

A unique pharmacovigilance event took place in Accra, Ghana from 10<sup>th</sup>–13<sup>th</sup> May 2010. For the first time ever, the West Africa Health Organization (WAHO) brought together all 16 countries in West Africa to hold a strategy and planning meeting on pharmacovigilance (Cape Verde was the only country not able to attend).



The WAHO meeting in session

WAHO is a regional organization bringing together all Ministers of Health in West Africa and thus has enormous political clout. The meeting was fully funded by WAHO with the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, University of Ghana Medical School providing technical support; WHO Headquarters and the Uppsala Monitoring Centre were also present. Participants spent the first day giving a SWOT analysis of their various national pharmacovigilance highlighting in particular the challenges faced in implementing pharmacovigilance in their countries. The facilitators from WAHO, WHO (AFRO; Geneva), UMC and the WHO-CC in Accra then took them through concepts in both basic and advanced pharmacovigilance after which participants were asked to draw up short- and long-term country plans with the assistance of the facilitators. It was an excellent exercise leading to the drawing up of a WAHO plan of action for pharmacovigilance, especially important since most of the challenges facing individual countries were similar. WAHO has promised to advocate with Ministers of Health in the sub-region for more support for pharmacovigilance and has offered to provide tangible assistance for the Collaborating Centre in Accra. This model appears to be one that other resource-constrained settings should watch closely.

A follow-up meeting is planned for just before the 33<sup>rd</sup> Annual National Centres meeting in Accra in October 2010. A fuller report on the May meeting in Accra was published in the *WHO Pharmaceuticals Newsletter* No 3; 2010, pages 19–22.

## UMC in Serbia

Sara-Lisa Fors

On the 27–28<sup>th</sup> of May an ISO training course Basic Concepts in Pharmacovigilance was held at the Faculty of Pharmacy in Belgrade. In connection with the course, Richard Hill and Sara-Lisa Fors from the UMC Pharmacovigilance Services department took the opportunity to spend a few hours at the Medicines and Medical Devices Agency of Serbia, in the next-door building. The professional and dedicated staff at the Serbian centre gave a much-appreciated presentation of the daily work at the agency and their preparations for a future EU membership, and also gave a guided tour around the agency premises. In return Sara-Lisa and Richard demonstrated some of the more advanced concepts of the UMC tools VigiFlow, VigiSearch and VigiMine.



Outside the Medicines and Medical Devices Agency of Serbia.

Standing left to right: Jelena Martinovic, Jasmina Babic, Anita Rakic Ignjatovic, Marco Eric and Marija Petronijevic  
Seated left to right: Jelena Pilic, Richard Hill, Milena Miljkovic and Sara-Lisa Fors

## WAHO funds multi-country research

Mobilizing resources for pharmacovigilance has been a key desire of all major players in pharmacovigilance. Until recently, there were few willing donors and fewer still making calls

for proposals on pharmacovigilance. This state of affairs is changing with several global health organizations and institutions placing pharmacovigilance at the heart of their current plans and activities. In April 2010 the West Africa Health Organization sent out a call for proposals for health system strengthening. One of the areas of interest was 'pharmacovigilance of antimalarial medicines'. The WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance at the University of Ghana Medical School responded to the call and roped in colleagues from Benin, Cote d'Ivoire and Sierra Leone. The final proposal submitted has been successful in the application process and a sum of US\$75,000 would be provided to the four countries to carry out the study entitled 'Pharmacovigilance of amodiaquine-artesunate and artemether-lumefantrine in selected districts in Benin, Cote d'Ivoire, Ghana and Sierra Leone – a multi-country cohort event monitoring study of patients with uncomplicated malaria treated with ACTs'.

## Africa update

The WHO Collaborating Centre for International Drug Monitoring (the UMC) has gone global. Aware of the need to provide even more direct technical support to national pharmacovigilance centres, the UMC set up UMC-Africa to cater for the needs of national centres in Africa. This different way of working is already yielding tangible and exciting results. In April 2010, the first ever VigiFlow Training for three national centres was held at the UMC-A offices in Accra with participants from Kenya, Sierra Leone and Ghana (see page 17). The immediate end-product was the admission of Kenya to full membership of the WHO Programme.



The sign outside the new UMC Africa office

## Virtual VigiFlow/ VigiSearch training in Ghana

*Helena Wilmar and Anders Viklund*

At the end of April, we were both prepared to go to Accra to hold a two-day training course for national centre staff from Ghana, Kenya and Sierra Leone. Unfortunately the ashes from the Icelandic volcano changed the plans for the course. So instead of live training for VigiFlow/VigiSearch in Accra, the internet phone link 'Skype' and an online meeting tool 'GoToMeeting' were used from the UMC office. Despite some technical



*Students watching and listening in Accra, here participants from Kenya and Sierra Leone.*



*Anders Viklund and Helena Wilmar communicate with Accra participants via headset and screen remote control.*

issues with poor sound quality (and echo) during the first day, we managed to give a brief and basic demonstration of the two tools VigiSearch and VigiFlow. Even though the overall quality of this training was not as good as live training, the UMC and national centre staff learned that this media could be used more often (as a complement to live training) whenever suitable and needed.

One positive outcome of this specific training was that Kenya became an official member of the WHO Programme after submitting 20 correct ICSRs via the web-based VigiFlow system.

## ...at the other end

*Alex Dodoo*

The VigiFlow training in Ghana showed in several ways how future training in pharmacovigilance could be run using existing technologies. The volcanic ash meant that the two facilitators from UMC Sweden could not attend the meeting.

However, with just a simple IT connection and the use of 'Go to meeting' and 'Skype', participants had very fruitful hands-on training in real time. It was indeed exciting for both the facilitators and the participants as they saw remote delivery of PowerPoint presentations, remote assistance with the mouse to highlight texts and open documents and as they allowed the remote

team access to their computers to correct wrong inputs or make new entries. All participants felt the training had been most successful though all of them wished the meeting had been longer.

There is now the intention to plan a longer meeting focusing not just on VigiFlow but rather on IT for pharmacovigilance.

In the internet age, distance clearly is no problem, even in sub-Saharan Africa. UMC, UMC-A and the three pioneer countries – Ghana, Kenya and Sierra Leone – have all shown that a lot can be shared and a lot can be gained even across thousands of miles.

# A trio of UMC publications

## Expecting the Worst 2<sup>nd</sup> edition, 2010



The UMC has just published a completely revised, updated and redesigned edition of its 2003 book.

*Expecting the Worst* is the UMC's practical manual for effectively anticipating, preventing or managing crises.

A comprehensive guide to all aspects of crisis planning and management, this book will provide you with the resources to make sure you, and your organisation, are thoroughly prepared for the worst that can happen, and have the knowledge, plans and skills to anticipate and prevent crises or to manage them capably and professionally.

Over two thousand copies of the 2003 edition of *Expecting the Worst* are circulating worldwide; now the UMC brings the book up to date with wide-ranging new material – and a complete redesign. The major enhancement of the book is the inclusion of dozens of mostly contemporary case studies from healthcare and beyond. These provide vivid illumination of the book's comprehensive principles and guidelines. There is also a new chapter on vaccine crises.

Crises can be a threat to the health and welfare of populations (MMR problems in the UK and oral polio vaccine in Nigeria are contemporary examples, thalidomide a frightening incident from the past), as well as to the reputation and credibility of health

authorities and facilities. Crises will happen, but those who have anticipated trouble and planned to manage it have a much higher chance of saving lives, protecting health, and maintaining the confidence and trust of their audiences.

While the primary focus of the book is medicinal product and other healthcare crises, it has direct applicability to crisis-preparedness for all organisations in all fields, although the book's main target audiences are:

- regulatory authorities
- pharmaceutical companies
- healthcare facilities and organisations
- national and regional pharmacovigilance centres.

*Expecting the Worst* provides a reliable, practical, actionable basis for crisis planning across the board.

Over 200 pages, 210x270mm  
9 chapters and 12 appendixes  
US\$75; SEK570; €60; £50 + post and packing

Order from:  
*Uppsala Monitoring Centre*  
Box 1051  
SE-751 40 Uppsala, Sweden  
Tel: +46 18 65 60 60 Fax: +46 18 65 60 88  
Email: [info@who-umc.org](mailto:info@who-umc.org)  
Internet: [www.who-umc.org](http://www.who-umc.org)

## A Lifetime in Safety

The UMC has also just published a collection of selected articles by Ed Napke.

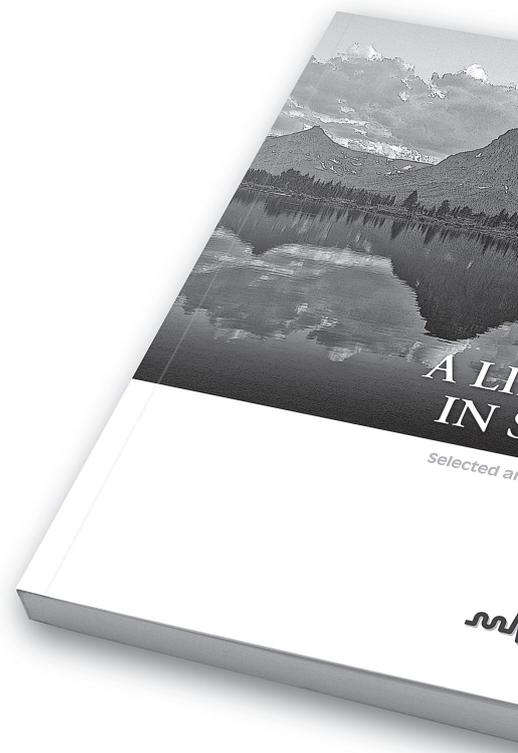
Ed Napke is not only one of the pioneers in pharmacovigilance, his work over the years has always brought the fresh air of innovation and controversy into medicine.

This collection of articles on pharmacovigilance by Ed challenges conventional thought and illustrates the breadth of Ed's work. It includes his 'pigeon-hole system', which was an open filing system into which reports were placed when they came in, so that it was obvious if there was a disproportionately high rate of reporting about a particular drug. It also includes his work on the need to pay attention to the dangers of excipients.

The writings also demonstrate Ed's broad view of his job, viewing it as patient safety, and his recognition of the benefits to be gained by having a single national organisation undertaking the monitoring of poisons and devices as well as medicines, including herbals. The introduction to this collection of writings by Ed summarises the themes, past and present of his work, as well the vigour and humour of the man.

Over 100 pages, A4  
Free of charge, post and packing may be charged.

Ordering details as above.



## The Risks of Being Alive

Living is not a safe occupation. There are potential hazards for each of us ranging from the activity of the toilet to cosmic catastrophes. Even our homes are filled with hazards and great numbers of accidents and misadventures happen in them. Driving a motor vehicle or being a passenger in one is amongst the most dangerous of everyday activities.

All of us engage in risky activity every day of our lives, but we willingly or unknowingly live with risk. We knowingly accept risks if:

- the probability of something harmful happening is small or distant in time, or
- the possible harmful event is not serious, or
- the possible benefits are sufficiently strong.

We may well be able to eliminate risk by more than one means:

- by eliminating the hazard
- by reducing the probability of the hazard occurring
- by reducing the severity of the hazard
- by reducing the exposure to the hazard

For each of us, the risks are different and we have different criteria to differentiate between them. Perception of risk is influenced by variables from the individual psychology through to the influence of language.

**Reducing Risk**  
In recent years there has been public pressure to reduce risk potential harm and improve safety requiring the wearing of seat belts, crash helmets, etc. Some measures stand for food and power supplies are two others. No amount of legislation, of course, will

the probability is high and the potential harm is great (smokers, for example).

### Risk-aversion

However, a social climate which is increasingly intolerant of risk, has created a tendency to seek absolute safety and security. This has led to a trend of blaming and punishing those who are seen to be the cause of accident or injury.

Part of this trend is to regulate dangerous sports by prohibiting or restricting them, and to restrict the rights and freedoms of those who are seen to be the cause of harm or injury.

It is not clear whether this is a positive or negative thing, but it is clear that it is a trend that is worth watching.

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# viewpoint

Watching for safer medicines

Part 1  
Second edition

Issues, controversies and science in the search for safer and more rational use of medicines

the UPPSALA MONITORING CENTRE

WHO Collaborating Centre for International Drug Monitoring

An account of the WHO Programme for International Drug Monitoring, the work of the Uppsala Monitoring Centre and the challenges of worldwide collaboration for improved patient care and public health.

## Vision and Goals of the UMC

### Our vision

is to support WHO's leadership in the field of public health by providing excellence in the science and concepts of all aspects of pharmacovigilance

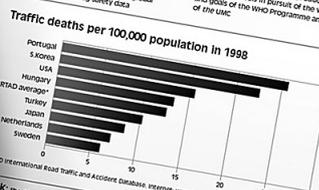
- to ensure harm to humans from the use of drugs, and the achievement of the highest standards in the field of drug safety through open and transparent means of communication
- to support the promotion of the rational use of drugs, and the achievement of the highest standards in the field of drug safety through open and transparent means of communication
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And in particular we aim to:

- ensure that effective, timely international collective efforts will never miss a signal of a potential hazard
- ensure that all stakeholders evaluate and learn from decisions and actions through positive impact assessment, follow-up and debate
- promote the growth of pharmacovigilance activities around the world, in particular the establishment of new national centres and other stakeholders in the field
- to contribute actively to the global vision of the WHO Programme
- to use and share available information openly and transparently
- to sponsor and support others in their pharmacovigilance activities
- stimulate the development of coherent, harmonised systems worldwide for pharmacovigilance through education, training, promotion of best practice and the publication of guidelines
- maintain and develop useful products, services and tools in pursuit of the vision and goals of the WHO Programme and of the UMC

We will achieve this by:

- developing leading-edge systems and scientific research for the identification and communication of safety hazards in drugs and other substances used in medicine
- carrying out research posing forward the ethical, intellectual and scientific boundaries of theory and practice in pharmacovigilance
- pursuing active collaboration and communication with all stakeholders
- pursuing the goal of a single, global database for drug safety data



WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden. www.who-umc.org

## Viewpoint – 2<sup>nd</sup> edition

The UMC's booklet covering 'issues, controversies and science in the search for safer and more rational use of medicines' has just been revised and reprinted from the original 2002 publication.

If you have not seen this 24-page colour booklet before, it provides an ideal introduction to risks, benefit, harm and effectiveness, pharmacovigilance and related issues (medical error, quality problems and counterfeiting) and much else.

Viewpoint also gives some background to the aims and work of the Uppsala Monitoring Centre. The issues of drug safety and the broader questions of patient safety are discussed in a widely accessible form.

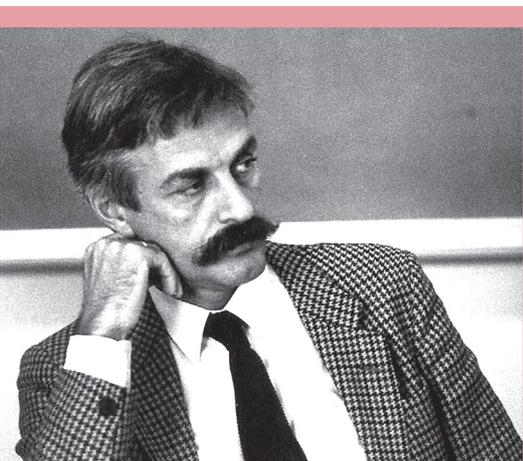
We hope that Viewpoint continues to :

- provoke comment and debate
- educate
- widen the audience informed about and involved in these issues
- provide useful technical information about UMC's activities and about pharmacovigilance
- promote the interests of patient safety and public health worldwide.

Viewpoint is freely downloadable from the Publications page of the UMC website, or by mail from the usual UMC contacts (bulk orders may incur a postage charge).



## Martijn ten Ham



Martijn ten Ham, born Ede, Netherlands in 1938, Chief of the Drug Safety Unit at WHO from 1990 to 1999, died in Culembourg on 28<sup>th</sup> May last. *Uppsala Reports* 9 (April 1999) carried an interview with Martijn ten Ham on his retirement as Chief of the Drug Safety Unit at WHO; here two colleagues recall working with him.

### Graham Dukes writes

I worked with Martijn in his various capacities. As Vice Chairman of the Netherlands Board for Evaluation of Medicines I first knew him during the early seventies when he was one of the pharmacological experts at the National Institute of Public Health (RIV) who wrote evaluation reports for the Board. Later in that decade he became Assistant Secretary to the Board. Martijn was a cheerful and enthusiastic pharmacologist with a good grasp of broad policy issues in the drug sector. I recall with amusement one occasion when the Board decided to cancel the licence of a problematic product from a less-than-ethical firm, Martijn (who had a large and powerful motorbike) did his best to persuade the Board to let him thunder down to the company's offices and deliver the product licence cancellation triumphantly in person.

### Mary Couper recalls

When I joined WHO in 1985 Martijn was already there; he sported a wonderful handlebar moustache and was quite dashing, added to which he was gentle and humorous. He was responsible for the WHO liaison with the UMC, the annual meeting of national pharmacovigilance centres, the Pharmaceuticals Newsletter and, together with John Dunne, running International Conference of Drug Regulatory Authorities (ICDRA). He was an early pioneer in the field

of counterfeiting and organized a joint meeting with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) in the early 1990s. He was also active in the DIA and received an award for long-standing service. When he retired he went back to the Ministry of Health Welfare and Sport in the Netherlands, where he continued to work on the problem of counterfeiting and among other things contributed to the WHO publication, *Priority Medicines for Europe and the World*.

Martijn had many hobbies, including gardening and bee-keeping, and a great love of literature. He said that he looked forward to growing old so that he could re-read the works of Dickens. He also totally refurbished a house that he bought in France, including the wiring and plumbing. A couple of years ago he proudly showed me a photograph of his family which consisted of himself (the patriarch), Grada, their three children and spouses, and 15 or 16 grandchildren. I think he would say that this was his greatest legacy.

*Two people who were not in the limelight of international drug safety, but were devoted servants of pharmacovigilance also recently passed on: Neda Voćanec and Bengt Lindeskog.*

## Bengt Lindeskog

### Marie Lindquist recalls

Bengt Lindeskog is dead. At the age of 65, Bengt should have been enjoying his retirement, with more time for all those things one puts off because of duty calling at work. This was sadly not to be.

Some people get their names into history books, whereas some make their vital contributions quietly, not aspiring to fame and fortune. Bengt was one of those. Starting with a university degree in Italian, he ended up spending more than thirty years of his professional life working to support the Swedish pharmacovigilance team at the Medical Products Agency. Dedicated, tireless, but unassuming, Bengt took care of everything from general administrative tasks to the front-end contact with many a patient worried about adverse reactions to their medicines.

For many years, Bengt and Beje Wiholm worked together, and what a wonderful team that was! I was fortunate to spend a year at the 'Adverse Reaction Section', as it was then called, and it was immediately apparent that Bengt was the hub of the operations. Beje was brilliant, as so many

already know, but he was the first to point out that it was thanks to Bengt, and other people in supporting roles, that he was in a position to shine as a professional. When there was panic in the air, Bengt stood calm; when a particularly important document was lost, Bengt found it. He was a sensitive listener, and a thoughtful discussion partner with a philosophical mind.

Dear Bengt! Little did I know when I sent those flowers on your retirement day that I would not see you again. I never got round to telling you in person that you are one of my heroes, but I want to tell the world that you are sorely missed, but never forgotten by your colleagues, and all those who benefited from your knowledge and wisdom.

## Neda Voćanec

### Igor Francetic writes

This April we lost the 'heart' of former Yugoslav, and afterwards, Croatian National ADR monitoring Ms Neda Voćanec, who died few days before well-deserved retirement.

Neda Voćanec was born in Zagreb in 1945 and spent all her life there. She was really the heart of our national centre from the very beginning and put all her capability and strength into everyday work and different activities especially at the initiation of the centre. She was one of those quiet people you hardly hear of, yet performing very efficiently. Neda was deeply connected to the founders of the UMC and never missed a chance for contact with them. Several photos, taken during the 1985 WHO meeting in Dubrovnik showing the then members of the ADR programme, hung above her desk.

Neda was very brave in her disease; diagnosed with colon cancer in October 2008, she worked practically up to her last days, never complaining. She died peacefully at our Department of Clinical Pharmacology where she had spent all her working life, and to which she contributed so much.

# Visitors

## From New Zealand...

Professor Stephen Duffull, Chair in Clinical Pharmacy and Associate Dean, Postgraduate Professional Programmes at the New Zealand National School of Pharmacy, University of Otago visited the UMC on 5<sup>th</sup> May 2010. His unit has a large undergraduate and postgraduate programme.



*Ralph Edwards, Marie Lindquist  
with Steve Duffull*

## ...and Chile

Ximena Lagos Morales, of the Faculty of Sciences at the Universidad Austral de Chile spent an afternoon at the Centre in May. She writes "It was a fascinating visit and in a couple of hours Elki summarized much of the work of collecting, analyzing and disseminating information that WHO Programme members develop and also the important work of promoting safety about the use of drugs. It was a dream to visit, after years of thoughtful conversations with my colleagues at Hospital Regional de Valdivia, Chile, about the pharmacovigilance system of our country, the need to be proactive and the possibility of being connected in a worldwide network with UMC." After her visit, she wrote of her hopes, despite limited



*Ximena Lagos Morales with  
Elki Sollenbring in the UMC library*

resources, to implement preventive measures and opportune detection and solution systems at institutional level, and to improve collaborative work with the clinical team, and establish active surveillance systems, as well as promoting pharmacovigilance, beginning with students at the Universidad Austral de Chile.

## Ruth Savage

We were delighted to welcome back recently Dr Ruth Savage from New Zealand. Ruth is a Senior Research Fellow at the New Zealand Pharmacovigilance Centre, Dunedin School of Medicine (and a practising general practitioner), and she was here to work on potential signals in the WHO database.

## American visitor

Elisabetta Patorno, MD, MPH, is a research fellow at the Division of Pharmacoeconomics and Pharmacoepidemiology and Pharmacoeconomics (Brigham and Women's Hospital, Harvard Medical School, Boston, USA) and DrPH (Pharmaco-epidemiology) candidate at the Harvard School of Public Health.



Her major areas of interest are the assessment of safety and effectiveness of therapeutics through the application of epidemiologic methods and the evaluation of medication utilization and medical prescribing patterns both at a national and international level.

Dr Patorno recently spent almost two months at the Research Department of the UMC working on the reporting characteristics related to anticonvulsant medications and suicidality, particularly focusing on children and adolescents.

## Hong Kong team

The UMC had the pleasure of receiving a delegation from the Department of Health, Hong Kong on 21 May 2010. The delegation, made up of Dr Heston Kwong, Dr Teresa Li, Ms Linda Woo and Mr Lot Chan, was interested in learning about services offered by the WHO Programme for International Drug Monitoring and the specific work carried out by UMC. Our guests explained that a recent internal review committee had suggested investments be made to upgrade institutions and processes in Hong Kong for the assurance of patient safety. A discussion was held regarding opportunities for collaboration in training and competence development in pharmacovigilance.



*Heston Kwong, Teresa Li, Linda Woo and  
Lot Chan at the UMC office*

# As well as work

It's not all preferred names, signals, ATC levels, coding, documentation grading, E2B and pattern discovery at the UMC!

## Spinning against cancer

There are regular 'extra-curricular' activities which staff take part in. This year 12 members of the UMC team got involved in a sponsored 'spin' in aid of The Swedish Childhood Cancer Foundation. From 7am on 27 March each person cycled for one hour in a national event entitled 'Spin of Hope'.

Throughout Sweden 4,500 people took part in 441 teams in 35 gyms where spinning is held.

## Magical Mystery Tour

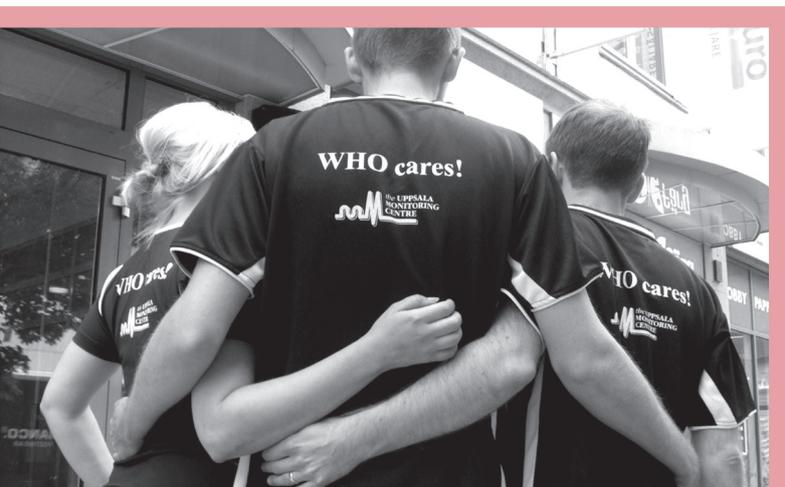
As their midsummer party this year, staff took part in a complex murder mystery tour in the city near the UMC office. The activity involved solving lots of clues, as well as dressing up.

## Blood donation

Staff from the UMC also recently participated again in the nationwide event held around Sweden on 1<sup>st</sup> of June to raise awareness, in a fun way, of the importance of donating blood. Two teams from the Centre entered, and walked or ran through the parks and leafier areas of Uppsala.

## Step competition

If all this weren't enough, some UMC staff have also been counting the number of footsteps they take every day in another nationwide competition to encourage fitness. The winner this year (as in previous years) was Thomas.



*The message on the special 'spinning' UMC t-shirts*

## Minimum Requirements drawn up

The minimum requirements for any national pharmacovigilance system sets out what needs to be done as a minimum to ensure that a national pharmacovigilance system exists and is able to provide some measure of assurance for, and security of, medicine safety (see *Global Fund report, page 7*). Such a system is expected to be sustainable with guaranteed funding and with a key focus on patient safety.

The minimum requirements were developed through a thorough and interactive process involving:

- face-to-face meeting of pharmacovigilance practitioners, disease control managers, technical agencies and donors in Geneva on 14<sup>th</sup>-15<sup>th</sup> January 2010
- discussion of the proposed minimum requirements document by the

World Health Organization's Advisory Committee on the Safety of Medicinal Products (ACSoMP) at its meeting on 26<sup>th</sup>-28<sup>th</sup> April 2010

- further e-mail and telephone consultations between WHO, Global Fund and ACSoMP members
- consolidation of all views and comments and production of the Draft Minimum Requirements Document for wider stakeholder consultation.

### Minimum Requirements for a Functional National Pharmacovigilance System

The following are the minimum requirements that the WHO and partners agree should be present in any national pharmacovigilance system.

1. A national pharmacovigilance centre with designated staff (at least one

full-time), stable basic funding, clear mandates, well defined structures and roles, and collaborating with the WHO Programme for International Drug Monitoring

2. The existence of a national spontaneous reporting system with a national individual case safety report (ICSR) form i.e. an ADR reporting form
3. A national database or system for collating and managing ADR reports
4. A national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management, including crisis communication
5. A clear communication strategy for routine communication and crises communication.

DATES	TITLE	PLACE	ORGANISER/CONTACT
19-22 August 2010	<b>26th International Conference on Pharmacoepidemiology &amp; Therapeutic Risk Management</b>	Brighton, UK	ISPE www.pharmacoepi.org/meetings/ E-mail: ISPE@paimgmt.com
8-9 September 2010	<b>Back to Basics in Pharmacovigilance</b>	Botley, Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
13-14 September 2010	<b>Medical Approach in Diagnosis and Management of ADRs</b>	Paris, France	DIA Europe Tel: +41 61 225 51 51 Fax: +41 61 225 51 52 E-mail: diaeurope@diaeurope.org
20-22 September 2010	<b>Drug Safety Surveillance and Epidemiology</b>	Horsham, PA, USA	DIA Phone: +1-215-442-6158 E-mail: Ellen.Diegel@diahome.org
22-23 September 2010	<b>Critical Appraisal of Medical and Scientific Papers: How to read between the lines</b>	Fareham, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
22-24 September 2010	<b>Advanced Pharmacovigilance</b>	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
30 September - 1 October 2010	<b>X Jornadas de Farmacovigilancia</b>	Valladolid, Spain	Spanish Medicines Agency in collaboration with Regional Health Authority of Castilla-y León www.farmacovigilancia2010.es
20-21 October 2010	<b>Risk Benefit Assessment in Pharmacovigilance</b>	Botley, Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
25-29 October 2010	<b>Excellence in Pharmacovigilance: Clinical Trials and Post Marketing</b>	Vienna, Austria	DIA Europe Tel: +41 61 225 51 51 Fax: +41 61 225 51 52 E-mail: diaeurope@diaeurope.org
29-31 October 2010	<b>5th Asian Conference on Pharmacoepidemiology</b>	Tokyo, Japan	ISPE www.pharmacoepi.org/meetings/ E-mail: ISPE@paimgmt.com
3 November 2010	<b>Introduction to Signal Detection and Data Mining</b>	Horsham, PA, USA	DIA Phone: +1-215-442-6158 E-mail: Ellen.Diegel@diahome.org
3-6 November 2010	<b>10th ISoP Annual Meeting: 'Pharmacovigilance in the Global Village' (Training courses on 7 November)</b>	Accra, Ghana	International Society of Pharmacovigilance www.isop2010.org
8-11 November 2010 14-17 February 2011 11-14 April 2011	<b>Certificate in Pharmacoepidemiology &amp; Pharmacovigilance</b>	London, UK and distance learning	London School of Hygiene and Tropical Medicine Tel: +44 (0)20 7299 4648 E-mail: shortcourses@lshtm.ac.uk; www.lshtm.ac.uk/prospectus/short/scpp.html
10-11 November 2010	<b>Case Narrative Writing for Reporting Adverse Events</b>	Fareham, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
24-25 November 2010	<b>Pharmacovigilance in products subject to licensing agreements</b>	London, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
1-3 December 2010	<b>Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing</b>	Paris, France	DIA Europe Tel: +41 61 225 51 51 Fax: +41 61 225 51 52 E-mail: diaeurope@diaeurope.org
2-3 December 2010	<b>Advanced Workshop on Pharmacovigilance Planning and Risk Management</b>	Fareham, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
13-16 December 2010	<b>Pharmacology Havana 2010, including 5th Workshop on Pharmacovigilance</b>	Havana, Cuba	Cuban Society of Pharmacology Tel: 537-271 8331 Fax: 537-272 0653 www.pharmacologyhavana.com



The Uppsala Monitoring Centre (*the UMC*) is the field-name of the WHO Collaborating Centre for International Drug Monitoring, responsible for the operational management of the WHO Programme for International Drug Monitoring.

An independent centre of scientific excellence, *the UMC* offers products and services, derived from the WHO global ICSR database, VigiBase™ reported from member countries of the WHO Programme.

With an independent and global perspective on drug safety, *the UMC* provides resources for regulatory agencies, health professionals, researchers and the pharmaceutical industry.

The UMC's important worldwide work is financed solely by the organisation itself, without support from WHO, the Swedish Government, member countries of the WHO Programme or any grant-making body.

## Communications information

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Sales & marketing enquiries: [info@umc-products.com](mailto:info@umc-products.com)

Drug Dictionary enquires: [drugdictionary@umc-products.com](mailto:drugdictionary@umc-products.com)

A full list of UMC staff may be found on the [About the UMC](#) page on our website.

Internet: [www.who-umc.org](http://www.who-umc.org)

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## A message on our 50<sup>th</sup> edition

We hope you have enjoyed reading this issue of *Uppsala Reports*.

*Uppsala Reports* is distributed to individuals all round the globe (over 150 countries) in the regulatory, commercial and academic sectors, as well as to journalists, policy-makers and others. For our second half-century we look forward to more contributions – and more readers!

We are always happy to consider items for inclusion alongside the solicited material from colleagues. Do get in touch and let us know what you think about *Uppsala Reports*, or if there is someone who you think should be receiving it.

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