

MUR52



Accra reports | News from Around the World

New Programme countries | Publications and Posters



Marie Lindquist
Director
the Uppsala Monitoring
Centre

One of the advantages of living in an egalitarian country like Sweden is that I get to do the house cleaning myself. This gives me time to think; time that I rarely have while I am at work, where the days are filled with activities which leave very little room for contemplation.

As I was fighting the build-up of lime scale on the appliances in the upstairs bathroom (hard water is a particular problem in this part of the country), it struck me that the principles of cleaning a house have a lot in common with the discipline of pharmacovigilance.

First, the result of the work is not really noticeable; it only shows when it is not done, or not done properly. This is one reason, I think, why pharmacovigilance still tends to be mostly under-funded: it is difficult to motivate the importance of your work for those who make the decisions to spend money if the outcome of your efforts is that 'nothing happened'.

Second, unlike a project, which has a definite start and end-point, pharmacovigilance is a continuous, never-ending, often tedious process. As soon as things start to slip, and proper attention is not paid to the gradual build-up of little problems (like specks of chalky residue on the taps), one day the tipping-point may be reached when a signal is transformed from an early, tentative sign of a problem, into a major, acute crisis which has to be dealt with immediately, and which may seem out of proportion to its seemingly innocuous start.

As constant attention and remedial action is necessary to keep a house in good shape, dealing promptly and appropriately with the first, individual case reports can prevent what could otherwise become a major public health issue.

This is where the analogy with house cleaning stops. Whereas the results of failure to do the job properly in the one area usually are limited to annoyance and repair costs, the consequences of malfunctioning or non-existent pharmacovigilance systems are on a different scale. Pharmacovigilance is about people, and people cannot be 'fixed' like faulty appliances when suffering harm. Human suffering cannot be altogether avoided, but unnecessary human suffering as a result of preventable injury is never acceptable. Herein lies the huge dilemma that anyone committed to pharmacovigilance, and to seriously thinking about what we are trying to achieve, is struggling with all the time. How can we do our daily work in a way that avoids human disasters to the largest

extent possible – for the individuals who could be stricken with debilitating illness or even death, and for society, if many individuals are affected – whilst not reacting prematurely or out of proportion to the evidence at hand, causing non justifiable scare.

So, you may ask, what is the solution? The honest, and rather unsatisfactory response, is that there is no simple answer. One thing I am sure of though: no definitions, guidelines or SOPs can replace the thinking person. The ability to observe and draw conclusions, to critically assess often scarce evidence and to learn from experience; intuition, good judgment, courage – these are characteristics of people that I admire, whether they regulate medicines, produce them, prescribe them or use them. In pharmacovigilance, we may use statistical methods to help us in our analysis, but we cannot rely on statistics alone. We must make decisions based on often incomplete and changing data, and explain the reasons for our early concerns and the rationale for the actions we are taking. The driving force must always be our concern about people. Therefore, we need to be good communicators too! There are many examples of situations that were managed as well as could be from the scientific point of view, but where there was a crisis because of failures of communication.

Good communication is founded on a genuine will not only to explain, but to listen and learn from others. In formulating a communications strategy for the UMC, I have considered who our audiences are, how we can best reach them, and do things that are useful to them. UMC has no regulatory role, nor are we involved in individual treatment decisions. Our contributions to pharmacovigilance lie primarily in our ability to provide technical and scientific solutions that help others to do their critical work and to make sound decisions – but it is also my ambition that we continue to challenge the boundaries of our profession by critical thought and the odd provocation.

With that, I hope all of you have – by the time you have read this – enjoyed a relaxing and joyous time these December holidays. To those of you who are working – keep up the good work! What you do does make a difference to the people of the world.

A handwritten signature in black ink that reads "Marie Lindquist". The signature is fluid and cursive.

PS In case you wondered, my husband does his share of domestic chores, too!

FEATURES

- 4-5**
Annual meeting in Ghana
- 12**
The Accra meetings
- 13**
Iraq posters
- 14**
The Accra meetings
- 15**
Iraq posters
- 17**
VigiFlow news - now in Russian
- 18**
News about WHO collaborations

REGULARS

- 2**
Director's Message
- 6-7**
WHO Programme news - introducing Slovenia, Iraq and Burkina Faso
- 8-11**
News from Around the World - news from South America, Kyrgyzstan, Spain, Abu Dhabi
- 20-21**
Publications - new books and publications from the UMC
- 22**
Visitors to Bredgränd
- 23**
Courses and conferences

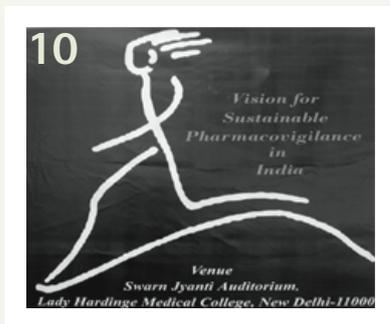


Reports from the 'global village'

The WHO Programme meetings in Accra, 2010

UMC staff out and about

Reports from conferences and training programmes

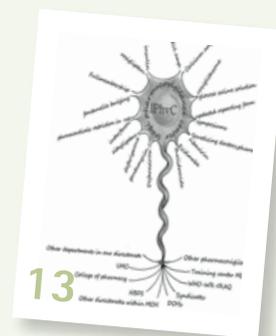


Full speed ahead in India

Major developments in New Delhi

Getting the message across in Iraq

The power of posters



Publications news

CIOMS, UMC and others for the pharmacovigilante bookshelf



Activity galore in Accra

Sten Olsson

There's usually little need for breaking the ice at the annual get-together of the WHO Programme for International Drug Monitoring. 2010's was no different, with a warm and constructive atmosphere at the 33rd Annual Meeting of the WHO Programme, hosted by the Ghana Food and Drugs Board (FDB) in their capital Accra. Nearly 150 people attended; besides representation from the host country, there were 40 delegates from Africa, 25 from Europe, 16 from Asia and Oceania and 10 from the Americas, as well as WHO staff from Geneva, WHO offices in Africa and America and a delegation from the UMC.

The opening ceremony was chaired by Mr TC Corquaye and included speeches from dignitaries Dr Benjamin Kumbour (Minister of Health), Dr Stephen K Opuni (Chief Executive of the FDB), and Dr Daniel Kertesz (WHO Representative for Ghana).

Topical discussions

Sessions of the meeting reflected strategic and topical issues, these including:

Proposal for a global WHO pharmacovigilance strategy and the development of minimum criteria for pharmacovigilance systems and a draft pharmacovigilance toolkit. New approaches to finding regional or age specific signals from VigiBase were presented and global lessons learned from the influenza H1N1 pandemic were debated.

Participants split into working groups on:

- 1) The role of pharmacovigilance centres in preventing medication errors
- 2) How to improve the quality of individual case safety reports
- 3) Difficulties in establishing new pharmacovigilance centres and possible solutions

- 4) Adverse effects following immunization including causality assessment and signal detection
- 5) Optimizing pharmacovigilance to fight substandard and counterfeit medicines
- 6) Building human resource capacity in pharmacovigilance
- 7) Improving awareness of drug safety issues: 'social marketing' of pharmacovigilance
- 8) Good practice for pharmacovigilance inspections.

Problems of current interest

As always, countries represented had the chance to share for discussion any 'problems of current interest'. These consisted of:

- Haemorrhagic events associated with varenicline: a possible new signal?
- Fatal bradycardia with nebivolol in a patient taking amiodarone for chronic atrial fibrillation
- Antibiotics overdose
- Etoricoxib, non-adherence to guidelines and 'dose creep'
- Review of reporting – Amodiaquine with artesunate
- How a missed diagnosis triggered a new pill scare
- Prevention of medication errors, a challenge in resource limited country
- Kidney body rejection and a generic product
- CYP2C9*2 and *3 allele variants increases susceptibility to fluvastatin myotoxicity

- Bisphosphonates and depressive reactions
- Itraconazole and dyspnoea
- HMG-CoA-reductase inhibitors and tendinitis or tendon rupture
- Thrombocytopenia and MMR vaccine
- Bisphosphonates and psychiatric reactions
- Aristolochia longa L. & tubulointerstitial nephritis
- Off-label use of methylphenidate in adults with ADHD
- Adverse events following immunization from pH1N1 vaccine in healthcare workers

Other activities

The main WHO Programme meeting was preceded as ever by a busy introductory day for delegates at their first meeting, to learn about the functions of the Programme and the services offered from the UMC, as well as practical skills.

The social activities comprised a convivial open-air conference dinner with music and dancing, and coach trip to open eyes to some sights of the Ghanaian capital.

The organization of the 2010 meeting was greatly facilitated by Mrs Akua Amartey, Acting Deputy CEO of the Ghana Food and Drugs Board, Mrs Edith Andrews of the Ghana WHO Country Office, and Mrs Delese Darko, Head of Safety Monitoring and Clinical Trials at the Ghana Food and Drugs Board, along with many staff from the FDB.



A Statement from the Representatives present at the 33rd Annual National Centres Meeting, Accra, Ghana, 2010

The development of pharmacovigilance continues to be impressive.

- Over one hundred countries are actively involved in the WHO Programme
- A powerful African network is already producing training, a web based toolkit, and more. It is coordinated from Accra, via UMC-Africa : a WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance
- New approaches are being used effectively to avert patient harm, such as knowledge finding approaches to longitudinal healthcare data, and increasing use of pre-marketing risk management strategies
- Pharmacovigilance is now recognised as an important public health discipline by some major international donor agencies who are cooperating in offering resources and funding possibilities

In spite of the above, the meeting identified some new and continuing factors that need serious consideration to ensure progress

In many situations where information on drug risks was necessary, other data sets will have useful information given that they are suitably designed and made available.

- Examples are: public health care cohorts, insurance information, patient health care data, pregnancy registers and more
- The representatives request cooperation with the owners of databases to have the needs of pharmacovigilance incorporated in their design and use to enable better patient safety investigations in respect of drug therapy

Several examples were presented at the meeting where old, known drug safety issues had re-emerged.

- All those involved in providing information and training to health professionals should be ready to reinforce old messages to enhance safest use of drugs, in cooperation with pharmacovigilance centres
- The recognition of medication error as an important area to address has been slow, particularly consideration of root causes, such as labelling of medicines packages and getting more useful patient reports. Better reporting formats and feedback to reporters was considered essential to achieve the latter

- The main aim of pharmacovigilance must always be improved patient safety

A number of retrospective evaluations of the H1N1 vaccination campaigns were presented at the meeting.

- Whilst there were few safety matters arising from these campaigns, it was generally felt that much more safety planning and cooperation during their running is essential to be sure that major harm could be detected early and limited
- Pharmacovigilance experts should be fully consulted as equal partners to vaccine experts during both planning and implementation, and their concerns heeded, if public health and public confidence is to be preserved
- The meeting urged WHO to assert its leadership role in coordinating international pharmacovigilance activities also in an influenza pandemic.

As recorded by Prof. I Ralph Edwards

Stakeholders Meeting

Sten Olsson

In *Uppsala Reports 50* (p7 and 22) we reported on the collaboration between WHO and the Global Fund to Fight AIDS, TB and Malaria (GF) to develop a joint pharmacovigilance strategy. The work so far has resulted in:

- a situation analysis of pharmacovigilance in grant applications to the GF
- minimum requirements for a functional pharmacovigilance system
- a joint document 'Towards a strategy on Pharmacovigilance'

- a draft web based toolkit to support development of pharmacovigilance systems

Global Fund and WHO invited expected stakeholders for the implementation of the pharmacovigilance strategy to review the results of the work so far at a meeting in Accra, Ghana, on 4 November 2010. Participants represented national pharmacovigilance programmes and other pharmacovigilance experts, national disease programmes, and partner organizations (USAID, Management Sciences for Health MSH, Médecins sans Frontières, Medicines Malaria Venture).

Shanthi Pal, WHO, and Serge Xueref, GF, provided the background to the meeting and presented their visions for the expected outcomes. Status reports on the

pharmacovigilance situation in some countries were given by representatives from different geographical regions and WHO disease programmes for HIV/AIDS, TB and malaria described their needs and wishes for pharmacovigilance development. The minimum requirements for pharmacovigilance systems and the draft pharmacovigilance toolkit were presented by Alex Dodoo from the WHO Collaborating Centre in Accra. Technical partners to be involved in the implementation of the strategy (UMC, UMC-A and MSH) presented their respective services.

The concluding discussion focused on a matrix to elaborate, in which stakeholders would take responsibility for the various aspects of the implementation of the strategy, e.g. funding, advocacy, capacity building, data management and analysis.

Pharmacovigilance in Slovenia

Anja Prešern, Milena Radoha Bergoč

Independent since 1991, Slovenia lies in the heart of Europe, where the Alps meet the Mediterranean and the Pannonian Plain meets the Karst. This small green country measures 20,273 km² in area and is home to two million people. Slovenia's exceptional natural beauty is a gift that it endeavours to protect, consciously and systematically; green is the country's dominant colour, thanks to its extensive forests and other areas of greenery. Slovenia was one of ten countries which joined the European Union in May 2004. In 2010 Slovenia officially became a full member of the WHO Programme for International Drug Monitoring.



Slovenia pharmacovigilance staff, from left: Katja Mohorčič, Jasmina Klopčič, Polona Golmajer, Milena Radoha Bergoč and Anja Prešern

Foundation

The Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) was formed as a public agency in January 2007 by the merging of the Agency for Medicinal Products and Medical Devices (ARSZMP), which already operated under the Ministry of Health since 1996, and the National Institute for Pharmacy and Drug Research (ZAF). JAZMP as a new legal entity assumes the rights and obligations of ARSZMP and ZAF.

Total vigilance

JAZMP is actively involved not only in pharmacovigilance of medicines for human and veterinary use, but also in vigilance of medical devices, human blood, tissues and cells. The pharmacovigilance department is part of the sector for medicinal products for human use. The pharmacovigilance staff of five consists of two medical doctors, two

pharmacists and one graduate engineer of laboratory biomedicine. Our main responsibilities are evaluation of ADR reports, maintaining the database on adverse drug reactions, risk assessment, regulatory action, risk communication and operating within the international pharmacovigilance system as well. We are actively involved in the project of 'work sharing' in the assessment of Periodic Safety Update Reports. A pharmacovigilance expert is a member of the pharmacovigilance inspection team and the first inspection was performed in 2009.

Reporting

The obligation of reporting of adverse drug reactions is provided by Medicinal Products Act. Healthcare professionals are obliged to report all ADRs; consumers may report as well. The reporting form and guidance document are

available on JAZMP's web site. In 2009 the pharmacovigilance department received and processed 573 reports of ADRs. Although the number of reports is gradually rising we share the concern with other countries about under-reporting. We are thus working on educating healthcare professionals about the importance of ADR reporting. The JAZMP collaborate with the Institute of Public Health in monitoring adverse events following vaccination, and with the Poison Control Centre at the University

Medical Centre Ljubljana, which is actively involved in the national pharmacovigilance system.

Iraq – a leap to safety

Manal Younus

In a big step forward, on 3rd November 2010, Iraq became the 102nd country to become a full member of the WHO Programme for International Drug Monitoring, after fulfilling all the required conditions.

First steps

In November 2008, during the total briefing seminar meeting, the head of the pharmacy department Dr Jamila Lafta approached Dr Shanthi Pal from WHO in Geneva on how to join the WHO Programme. Shortly after, a request was submitted for membership, and Iraq became an associate member in February 2009.

Setting up a centre

The Directorate of Technical Affairs (DOTA) had worked closely with the Directorate of Planning in the Ministry of Health headquarters to complete the requirements for establishing the centre. A ministerial decree at the end of 2009 gave the green light for the centre to commence its duties in January 2010, with a vision focused on achieving a safe medicinal environment that ensures every patient's safety. In May 2009, Iraq had participated in the pharmacovigilance course in Uppsala, followed by training on risk management, vaccine safety and on patient safety in 2010.

National system for ADR reporting

There are three main activities on-going:

Vaccinovigilance: in a joint meeting with the expanded programme on immunization (EPI) in Iraq, aimed at creating a solid collaboration ground with the pharmacovigilance centre, the national EPI manager Dr Muataz Abbas stated "we have come a long way since the 1950s to ensure vaccine safety in Iraq, and since 2001 a very strong vaccinovigilance system and guidelines including the required tools have been developed, and training on reporting adverse effects following immunization (AEFI) for all health care workers in public health centres in all directorates of health is continuing".



At the Iraq centre (from left): Clinical Pharmacist Marwah Faisal, Dr Eman Assem, DG of DOTA and Manal Younus, head of the centre

Another important activity is dealing with poor quality products, using a special reporting form for this purpose in the pharmacy department in the DOTA.

While the reporting of AEFI and poor quality products were very well managed, the reporting of ADRs was very poor, although a reporting form had existed since 2002. One of the early tasks of the centre was to update the existing ADR reporting form to maintain comprehension and simplicity, to add reports on medication errors (ME) and have them collected at the centre, to take measures towards disseminating information, and offer advice on how best to deal with ME.

Active communication with partners

On its establishment, the Iraqi pharmacovigilance centre has adopted the mission of sensitizing and raising the awareness of the importance of reporting ADRs in ensuring patient safety through face-to-face communication with all health care workers in Iraq, where the need to create a reporting culture will be an intense challenge.

The centre has also participated in activities inside and outside the ministry to reflect the importance of having pharmacovigilance for the country: workshops for hospital managers, workshops on rational drug use (RDU) in three different directorates, workshops within the clinical pharmacy programme in MOH, symposiums, in addition to conferences with the Ministry of Higher Education, and the NGOs.

Having a stronger national pharmacovigilance system with clear guidelines and a national training package is the next challenge for the coming year.

We acknowledge the support and assistance of WHO, UMC and all colleagues for helping us to take this leap forward.

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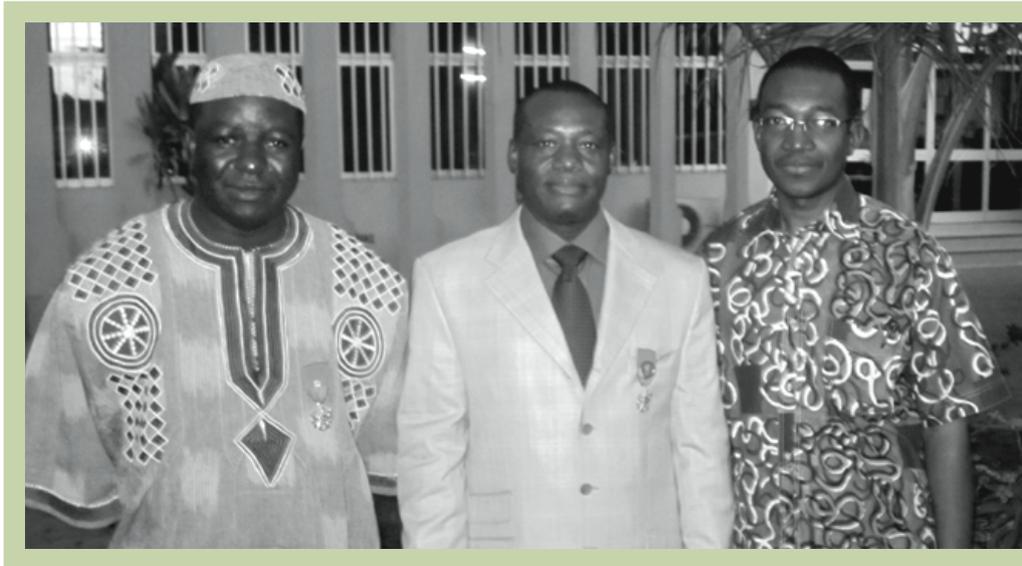
Setting out in Burkina Faso

Claude Roger Ouandaogo

Since 2005 Burkina Faso has undertaken the setting-up of its national pharmacovigilance system. After various consultative meetings a national ADR reporting form was adopted, and is being widely used. At the same time a reporting network and list of interested

vigilance service, which will assume the role of secretariat for other parties with an interest in pharmacovigilance.

An extensive programme, supported by Global Fund, will allow us to carry out training for health care professionals, whether in the state or private sector, in 2010 and 2011, to sensitize them on the importance of recognizing and reporting adverse drug reactions.



From left, Pr Jean Baptiste Nikiema, Dr Mahamadou Compaore and Dr Claude Roger Ouandaogo.

reporters was identified. Burkina Faso began its association with the WHO Programme for International Drug Monitoring in March 2009 and has remained in contact with the Uppsala Monitoring Centre. In November 2010 our country became a full member of the Programme.

Pharmacovigilance at the centre

After the reorganisation of the Ministry of Health of Burkina Faso in February 2009, the 'Direction générale de la pharmacie, du médicament et des laboratoires' (DGPML – pharmacy, medicine and laboratories) was designated to carry out the creation of the pharmacovigilance system. The technical department 'Direction de l'approvisionnement pharmaceutique' (DAP) led by Professor Jean Baptiste Nikiema was in charge of the process. A section devoted to vigilance, clinical pharmacy and therapeutical innovation was created at the centre of this department.

Our system, which is still in the process of settling down suffers however from a lack of dialogue with others. Therefore, in the formulation of regulations, technical committees will be involved in all the notifications which are transmitted to the

Currently, the vigilance service receives ADRs on a regular basis from health centres and from the research centre for testing of new medicinal products.

Staff resources

The vigilance service which leads pharmacovigilance nationally consists of three persons. It benefits from the offices of the DGPML, its administration and business services. The head of the centre is Dr Mahamadou Compaore, the information officer Professor Jean Baptiste Nikiema, and technical responsibilities (and local VigiFlow manager) are covered by Dr Claude Roger Ouandaogo. Our well-motivated team is still short of staff capacity, and is working to remedy this.

New Associate

As mentioned briefly in UR51, we have received from the Ministère de la Santé Publique et de lutte contre le SIDA in Burundi a request to join the WHO Programme. The contact person is pharmacist Bonaventure Nyabenda, and we look forward to developing ties with this east African country.

Training in Bolivia

Mariano Madurga

A new training course on analysis and risk management on pharmacovigilance was held in Santa Cruz de la Sierra from 18-22 October 2010. The course was supported and held in the Training Centre (Centro de Formación) of the Spanish International Agency for Co-operation for Development (AECID) in Bolivia. Mariano Madurga (director), Ramón Palop, Edurne Lázaro and Diego Macías, from the Spanish Medicines Agency were the teachers and course leaders.

Participants were healthcare professionals responsible for pharmacovigilance from several ministries of public health, and social security administrations (Argentina, Brazil, Chile, Mexico, Panama, Peru), and newcomers working in pharmacovigilance (Ecuador, El Salvador, Paraguay, Uruguay, Venezuela), and others involved in regulatory affairs, or pharmacology professors.

In a beautiful setting, 22 professionals (medical doctors, and pharmacists) from 11 different Latin-American countries had a unique opportunity for concentrated training in spontaneous reporting, pharmacovigilance systems, risk assessment of medicines, methods of drug utilization research, lack of efficacy, pharmacovigilance of vaccines and biotechnological products.



Participants at the Santa Cruz training

Practical cases were discussed during the workshops about individual causality assessment, qualitative and quantitative analysis of signal risk management, planning a new national Pharmacovigilance system, and taking regulatory decisions. These sessions were based on an intranet system (e-Room) between a local network connected to a server at Madrid.

MeTA work in Kyrgyzstan

Naomi Jessurun

In May 2010, Medicine for Transparency Alliance (MeTA) provided pharmacovigilance assistance for the Department of Drug Provision and Medical Equipment (DDPME) of Kyrgyzstan. The objective of MeTA is increasing transparency around the selection, procurement, sale and distribution of medicines in low-income and lower-middle-income countries, thereby strengthening governance and encouraging responsible business practices.



Gulbara Kulusheva, Naomi Jessurun and their translator

For this assignment, as the coordinator of the pharmacovigilance centre in Suriname, I went to assist the Kyrgyz pharmacovigilance team to reinvigorate their work (Kyrgyzstan joined the WHO Programme in 2003). Together with Gulbara Kulusheva (pharmacovigilance coordinator and deputy head of the DDPME), guidelines, legislation and pharmacovigilance practices were assessed. A pharmacovigilance project was drafted with the aim to draw attention to the reporting of adverse drug reactions. Suggestions for posters and leaflets (information, education and communication materials) and recommendations to increase the number of reports were shared.



The Kyrgyz poster promoting ADR reporting

With the help of a translator (English / Russian), presentations were made for physicians and pharmacists, and despite turbulent political times, the suggestion of a pilot project was received with great enthusiasm. In September 2010 a national forum was held and the poster (see picture) and the revision of the pharmacovigilance guideline (booklet) were presented.

It was a great pleasure working with colleagues so far away, and it was good to contribute to pharmacovigilance in the Kyrgyz Republic.

Mexican mission

Elki Sollenbring

Richard Hill and I visited Mexico from 22-27 November. The aim of our trip was to spend time at the national centre of pharmacovigilance COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios), and then to participate in the annual Mexican Pharmacovigilance Congress.

Discussions at COFEPRIS

We spent a day at the national centre. The whole pharmacovigilance staff were waiting for us, as well as for Mariano Madurga and Ernesto Vera from the Spanish national centre AEMPS (Agencia Española de Medicamentos y Productos Sanitarios).

The Executive Director of Pharmacopeia and Pharmacovigilance, Carmen Becerril, presented an overview of the COFEPRIS structure and functions. Twenty professionals work at the national centre, and they have 42 regional centres located in the 32 states of Mexico.

César Alik talked about the national ADR database and improvements they have made to it in the last few years, including incorporating WHO-ART into the tool (as a drop-down list), to avoid typing mistakes. They have also started to send concomitant drugs, something not included before. Mexico is still using the INTDIS format, but are thinking of changing to ICH E2B in the near future.

It was a very interesting meeting, where we all had the opportunity to discuss many different concerns from both sides. The major questions were the possible use of VigiFlow, how to improve signal detection, and how to upgrade communication with the regional centres. In general the discussions were most useful, and UMC and AEMPS can contribute to helping the national centre in various ways.

Meeting the regions

On our second day we travelled to León, Guanajuato, where the congress, organized by the health department of Guanajuato, the national centre and the Mexican Association of Pharmacovigilance, would take place.

We had a meeting next day with staff from the national and regional centres – about 40 people from the different states of Mexico. I set out the 'WHO expectations for national centres', Mariano Madurga talked about 'the Regional Centre programme in Spain', and Ernesto Vera presented 'Audit in hospital units'. During this meeting we also had a lot of discussions about the role of the regional centre, the WHO Programme, and how the Programme works with other countries like Spain.



Mexico staff, UMC and AEMPS visitors in León

A comprehensive congress

The annual congress was opened by the Health Department Secretary of Guanajuato, Jorge Aguirre Torres, who welcomed 620 participants (Ministry of Health, health care workers, pharmaceutical industry workers, pharmacy students, etc) and 15 speakers from Mexico and abroad. I presented the 'WHO Programme for International Drug Monitoring', and Richard gave an overview on signal detection; Mexico, Guatemala, Peru and Uruguay all presented their own pharmacovigilance programmes. The congress covered other key topics: standards of good pharmacovigilance practices for the pharmaceutical industry, strategies to improve pharmacovigilance in developing countries, psychotropic drug interactions, safety of medical devices (techno-vigilance), pharmacovigilance in otolaryngology, pharmacovigilance in biotech drugs, pharmacovigilance and its professional implications.

The congress also held a poster competition where students and health care workers had the opportunity to display their studies regarding pharmacovigilance. Of the 31 posters, the winner was Karina Hernández Mercado and colleagues from Guadalajara. They had developed educational materials to teach paediatric patients and their families about pharmacovigilance. We congratulate

the winners for the fantastic initiative and the valuable work they have done!

We had also the opportunity for discussions with the heads of national pharmacovigilance centres Silvia Alvares (Peru), María Cristina Alonzo (Uruguay) and Herbert Saenz Castillo (Guatemala). The importance of meeting face-to-face people that you only know through e-mail cannot be over-stated.

Relaxation

The organizers not only provided interesting presentations, they also planned cultural activities – dinners with typical Mexican dishes while enjoying traditional Mexican music (Estudiantina, Mariachi) – a wonderful experience. We thank the organizers of the congress and the Mexican national centre for the superb hospitality.

Pharmacovigilance journey in Valladolid

Mariano Madurga

The Spanish pharmacovigilance system held its "X Annual Pharmacovigilance Journeys", on 30th September to 1st October, 2010, at Valladolid, in Castilla y León region. Near three hundred participants; healthcare professionals, those responsible for pharmacovigilance from pharmaceutical companies, and staff from the Spanish regional centres, attended the meeting.

The inaugural presentation from Dr David Prieto of the London School of Hygiene and Tropical Medicine, looked at 'Statistical Methods of research and analysis in large databases', and drew many questions from the participants.

Topics on the two-day programme included in three round tables:

- New EU legislation on Pharmacovigilance, with Dr D Montero (AEMPS),

Prof JR Laporte (ICF), Prof C Aguirre (País Vasco), and Dr E Esteve (Farmaindustria)

- Social Projection of Pharmacovigilance: direct patient reporting, moderated by Prof FJ de Abajo (University of Alcalá), with Dr A Herxheimer (UK Cochrane Centre, HAI and DIPEX), Prof G Manso (Asturias), and Dr A Sanchez (OCU, a Spanish consumer association)
- Research in Pharmacovigilance: current networks in pharmacovigilance, moderated by Prof A Carvajal (Valladolid), with Prof FA de Abajo and Dr Henry Fitt (EMA).

The closing address was given by Ralph Edwards (Uppsala Monitoring Centre); 'The Challenge of Pharmacovigilance', gave a review and update of all subjects included at the programme. In total more than 15 oral and 99 poster presentations were scheduled at the meeting.

The closing session was also the time to give the annual awards to acknowledge those who had contributed to the different aspects of pharmacovigilance activities, signal detection and training activities. The 'Premios AEMPS de Farmacovigilancia, 2010' was awarded to the Pharmacy Service of the Hospital Universitario Río Hortega, from Valladolid, for its contribution to several activities including training hospital specialists, signal detecting, and development of IT applications to assure the patient safety in hospital. The second prize went to the Hospital de Navarra for its contribution to the development of regional pharmacovigilance over 20 years.

Next year Bilbao will host the XI Annual Pharmacovigilance Journeys. See you there!!

Conference Proceedings and more information at the website: <http://www.aemps.es/actividad/actCongresos/home.htm>



Staff of the Spanish Pharmacovigilance System, with guests Ghita Benabdallah, Henry Fitt, Andrew Herxheimer and Ralph Edwards

New pharmacovigilance initiatives in India

Sten Olsson

Many attempts have been made over the last 20 years to establish pharmacovigilance in India. As a result a lot of experience has been gained and many committed scientists in this vast country have learned much about drug-related problems in their local settings, to the benefit of their own patients. What they have learned has so far not been made useful for policy decisions for the whole country, however. A frustration has been growing at the federal drug regulatory authority, the Central Drugs Standard Control Organization (CDSCO), that decisions to restrict the use of certain medicines in the country have been made exclusively on the basis of foreign data.



Remote VigiFlow training at AIIMS; Ulrika Rydberg (in Uppsala, on screen) with technical associates participating in groups

Government initiative

The Indian government has realized that it requires political leadership and commitment if a sustainable, nationwide pharmacovigilance system is to be established in the country. In July 2010, the Indian Ministry of Health established the Pharmacovigilance Programme of India (PvPI) with a coordinating centre at the All Indian Institute of Medical Sciences (AIIMS) in New Delhi. Head of the PvPI is Dr YK Gupta, Professor of Pharmacology at AIIMS. The political commitment of the government has also translated into a specific budget for the Indian pharmacovigilance programme. The intention is to build the PvPI on the participation of medical colleges around the country. The government has taken the crucial decision that training in pharmacovigilance has to be part of the curriculum of all Medical Colleges.

Scaling up gradually

In the first phase of development the PvPI has established 12 ADR Monitoring Centres (AMC) in different parts of the country. At each AMC technical associates are trained to receive and manage ICSRs and to

transcribe the information into the national database. It has been decided to use VigiFlow from the UMC as the ICSR management system for India. The aim is to have established 40 AMCs by 2011, 60 by 2012 and ultimately 300 throughout the country. The development plan for PvPI relies on support from UMC for training and capacity building of staff engaged in the Indian pharmacovigilance system. The most urgent training need concerns operators of the Indian VigiFlow system.

Kick-off workshop

The pharmacovigilance centre at AIIMS organized a workshop on 'Operationalizing the Pharmacovigilance Programme of India' on 24–25 November. In addition to representatives of the AMCs, dignitaries from the Ministry of Health and Family Welfare and DCSCO were present, including Dr RK Srivastava, Director General of Health Services and the Drugs Controller General of India, Dr Surinder Singh. WHO was represented by Shanthi Pal from WHO headquarters and two officials from the WHO country office for India. UMC was represented by Marie Lindquist and myself. A delegation from the local office of the US FDA was also present.

After initial plenary presentations the workshop was divided into two parallel tracks. Heads of the AMCs and the centre at AIIMS worked on developing standard operating procedures for the Indian pharmacovigilance network. The technical associates received VigiFlow training through videoconferencing and internet from Ulrika Rydberg based at the office in Uppsala. The training had to be organized remotely since Ulrika failed to get her Indian visa in time for the workshop. With me available as a local support person the remote VigiFlow training proved successful. After a few days the Indian technical associates had entered more than 1,500 ICSRs into the Indian VigiFlow system. These case reports had been submitted by health professionals through the earlier Indian pharmacovigilance activities but had never been computerized. It is now a priority to create a computerized evidence-base of drug-related harm suffered by Indian patients.

At the final panel discussion, unified and coherent support was given to the new initiatives for strengthening Indian pharmacovigilance by the Drugs Controller General of India, all domestic experts and representatives of foreign organizations. There was a strong commitment for a



Poster for the sustainable pharmacovigilance conference in New Delhi

controlled roll-out of the pharmacovigilance system with the view of ultimately involving all healthcare professionals in all parts of the country. This commitment also includes the Indian systems of medicines e.g. ayurveda, unani and siddha. It was pointed out that a lot of competence is available in the private sector since many Indian companies are already heavily involved in pharmacovigilance activities.

Post-workshop activities

Following the workshop at AIIMS I participated in a three-day conference with the theme 'Vision for Sustainable Pharmacovigilance in India' jointly organized at Lady Hardinge Medical College, New Delhi, by the Indian Society for Rational Pharmacotherapeutics and the Society of Pharmacovigilance India. Many scientists from around the country presented their studies and discussed how to best promote pharmacovigilance, build capacity and conduct training to provide momentum to the new governmental initiative.



Speakers on the dais at the November AIIMS workshop (from left): YK Gupta, Shanthi Pal, Surinder Singh, Marie Lindquist

I also had the privilege of meeting students at the Empower School of Health, the Institute for Clinical Research India and the Delhi Institute of Pharmaceutical Sciences & Research. I had the impression that many students are optimistic about pharmacovigilance becoming a new career opportunity for health professionals in India both in clinical care and in the pharmaceutical industry.

All systems go in multi-cultural Abu Dhabi

Bruce Hugman reports from the capital of the United Arab Emirates

The Health Authority of the Emirate of Abu Dhabi (HAAD) launched its pharmacovigilance programme in June 2008. Since then, under the energetic management of its two permanent members of staff, Dr Shajahan Abdu and Dr Sahar Fahmy, extraordinary progress has been made, not least, with the receipt of a total of 1380 reports of ADRs and medication errors since launch, and currently more than eighty reports submitted per month (in a ratio of approximately 2:1).

Abu Dhabi is a remarkable place in its achievements, energy and social characteristics, including highly subsidised public utilities and health-care, and the high percentage of expatriates (80%), within the total population of 1.9 million.

The Pharmacovigilance section, currently with two dedicated officers, is located in the Drugs and Medical products Regulation Section (a team of six people) within the Pharma/Medicines and Medical products Department – alongside the Poisons and Drug Information Centre.

standard ADR form. Adverse events following immunisation will be added shortly. HAAD's rational drug use programme, with policy and implementation spearheaded by the pharmacovigilance team, is integrated within the pharmacovigilance programme.

The team has been responsible for studies into drug utilisation and consumption; consultation and prescribing time; prescription and dispensing practice audits; audits of the patterns of prescribing for high-use drugs (statins, anti-diabetics, PPIs) and implementation of the Generic Medicine Programme in the Emirate of Abu Dhabi.

What has been achieved?

Dr Mohammed Abuelkhair, Head of the Drugs and Medical products Regulation Section and Manager of the Pharmacovigilance team, says that much has been achieved in a relatively short time:

"We have focussed very strongly on professional relationships within the system, and on regular interaction, sensitisation, and communication with, for example, our focal persons at all facilities and pharmacies. Under-reporting remains a concern, but we hope the launch of patient reporting this year will help address that.

"Pharmacovigilance now has a strong basis in the Emirate, but there is, of course, much to be done in the areas of development and sustainability."

Administrative complexity

Abu Dhabi is one of the seven Emirates which form the UAE and is unique in having established an active pharmacovigilance programme, within the healthcare system. The Federal Ministry of Health has also taken a lead by establishing a national system covering all Emirates and is in the process of applying for membership of the WHO Programme. The Abu Dhabi Health Authority, in that respect, has the slightly odd status of a stand-alone regional centre, without access to the usual resources and tools available to members of the WHO Programme, including VigiFlow.

A fine model

The Abu Dhabi system has been based on intensive study of WHO guidelines and best practice in other parts of the world, and appears to have very solid foundations along with devoted and highly effective staff. HAAD has high ambitions, and on the basis of the first two and a half years, looks set to provide an inspiring example to other countries in the region and beyond.



Dr Mohammed Abuelkhair, with Dr Sahar Fahmy and Dr Shajahan Abdu at HAAD HQ

For more information, go to: www.haad.ae

The author recently spent three days working with the HAAD PV team and providing some Continuing Medical Education teaching.



This elegant image is the promotional face of the HAAD PV Section

Morocco lends a hand

The Abu Dhabi programme was launched with a national workshop, led by Moroccan Poisons and Pharmacovigilance Centre Director Dr Raja Benkirane and members of her team, Dr Souad Skalli and Dr Loubna Alj. Training workshops were also held for key personnel at thirteen major health facilities during this period.

This intensive schedule of workshops, training and outreach has continued, with more than 500 health facilities expected to have been visited by early in 2011. Each facility has an identified focal person with whom the team keeps in regular contact. Later phases will include around 350 pharmacies. The final phase in the current plan, on the cards for October 2011, is the launch of a patient reporting system across the country.

A broad vision

From the beginning, the pharmacovigilance scheme has included medication error, for which there is a special form, alongside the

Outcomes		
1.	Reports received since launch:1380	
	ADR	825
	ME	555
	Reports by profession	
a.	Physicians	653
b.	Pharmacists	86
c.	Nurses	78
d.	Allied healthcare professionals	8
e.	Public	1
2.	Most commonly reported classes of drugs associated with ADRs (by %)	
a.	Antibiotics	44.25%
b.	Anti-inflammatory	16.18%
c.	Analgesics	11.88%
d.	Anti viral	5.44%
e.	Anti hypertensive	3.41%
f.	Anti histamines	1.90%
g.	Genito-urinary medicines	1.77%
h.	Ophthalmologic drugs	1.64%
i.	Anti-diabetic and insulins	1.52%
j.	Anticonvulsant	1.39%
k.	Anti allergic	1.14%
l.	Anti asthmatics	1.01%
m.	Antifungal	1.01%
n.	Muscle relaxant	1.01%
o.	Others (including herbals and dietary supplements)	6.45%
3.	Patient outcomes	
a.	No improvement	10
b.	Recovered	560
c.	Recovering	147
d.	Require intervention	1
e.	Unknown	105
f.	Death	2

ISoP Celebrates 10th Anniversary

Alex Dodoo

The International Society of Pharmacovigilance (ISoP) held its 10th Annual Meeting in Accra, Ghana from 3rd to 6th November 2010 under the theme 'Pharmacovigilance in the global village'. The meeting celebrated the 10th anniversary of ISoP and a spectacular gala dinner-dance was held to mark the occasion. Several people commented later that this was the first time they had danced in decades – the pictures of ISoP 2010 speak volumes!

International attendance

ISoP 2010 was truly a global event being only the 3rd ISoP meeting in Africa (2001 was held in Tunis-Carthage and 2006 in Marrakech, Morocco), and the first in sub-Saharan Africa. There were nearly 300 participants from over 60 countries at the meeting and the Scientific Committee gave participants an excellent scientific programme which was probably surpassed only by the lavish and intensive social programme and wonderful meals and drinks laid on by the Local Organising Committee. Over one and a half days, five post-conference courses were offered, on *Creating a Safety Culture* (leaders: Sarah Daniels and Steve Powell), *Clinical Trials Safety* (Jing Bao, Brian Edwards, Hervé Le Louet), *Vaccine Safety* (Jan-Willem van der Velden, Katharina Hartman, Delese Mimi Darko, Alexander Dodoo), *Principles of Risk Management* (Eugene van Puijenbroek, Kenneth Hartigan-Go) and *Basic Concepts in Pharmacovigilance* (Deirdre McCarthy, Elliot Brown, Saad Shakir, Jayesh Pandit, Opper Greeff, Delese Mimi Darko), forming the icing on the cake on what was truly a memorable, enjoyable and extremely invigorating conference.



Andrew Herxheimer and Mary Couper, two new honorary members of ISoP

The meeting opened with a plenary on Pharmacovigilance in the Global Village (chaired by myself as ISoP President), and then came an insightful talk from Pia Caduff (Switzerland) on how to ensure safety during



ISoP General Assembly

mass deployment of medicines and vaccines. Dr Caduff shared the experiences of Swissmedic in managing AEFI reports during the recent H1N1 pandemic. Gerald Dal Pan (FDA, USA) gave a keynote lecture on 'New Frontiers on Pharmacovigilance' showing how initiatives in the US and Europe could be used as models by other regions to expand the frontiers of pharmacovigilance. Peter Arlett (EMA) gave an important presentation entitled 'Science, Medicines, and Health: Strengthening regulatory science and improving pharmacovigilance law to the benefit of public health', during which he explained the importance of good science and sound laws towards better pharmacovigilance and enhanced protection of public health.

More keynotes

The important role of epidemiology in drug safety was highlighted by Judith Jones (US) who spoke on 'Epidemiological Progress in the US' whilst Yola Moride (Canada) and John Freeman (Celgene, USA) discussed how to develop and implement risk management programmes. June Raine (MHRA, UK) gave an excellent final plenary lecture 'International Cooperation to Deliver a Global PV System'. She urged all countries to share information and experiences on drug safety to permit quick identification and communication of signals. She also called for the sharing of resources and for improved communication among regulators – in both developed and developing countries.

The Minister of Environment, Science and Technology of the Republic of Ghana, Ms Sherry Aryeetey gave a rousing presentation during the Eco-pharmacovigilance session, whilst Andrew Herxheimer and Kenneth

Hartigan-Go kept participants spellbound with the representations and discussions during the 'Forensic Pharmacovigilance' session.

A developing Society

Three eminent pharmacovigilantes – Andrew Herxheimer, Mary Couper and Chalbi Belkahlia were elected honorary members of ISoP during the conference.

According to the evaluation forms received ISoP 2010 was an excellent success. Mimi Darko (Chair of the Local Organising Committee), as well as Brian Edwards (Chair of the Scientific Committee), deserve great praise for putting together such a splendid social and scientific program. Yaw Asamoah and the Creative Trends team also need commendation for being responsive to the needs of participants.

ISoP 2010 was attended by all the past Presidents of ISoP – Ralph Edwards (Sweden), Giampaolo Velo (Italy), and Nicholas Moore (France), who together with me cut the 10th birthday cake supported by all past executive committee members. Sophie Spence, the founding and current ISoP Administrator, who is also the General Manager of the ISoP Secretariat in London, was given a surprise award for her hard work over the years to the loud cheers of members.

The sweet memories of ISoP 2010 will surely linger in the minds of participants, most of whom were making their first ever trip to sub-Saharan Africa. Full details of ISoP 2010 can be found on the ISoP website (www.isoponline.org)

See you next year in Istanbul!

Exceptional posters

Bruce Hugman

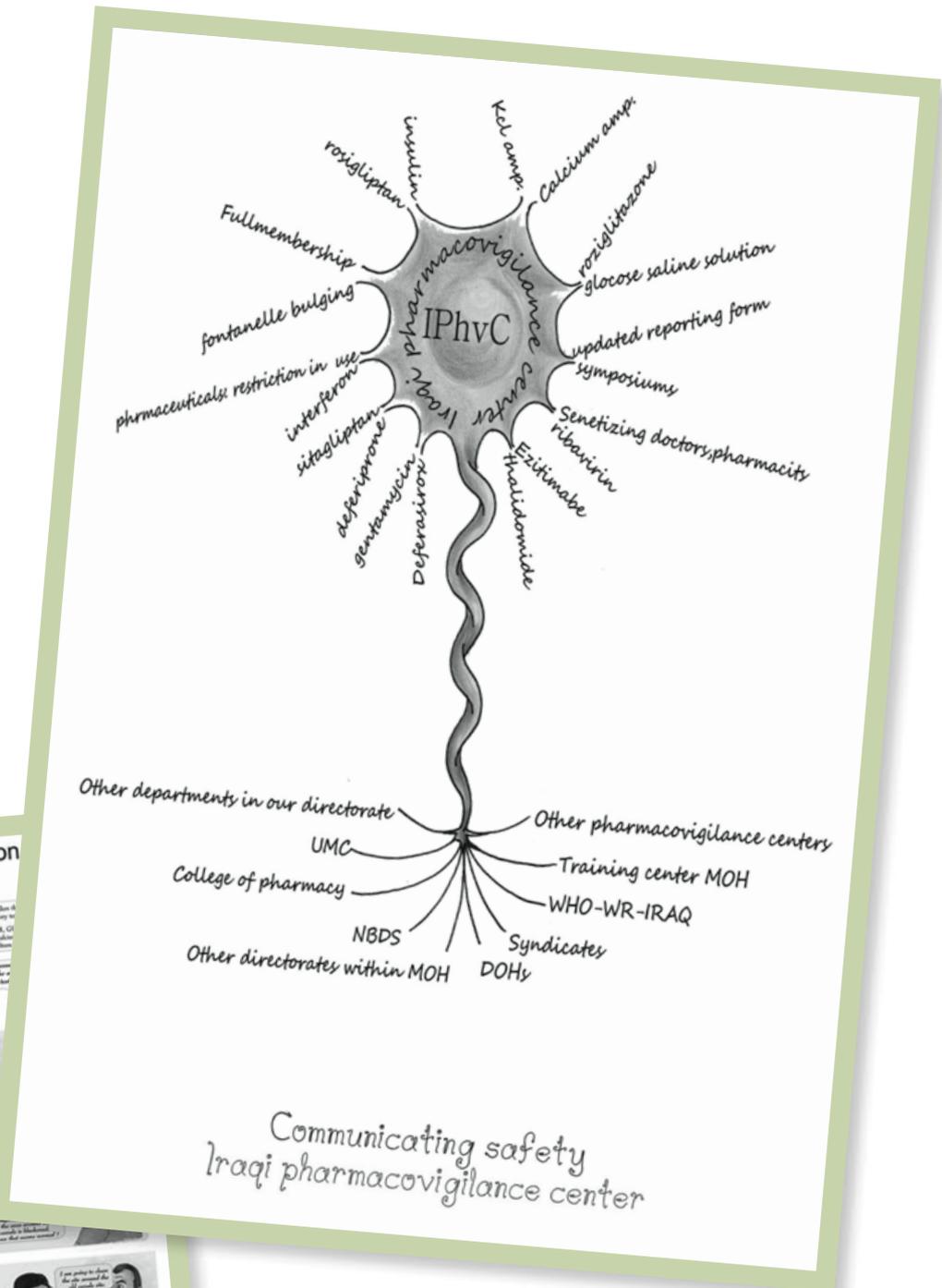
There were nearly two hundred posters on display at the ISoP meeting in Accra, most of them presenting interesting and important work in pharmacovigilance and patient safety. However, for visual impact and originality, the two posters from Manal Younus and her team at the Iraqi pharmacovigilance centre were outstanding.

A striking image

Presenting the basic functions, relationships and communications of their centre, instead of conventional text and bullet-points, they chose the suggestive structure of a multipolar neuron, and produced this strikingly unusual and beautiful image. At full size, of course, the textual details are easily legible, but in this version, you can clearly see the overall aesthetic quality. Their second poster, tracing the cause of an ADR from a medication error, was presented in the form of an illustrated comic strip.

Eye-catching work

Many people at the meeting remarked on how exciting it was to see pharmacovigilance communications being approached with such creativity and originality.



News from the European Medicines Agency

Priya Bahri

Two important developments of interest also to those outside the European Union (EU) have recently occurred. The first relates to the commitment of the European Medicines Agency to facilitate the submission of adverse reaction (ADR) reports from EU member countries to the WHO database maintained by the Uppsala Monitoring Centre by means of the EU central ADR database EudraVigilance. A statement was issued by the agency to coincide with the annual meeting of countries participating in the WHO Programme for International Drug Monitoring in Accra, and strengthens the agency's commitment to ensure that EU ADR reports become available within the WHO Programme as promptly as possible.

Statement on reporting of adverse reactions occurring in the European Union to the World Health Organization in preparation for the implementation of the new EU pharmacovigilance legislation. The new EU pharmacovigilance legislation, adopted by the European Parliament on 22 September 2010, requires the European Medicines Agency to make available promptly all suspected adverse reaction reports that occurred in the European Union (EU) to the World Health Organization (WHO).

De facto, this transmission should occur to the VigiBase database of the Uppsala

Monitoring Centre (UMC), which acts as the WHO Collaborating Centre for International Drug Monitoring. While the new legislation will formally apply 18 months after its publication in the Official Journal of the EU expected for early 2011, the new reporting provisions will only apply following successful testing of new functionality of the EudraVigilance database.

The agency, in collaboration with the Member States, has started its planning for the implementation of the new legislation, including this specific legal provision. For this purpose, the agency held a teleconference with WHO and the UMC in July 2010, followed up by a visit to the UMC in September. The agency is working on new functionality for the EudraVigilance database, allowing for transmission of reports to VigiBase, likely on a weekly basis.

Working party reports

The second development has been the publication on the agency's website of the meeting reports of its CHMP (Committee for Medicinal Products for Human Use) Pharmacovigilance Working Party. These contain information which is likely to be valuable also to those working in the field outside the EU.

The Pharmacovigilance Working Party (PhVWP) has been publishing these monthly reports after each of its meetings since September 2009. The reports include the following outcomes:

- PhVWP recommendations to the competent authorities of the EU Member States for nationally authorised products (unless subject to a procedure by the CHMP)
- information on the status of discussions for which PhVWP recommendations have not yet been finalised, where the safety concern is already in the public domain
- final guidelines on pharmacovigilance
- draft guidelines on pharmacovigilance and related documents for public consultation
- information on topics where the PhVWP contributes to publicly announced meetings or public consultations
- general matters, such as organisational issues of the European Union's regulatory network, policies and methods.

The link to access these reports is:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000198.jsp&tmurl=menus/about_us/about_us.jsp&tmid=WCOb01ac0580033aa1_jsp&tmid=WCOb01ac0580033aa1

Enhancing public involvement in reporting

Ennita Nilsson

The Monitoring Medicines (MM) project has invited patient organisations to join the review panel to further the discussions on public reporting of drug related problems. The patient organisations invited were HIV Europe (Henrik Arildsen), European Aids Treatment Group (Svilen Konov) and Kilen, a Swedish consumer organisation (Lena Westin). A survey on consumer reporting had been conducted by Florence van Hunsel, Linda Härmark and Kees van Grootheest from the Lareb.

The aim of the survey was to give a detailed review of methods used for consumer reporting of adverse drug reactions (ADRs) in 11 countries. The results will be used to identify optimal methods for public reporting, and create general tools that will allow such reporting mechanism to be made

available. The report indicated that although there are differences in the way countries handle consumer reports of ADRs, the importance of giving the public the possibility to report was widely recognized. The panel also acknowledged that new European Union (EU) legislation will require EU countries to have consumer reporting systems in place. The legislation is to be implemented after July 2012 and the deliverables of the MM project will be available by that time. The importance of having patient organisation involvement at every stage and influencing decisions was reinforced by the panel.

The European Union council recommended in 2009 that "Information and communication technology tools should also aim to improve the understanding of users of the medical

products." The review panel used this as a basis for examining the decision to develop a communication tool. The project will concentrate its aim and vision on this work throughout 2011 and hope to conduct the training in its use towards the end of the year. The survey report will soon be available at www.monitoringmedicines.org.

(For more recent developments in EU legislation on Patient Safety, you can refer to the official Journal of the European Union, Legislative acts REGULATION (EU) No 1235/2010 of the European Parliament and the council meeting held on 15 December 2010.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0001:0016:EN:P DF>

The tool kit takes shape

Geoffrey Bowring

As reported in UR50, the World Health Organisation with financial support from the Global Fund Against AIDS, TB and Malaria (Global Fund) has commissioned the establishment of an online Pharmacovigilance Toolkit to provide SOPs and full hands-on information on pharmacovigilance. The toolkit has been developed and is being maintained by the team at the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance at the University of Ghana Medical School in Accra, Ghana.

Participants at the Pharmacovigilance Stakeholders meeting in Accra on 4 November 2010 got a live demonstration of the toolkit after which the password and username were given out to enable participants and other stakeholders to use the toolkit and comment on it (see p5 for full report).

The WHO Advisory Committee on the Safety of Medicinal Products (ACSoMP) as well as key personnel from the UMC, WHO-Geneva and the Global Fund have had the chance to review the toolkit and to make suggestions for additions, review and improvement. It is an exciting project that will surely expand.

Basic tools and support

The Pharmacovigilance (PV) Toolkit itself is a package of simple pharmacovigilance tools and a description of supporting processes for the conduct of pharmacovigilance. It is targeted at pharmacovigilance professionals

in low- to middle-income countries, and provides the framework, tools, SOPs and support needed for the effective conduct of pharmacovigilance at sub-national, national and international levels.

By the end of 2010 the toolkit has extended to the following material, all available on the internet:

1. Introduction
2. Functions a national pharmacovigilance system
3. Minimum requirements for a functional pharmacovigilance system
4. How to set up a PV Centre
5. National Pharmacovigilance Centres
 - 5.1. Roles, responsibilities and coordination with the WHO Programme for International Drug Monitoring
 - 5.2. How to join the WHO Pharmacovigilance Programme
 - 5.3. ACSoMP
6. Pharmacovigilance Methods
7. Literature Resources for Pharmacovigilance
 - 7.1. Books
 - 7.2. Journals
 - 7.3. Computerized References
 - 7.4. Online References
 - 7.5. WHO Publications
 - 7.6. PDFs or Links to Selected Useful Publications
8. Definitions and terminologies in pharmacovigilance
9. Causality Assessment
10. Signal Generation in Pharmacovigilance
11. Communication in Pharmacovigilance
12. Crisis Management in Pharmacovigilance
13. Outline of curriculum for a standard course in Pharmacovigilance
14. Resources for pharmacovigilance
15. Financial issues involved in Pharmacovigilance
16. Monitoring and Evaluation in Pharmacovigilance including Pharmacovigilance indicators
17. Websites of organizations and societies involved in pharmacovigilance
18. List of Technical Assistance providers in Pharmacovigilance
19. Description of required activities so that PV would be included and implemented in Global Fund grants

Appendices

1. Standard Operating Procedure for Spontaneous Reporting
2. Standard Operating Procedure for Cohort Event Monitoring
3. Glossary of Terms

For further information on the toolkit and to obtain the username and password, do kindly contact Alex Dodoo by email on alex.dodoo@who-umc.org OR alex000@yahoo.com



Pharmacovigilance Toolkit
sponsored by:
The World Health Organisation & The Global Fund


hosted by:
WHO-CC, CTCPT,
Univ. of Ghana Med. Sch.

1. Introduction
2. Functions a national pharmacovigilance system
3. Minimum requirements for a functional pharmacovigilance system
4. How to set up a PV Centre
5. National Pharmacovigilance Centres
 - 5.1. Roles, responsibilities and coordination with the WHO Programme for

User group meetings in Accra

Monica Plöen

At the annual meeting of national centres in Ghana, UMC staff met on the 31st of October with mainly new members of the WHO Programme, for them to get an opportunity to learn about UMC's services and tools. This was followed by the first VigiSearch™/VigiMine™ user group meeting and the 3rd user group meeting for VigiFlow™.

Those meetings were preceded by educational sessions for the two systems. Anders Viklund guided us through VigiSearch/VigiMine, and a VigiFlow Basic Concept Course was held by Sara-Lisa Fors. In parallel a VigiFlow Advanced Course was run by Magnus Wallberg covering communication with regional centres, exchange of ICSRs with manufacturers, and search and statistics.

VigiSearch and VigiMine user group

Heather Morrison gave a brief presentation on how Health Canada uses VigiSearch/VigiMine in their signal work. In Canada the VigiSearch/VigiMine is used in working up signals and when completing signal detection. Review of the data in VigiSearch may be included as evidence to support potential associations between drugs and adverse reactions. If the substance names differ in different countries and the INN name is unknown, they make use of the search by drug name feature in order to find other products with the same active

substance. The IC value and stratification possibilities in VigiMine are also used in signal detection and signal evaluation.

Group exercise

In groups participants then discussed:

- What they are using the VigiSearch/VigiMine system for, and
- What the users may need that is not available today.

Some of the discussions were shared among all participants and feedback will provide valuable information in further development work on the tool.

VigiFlow user group

Viola Macolić Šarinić from the National Centre in Croatia described the pharmacovigilance history, development and workflow in Croatia, especially in relation to how they use VigiFlow in their work.

Magnus Wallberg gave a short description of new features in the next release (VigiFlow 4.2, December 2010). Among them was the adaptation to handle automatic E2B transmission ('gateway' functionality) developed with, and funded by Swissmedic. (See also report on new features in VigiFlow, page 17.)

Feedback from a survey conducted before the annual meeting was presented, relating

to internet connections, training needs, and general knowledge among the users about VigiFlow.

Group exercise

After the presentations participants split into groups to discuss the questions:

- What new functionality do you need in the VigiFlow system?
- Why do you need the new functionality described above?
- What would be the consequences if the new function is not implemented?

The results of this discussion are most valuable for the future development plans for VigiFlow. As always, suggestions for improvements are very welcome and necessary for the tool to be as useful as possible for the users. Suggestions can be sent to UMC by sending an e-mail to vigiflow@who-umc.org.

Currently UMC staff are compiling and analysing the responses we received from the two working groups. UMC is always interested in your views and wishes, please do not hesitate to contact us and tell us what you need and think. We may not be able to help you on all instances but we will certainly try. Write to: info@who-umc.org

Vigimed is dead – long live Vigimed

Geoffrey Bowring

For many years the Uppsala Monitoring Centre (UMC) has provided a closed e-mail distribution list to stimulate discussion and facilitate rapid exchange of information between representatives of National Centres participating in the WHO International Drug Monitoring Programme.

New portal

For some time the needs of national centres have not been fully met by the functionality of the Vigimed distribution list. This year the UMC has finally planned a newer means of exchange within the WHO Programme – a portal for themed exchanges, which we hope will meet the requirements of national centre colleagues around the world and encourage greater participation in discussions.

The overall aims of the Vigimed forum remain : to provide a restricted forum for those working in the WHO Programme to have easy access to safety concerns in other countries, to check regulatory status, and to expedite the sharing of drug information.

Extra possibilities

All members of the old Vigimed system are to be added to the new portal, but there are changes such as the possibility of uploading documents to share with colleagues, differentiation of subject areas for participants (Regulatory status, Product warnings, Pharmacovigilance issues (including early signals), Meetings, courses, events, and Other). These divisions, and other aspects of the new Vigimed will be reviewed after six months.

The new system will allow better searching and archiving of old threads and discussions. This will in time provide a resource for new participants as they join the Vigimed forum.

New features in VigiFlow

Magnus Wallberg

The latest improvements in VigiFlow 4.2 were released on 8 December 2010 to all users of this ICSR (individual case safety report) management and reporting system from the UMC.

Therefore it is now optional to send an uncoded drug request to the UMC. If users wish the UMC to code the drug, they tick a new checkbox 'send drug request to the UMC' on the page where an uncoded drug is

transmissions and will show error messages if a transmission fails. Import of E2B files will automatically be transferred to VigiFlow where the reports will be imported and the resulting acknowledgment will automatically be sent back. Reports will be automatically exported when they are committed to any added receivers with 'automatic E2B' set as preferred transmission type in the address book (see Figure 2). If no acknowledgment is returned within a specified period, a warning will be shown in the dashboard.

The automatic E2B transmission functionality will not be available to VigiFlow customers automatically, unless they have a special agreement with the UMC. Contact vigiflow@who-umc.org if you want more information.

Figure 1

The screenshot shows a web form titled "Add drug that doesn't exist in search". On the left is a navigation menu with options like "contacts", "give feedback", "user guide", and a numbered list from 0 to 10. The main form has several input fields: "name of product", "form" (dropdown), "strength", "MA-holder", "active ingredients" (text area), "obtain country" (dropdown), "comments/references" (text area), "ATC-code" (with a "pick ATC-code" button), and "indication" (with a "code" checkbox and a "search term" input). At the bottom, there is a checkbox "send drug request to the UMC" which is highlighted by a callout bubble. A note on the right side of the form reads: "Please help us out by specifying why an existing WHO Drug Dictionary record cannot be used." Buttons for "check entries" and "next" are at the bottom.

Included among the improvements were features on:

Russian, the fourth language

VigiFlow is now also available in Russian. This means that there now is a choice between four different languages: English, French, Spanish and Russian. Thanks go to WHO, Department of Immunization Vaccines and Biologicals, for the funding of the latest translation.

Performance improvement

In the list of reports under central assessments, a new option is added to the filter to increase performance of the page when the list contains many reports. The new option will limit the number of shown reports in the list of reports under central assessment to 50 as default, but this can be changed, for example if all are needed.

New option when suggesting new drug

If the appropriate drug cannot be found in the WHO Drug Dictionary™, it is possible for VigiFlow users to suggest a new drug to be added to the Dictionary. However, often there is not enough information known about the drug, or the drug is of less importance to the case in question (e.g. a concomitant drug).

described (see Figure 1). It is possible to change your mind by making a follow-up or amendment of the report and tick or untick the checkbox later. National Centres are encouraged to submit their national drug reference list to facilitate the coding process.

Automatic E2B transmission 'gateway'

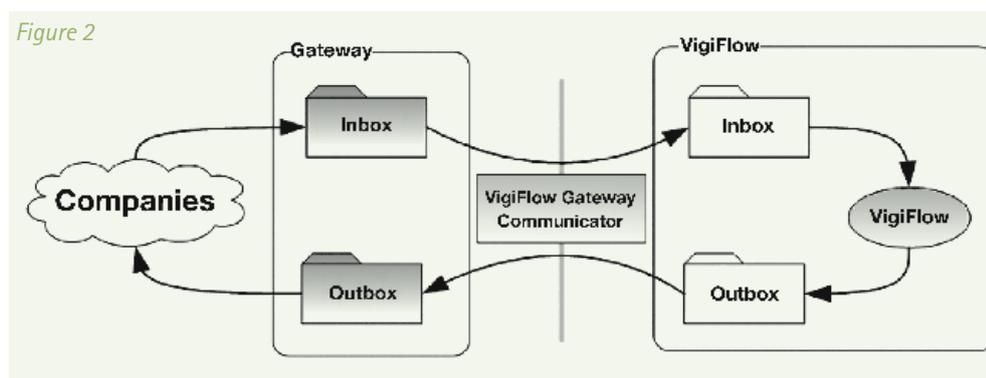
The main effort in the development of VigiFlow 4.2 has been made together with the Swiss Medicines Agency, Swissmedic and is funded by them. The aim is to allow for automatic transmissions of E2B files via a gateway.

A new page, called 'dashboard' has been developed to monitor the automatic

Other changes

Many other changes have also been introduced in VigiFlow 4.2; the E2B import has several new options and a copy function to facilitate quicker data entry has been added on the drugs and reactions pages. All changes are listed in the release notes available from the UMC. The User Guide available from the VigiFlow interface after logging in has also been updated and describes the new functions.

Currently 35 national centres and other organisations are actively using VigiFlow.



Consultation on WHO Family of International Classifications

Sten Olsson

UMC hosted an informal meeting on 12 November with representatives from WHO Classification Terminologies and Standards (Bedirhan Üstun, Molly Meri Robinson, Nenad Kostanjsek), WHO Quality and Safety of Medicines (Shanthi Pal) and the WHO Collaborating Centre for Drug Statistics Methodology in Oslo (Solveig Sakshaug) as well as several UMC representatives. The topic of the consultation was to agree on how best to organize collaboration between the organizations and WHO departments to support progress regarding:

- International Classification of Traditional Medicines (ICTM)
- ICD (International Classification of Diseases) revision leading up to ICD-11
- International Classification of Patient Safety (ICPS)
- International Classification of Health Interventions

Updates were initially given by representatives from WHO headquarters about these four projects. Representatives of the two WHO Collaborating Centres then presented their views on how their respective competences and activities could be of support to the projects. Of particular relevance was the WHO Drug Dictionary Enhanced, including herbal ATC classifications, maintained by the Uppsala Monitoring Centre, and the system of Defined Daily Doses and the standard system for ATC classification maintained by the Oslo Centre. There was agreement that compatibility between the WHO Adverse Reaction Terminology and the ICPS is also an important issue. It was concluded that the UMC and Oslo centre could be helpful in providing useful case scenarios for the various classifications.

Discussions followed regarding working methods, timelines and other relevant issues for the next stage of the overall project.



Dr Bedirhan Üstun

The Global Network in Dakar

Jerry Labadie

From 18–19 October 2010 the WHO Global Network for Post-marketing Surveillance of Newly Prequalified Vaccines (Network) held its 4th annual meeting in Dakar, Senegal. Network countries presented the current status with focus on four key areas

- scope of AEFI reporting over the last three years and analysis of their AEFI data
- experiences with data entry in VigiFlow and their evaluation of the VigiFlow system
- evaluation and feedback of the Network activities; and
- an update of their work plans for 2010–2011.

China and India were invited to share information on their AEFI reporting systems in general since this was the first time they had participated in a Network meeting.

Reporting and the UMC

UMC plays a crucial role in data entry (VigiFlow and WHO-ART) and data analysis and this is the focus of this report. Most Network countries use VigiFlow and they

were content with its performance. Comments related to compatibility with pre-existing databases, unstable internet connection and the relevance of some of the content for AEFI reporting. During the past year the UMC has completed a number of modifications to facilitate AEFI reporting by the Network countries. However, these vaccine specific data-entry fields are currently not to be used by other VigiFlow users since they will first be tested by the Network countries.

Examination of the data

Data submission by Network countries was launched in two phases (starting at the end of March 2010) based on the readiness of the countries to report with VigiFlow. As of 5 October 2010, five countries in the first phase (Iran, Mexico, Senegal, Sri Lanka and Uganda) had entered data into VigiFlow and committed the reports to the database. Dr Jeremy Labadie (UMC) gave an overview of these data. Due to incomplete data only preliminary results of a descriptive data analysis could be presented. The dataset was limited to 621 serious AEFI reports from 4 countries (Iran, Kazakhstan, Senegal and

Uganda) out of a total of 2489 reports. These serious AEFI reports concerned BCG, DTP, Hepatitis B, MMR and OPV vaccines, either administered as single vaccines or simultaneously. Death was the outcome reported in 71 reports with the majority, 59 following immunization with BCG vaccine. The data, including narrative, was not sufficient to reach conclusions on the cause of death and the causal relationship with the suspected vaccine(s). Most frequently reported AEFI were fever and febrile seizures for all vaccines except BCG vaccine for which lymphadenitis was most frequently reported. The dataset was too small to attempt to find new signals.

Work to come

Future priorities for the Network would include strengthening the submission and analysis of quality AEFI data, training in causality assessment and the use of VigiFlow, and planning for the future after 2012 when the current funding for the Network is scheduled to end.

New staff at the UMC

Fairytales and flyers

Ghazaleh Khodabakhshi



"It was a hot July morning in down-town Tehran. My dear mother was in terrible pain." That is how I usually start when asked to tell something about myself. One might question its

relevance, but one mustn't underestimate the impact of origin. At the age of 26 I have barely spent a fifth of my life in Iran and my last visit was the summer of '98. Yet, I am absolutely convinced that those crucial first five years in life have had huge influence on who I am today.

By contrast to the turbulent start of birth during war (Iran-Iraq 1980-1988), I had the privilege of a calm and quiet childhood in the harbour town Nynäshamn south of Stockholm. Uppsala became my home when I attended Uppsala University to study pharmacy.

I am currently Junior Researcher at the Research department, where I work on both internal and collaborative projects, including coordination and administrative tasks. My first encounter with UMC was a flyer on one

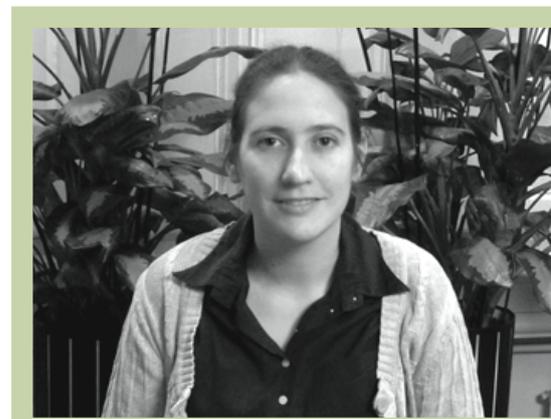
of the boards at uni. It turned out to be an ad from the Drug Dictionary team looking for summer associates, but more importantly it contained all the basic facts about the UMC.

Ever since that flyer, which I still keep in a drawer at home, I have spent a summer at the DD-department (as it was called back then), finalized my MSc with a study on the latency of adverse drug reactions as reported to VigiBase, and held my first qualified employment as Drug Safety Analyst at the Research department.

The written word accounts for one of my passions in life. At the age most little girls (including myself) dreamt of being a princess, my plan B was to write fairy tales. If you can't live it, write about it, I figured. Twenty years later I am still writing, switching genres with age, mood and occasion. One of my projects is writing my memoirs, which are being typed on my old typing machine Edwin. Yes, it has a name. With all that 50s charm and character I felt it deserved one.

With the writing comes a natural appeal for reading, or vice versa. Currently I am reading a recommendation from my former tutor, nowadays colleague and leading Star on the sometimes dark skies of pharmacovigilance, Kristina Star. Despite the title 'Just a little white sleeping pill' this book by Nadja Yllner has the potential of keeping you sleepless, as it retells the dreadful course of the thalidomide catastrophe. Read-worthy not for the literary experience, but for the story itself. It is a reminder of the purpose of our daily work being a contribution, if yet small, to public health.

Welcome, Anita



Anita Grabham, who is originally from New South Wales, Australia, has joined the UMC and is working with information retrieval within the Reporting, Analysis & Country Support Section. The responsibilities include dealing with requests for information from VigiBase from both external and internal sources, and being involved in signal detection work and other activities within the RACS section.

Anita worked at the UMC for 2 years as a consultant within the WHO-DD team. "I have a Bachelor degree in Pharmacy and a Masters Degree in Medical Science (Clinical Epidemiology). I worked in Australia as a pharmacist and then my husband and I moved to Sweden. Before I was employed by the UMC, I had several part-time jobs, including delivering mail and working in a restaurant."

"I like to travel and explore new places; geocaching* is a good way to find points of interest that you otherwise might not know about."

** Geocaching is a treasure-hunting game played around the world by people equipped with GPS devices. The basic idea is to locate hidden containers, called 'geocaches', outdoors, and then share the experience online.*

UMC posters

The UMC regularly has posters accepted for presentation at international meetings. These cover all areas of research and study engaged in by the UMC, either independently or in collaboration with others. Over 20 are available in Adobe pdf format for viewing or downloading (maximum size 750 Kb). Most recently we have added *Reporting patterns indicative of emerging drug interactions* and *Temporal pattern discovery for trends and transient effects: its application to patient records*.

CIOMS VIII

Practical Aspects of Signal Detection in Pharmacovigilance: Report of CIOMS Working Group VIII, mentioned in our 60th birthday article on the Council for International Organizations of Medical Sciences (UR49, p14) has now been published.

The report aims to provide a comprehensive resource for those considering how to strengthen their pharmacovigilance systems and practices, and to give practical advice. But the report acknowledges that solutions will inevitably be situation-specific and require careful consideration of local needs. However, the CIOMS Working Group VIII is convinced that "the combination of methods and a clear policy on management of signals will strengthen current systems".

The report anticipates a number of ongoing developments, including techniques involving other data forms than individual case reports. As the ultimate test for pharmacovigilance systems is the demonstration of public health benefit, signal detection methodologies need to meet this test if the expectations of all stakeholders are to be met.

The report (ISBN 92 9036 082 8) costs 39 Swiss francs and may be ordered from CIOMS website, www.cioms.ch

Expecting the Worst

The revised and updated edition of *Expecting the Worst* – the UMC's practical manual for effectively anticipating, preventing or managing crises has attracted attention as a resource for educational courses. We also anticipate several translations in the near future, which will be reported here when completed.

This guide presents all aspects of crisis planning and management, to help prepare for the worst that can happen, and give users the knowledge, plans and skills to anticipate and prevent crises, or to manage them capably and professionally.

The book is enhanced by 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 chapter on vaccine crises.

While the primary focus of the book is medicinal product and other healthcare crises, it has direct applicability to crisis-preparedness for all organisations, 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.

200 pages, 210x270mm, 9 chapters and 12 appendixes.

US\$75; SEK570; £60; £50 + post and packing. Order from the Uppsala Monitoring Centre's webshop via <http://www.unc-products.com/> > webshop

Being a Member in French

The UMC booklet for national centres, setting out the workings of the WHO Programme for International Drug Monitoring, has been translated into French. We are now able to provide material in French on advantages of membership – things that countries receive automatically from the UMC (VigiBase access,



Signal, terminologies and software, guidelines, and access to the international network). The booklet also sets out what is expected from national centres, including reporting format compatibility and quality, frequent submission of ICSRs, and involvement in Vigimed and the National Centres Annual Meeting.

Recent UMC publications

African Heat

Edwards, I Ralph. *Drug Safety, Volume 33, Number 12, 1 December 2010, 1059-1063(5)*

A report from the pharmacovigilance meetings in Ghana in November 2010.

Earlier discovery of pregabalin's dependence potential might have been possible

(Letter to the Editors). Ola Caster, I Ralph Edwards, G Niklas Norén, Marie Lindquist, *Eur J Clin Pharmacol*. DOI 10.1007/s00228-010-0920-4

Spontaneous monitoring : lessons from the past, uses in the future

RHB Meyboom. *Rheumatologia (časopis pre otázky pohybového ústrojenstva a spojiva)*, Vol 24, no 3 (2010), p73-80.

ISoP posters

The UMC presented the following posters at the ISoP conference in Accra. Full abstracts may be found in the October 2010 edition of *Drug Safety*, online reference *Drug Saf* 2010; 33 (10): 891-962. 0114-5916/10/0010-0891.

Free Text Extraction from Case Narratives to Highlight Suspected Drug Interaction

J Strandell, O Caster and GN Norén

A study to determine the extent to which text extraction from case narratives can improve ascertainment of suspected drug interaction on ICSRs.

Reporting Patterns Indicative of Emerging Drug Interactions

J Strandell, O Caster, A Bate, GN Norén and IR Edwards

Most efforts to implement systematic drug interaction surveillance in collections of Individual Case Safety Reports (ICSRs) have focused on disproportionality analysis. There has been little discussion of what detailed information on case reports could contribute to improved drug interaction surveillance. This study aimed to identify reporting patterns characteristic of emerging adverse drug interactions in the WHO Global ICSR Database, VigiBase.

An Overview of International Reporting to WHO of Adverse Reactions to Anti-Tuberculosis Medication

SN Pal, S Olsson, A Viklund, D Barter and D Falzon

This poster described patterns of spontaneous reporting of adverse drug reactions to anti-TB drugs.

Variations Across Drug Classes in Reported Time-to-Onset of Suspected Adverse Drug Reactions

G Khodabakhshi, K Star, GN Norén and S Hägg

The time from treatment start to onset of a suspected adverse drug reaction (ADR), hereby denoted time-to-onset, is fundamental to causality assessment. This study examined the extent to which reported time-to-onset for a selection of ADRs in the WHO Global individual case safety report database, VigiBase, corresponds to information in the literature and is subject to variation by drug class.

Specific Characteristics of African Individual Case Safety Reports

K. Star and J. Strandell

This poster investigated the characteristics of African reports in VigiBase in comparison to reports from the rest of the world.

Bulging Fontanelle Following Vaccination

Jeanette Johansson, Jerry Labadie and Richard Hill

Routine screening of VigiBase highlighted an association between Pneumococcal vaccine and Intracranial Hypertension (IH). This study analysed 175 reports in VigiBase of an association between vaccines and subsequent development of fontanelle bulging. Clinical review was made of all reports of intracranial hypertension (specifically those which refer to 'fontanelle bulging') possibly attributable to vaccines.

Cohort Event Monitoring: A WHO Strategy to Complement Spontaneous Reporting Systems

SN Pal, M Wallberg, D Coulter, IR Edwards and L Rågo

This poster presented current strategies in WHO to develop and promote a model of active surveillance that addresses current needs in public health programmes, and lends itself to systems and structures within countries in resource limited settings.

Books received

Textbook of Pharmacovigilance

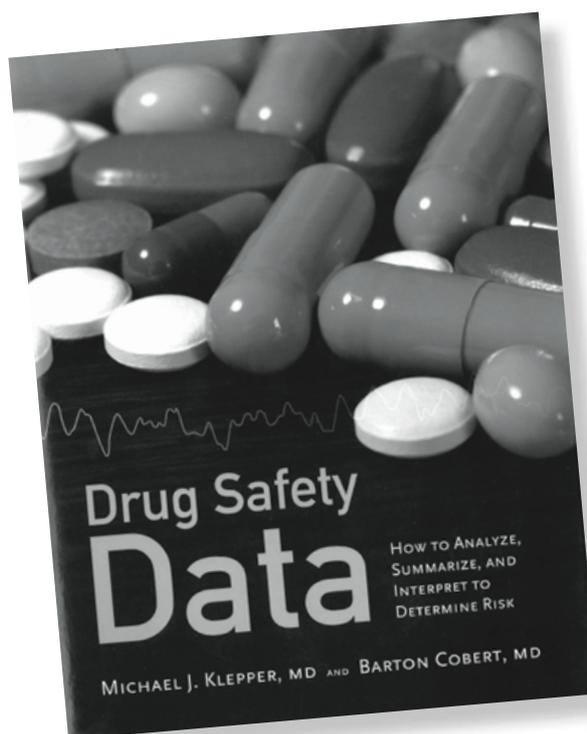
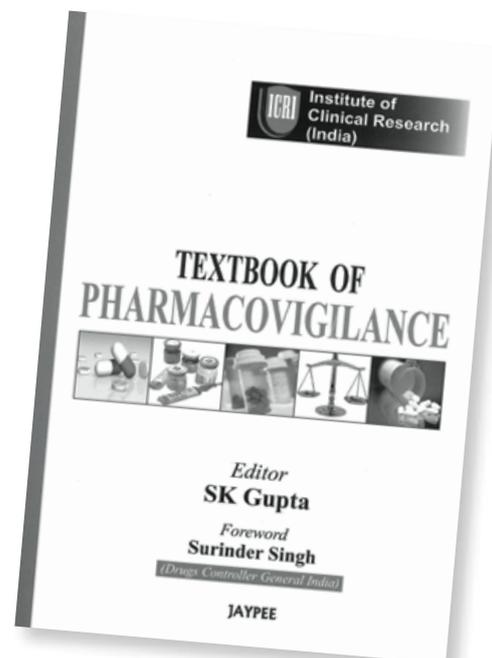
Ed SK Gupta. Jaypee Brothers Medical Publishers (P) Ltd, New Delhi, 2011.

This is an excellent basic text for a comprehensive approach to pharmacovigilance, edited by the former head of the national pharmacovigilance centre in India. Despite its focus on India, it covers regulations and guidelines from other countries (USA, China, Japan) and EMA. It links closely with accepted international standards and UMC objectives.

Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk

By: Michael J. Klepper, and Barton Cobert

The only guide of its kind, Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk is a valuable reference for pre- and post-marketing risk assessment. Paperback Length: 376 pages



Uppsala Reports print company wins green award

Copyprint UK Ltd, which prints *Uppsala Reports*, has won an award after having taken major steps to minimise their impact on the environment. Working closely with Carbon Smart consultants, they measured their carbon footprint and set a target to cut their emissions by 15% over three years – the equivalent of taking three cars off the road each year. Copyprint is one of the few printers in the UK to be Forest Stewardship Council (FSC) certified, uses eco-friendly inks which are vegetable-based and non-toxic, and has a recycling scheme to donate paper to local schools. They now aim to reduce Copyprint's emissions by a further 5% and switch their current gas-powered vans to hybrid or electric versions.

Finnish embassy



Mr Timo A Tanninen, Councillor for Social Affairs and Health, paid UMC a short visit in October last year. He works at the Finnish embassy in Stockholm and is performing an inquiry on the most significant international organisations with Finnish representation. Finland has been a member of the WHO Programme

for International Drug Monitoring since 1974. The Finnish Medicines Agency is regularly sending ICSRs to UMC and has recently converted to E2B format. Mr Tanninen will summarize his collected information in a report to the Finnish Ministry for Social Affairs and Health. The main purpose of the inquiry is to find out whether the organisations have any wishes in relation to the collaboration with Finland and how the Finnish embassy can support and further strengthen the future collaboration.

Top students from India

Empower School of Health in New Delhi offers a post graduate diploma course in clinical research management and pharmacovigilance. In November 2009, the best students of the class were rewarded with a study trip to Europe. The first stop on the tour was the University College in London (UCL) where they visited the University College Hospital and the Clinical Research Facility. The aim of these visits was



Anna Hegerius with the New Delhi students

to learn how to conduct clinical trials. There was also an opportunity to attend lectures by UCL faculty and interact with other clinical research students. After four exciting days in London, the group continued to Sweden and the next interesting stop – the UMC. For two days the students listened to a number of presentations by UMC staff to get a deeper understanding of drug safety. The students – most of them working in the pharmaceutical industry – felt that the visit provided them with a global perspective on pharmacovigilance. As the Indian national pharmacovigilance system is currently being implemented, the students may be able to contribute to its growth.

Libyan visitor



In November the UMC received a very welcome request for receiving a visitor. It was Dr Rida Al-Tubuly, head of registration department of the medicines regulatory authority of Libya who wished to come to Uppsala for two days to discuss how to develop pharmacovigilance in the country. Dr Al-Tubuly, who is also Professor of Pharmacology at the Faculty of Pharmacy, Al-Fateh University in Tripoli spent 6 – 7 December in Uppsala. At our request she started off by giving a lecture to UMC staff on the healthcare system and medicine use in Libya, of which we knew very little before.

Having that information as a background Dr Al-Tubuly spent time with the various technical specialists in the UMC pharmacovigilance services department, discussing how best to develop and promote pharmacovigilance and how best to use the facilities and services of the WHO Programme. We all realized that we had a very attentive and dedicated guest, and by the end of the two days we agreed to keep in close contact in the future.

CemFlow



Monica Plöen, Magnus Wallberg, Chris Duncombe, Geraldine Hill

Dr Chris Duncombe, Bill and Melinda Gates Foundation (BMGF) Programme Co-ordinator for HIV/AIDS at WHO, together with Dr Geraldine Hill, CEM Consultant at WHO, visited UMC in December to continue discussions on usability of the questionnaires for collection of information for patients in HIV/AIDS treatment, to be entered in CemFlow. CemFlow was originally built to manage information about malaria treatment, and is now being adapted to capture information on HIV/AIDS treatment.

Also on the agenda was also to review performance of CemFlow and look at the possibility of using it off-line. The plan is to have a pilot project up and running during 2011.

Participants from UMC were Magnus Wallberg, Ralph Edwards and Monica Plöen; Shanti Pal from WHO/QSM was involved in parts of the discussions.

DATES	TITLE	PLACE	ORGANISER/CONTACT
21-25 February 2011	Excellence in Pharmacovigilance: Clinical Trials and Post Marketing	London, UK	DIA Europe Tel.: +41 61 225 51 51 Fax: +41 61 225 51 52 Email: diaeurope@diaeurope.org
22 February 2011	Pharmacovigilance aspects of licensing agreements	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
2-3 March 2011	Monitoring Safety in Clinical Trials and Drug Development	London, UK	DSRU Tel: +44 (0)23 8040 8621 www.dsru.org/ E-mail: jan.phillips@dsru.org
14- 15 March 2011	Pharmacovigilance Summit (Risk management, life cycle management and post-marketing surveillance)	London, UK	Smi http://www.smi-online.co.uk/events/overview.asp?is=4&ref=3492
16-18 March 2011	Advanced Pharmacovigilance	London, UK	Management Forum Ltd (see above)
22-24 March 2011	P2T Congrès de Physiologie, Pharmacologie et Thérapeutique, including Journées de Pharmacovigilance	Grenoble, France	Société Française de Pharmacologie et de Thérapeutique www.congres-p2t.fr
23-24 March 2011	Back to Basics in Pharmacovigilance	Southampton, UK	DSRU (see above)
28-30 March 2011	23rd Annual EuroMeeting	Geneva, Switzerland	DIA Europe (see above)
4 April 2011	An essential guide to pharmacovigilance	London, UK	Management Forum Ltd (see above)
6-7 April 2011	Interpretation of laboratory results in pharmacovigilance	Southampton	DSRU (see above)
9-11 April 2011	ISPE mid-year meeting	Florence, Italy	ISPE www.pharmacoepi.org/meetings/ E-mail: ISPE@paimgmt.com
2-13 May 2011	Pharmacovigilance – the Study of Adverse Drug Reactions and Related Problems.	Uppsala, Sweden	UMC www.who-umc.org
18-19 May 2011	Staying current in the regulatory environment for pharmacovigilance	London, UK	DSRU (see above)
26-27 May 2011	ISoP training courses	Minsk, Belarus	International Society of Pharmacovigilance www.isoponline.org/training.html
8-9 June 2011	6th Biennial Conference on Signal Detection (pre-conference workshop on 7 June)	London, UK	DSRU (see above)
22-23 June 2011	Periodic Safety Update Reports 27th International Conference on	Southampton, UK	DSRU (see above)
14-17 August 2011	Pharmacoepidemiology and Therapeutic Risk Management	Chicago, USA	ISPE (see above)
26-28 October 2011	11th ISoP Annual Meeting: (also training courses)	Istanbul, Turkey	International Society of Pharmacovigilance www.isop2011.org



The Uppsala Monitoring Centre (UMC) is a not-for-profit foundation and an independent centre of scientific excellence in the area of pharmacovigilance and patient safety. We provide essential research, reference, data resources and know-how for national pharmacovigilance centres, regulatory agencies, health professionals, researchers and the pharmaceutical industry round the world.

Many of our services and products have been developed as a result of our responsibility - as a World Health Organization Collaborating Centre - for managing the WHO pharmacovigilance network of over 100 countries and the WHO global individual case safety report database, VigiBase™. A core function is the screening and analysis of data with the aim of detecting potential issues of public health importance in relation to the use and safety of medicines. Other services include technical and scientific support to WHO and its member countries, and provision of tools, such as VigiSearch™ and VigiFlow™, for data entry, management, retrieval and analysis.

Our main commercially available products are the family of international WHO Drug Dictionaries, used by most major pharmaceutical companies and CROs.

Communications information

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

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