

MUR60



In Brasilia | ICDRA

On the Jamaica beat | VigiFlow 5.0



Marie Lindquist
Director
Uppsala Monitoring
Centre

After a couple of weeks blissful holiday, where the biggest challenge of the day was to feed hungry grandchildren, my mind has had a good rest, from which it may not be so easy to kick-start into the rather higher gears needed for work. Having said that, catering for a larger group of people requires management efforts which should not be underestimated. We would not have ended up having a wonderful Christmas turkey meal unless a decision had been made (yes, we all think that having turkey is a good idea); the shopping list written and the necessary purchases completed; the oven started on time; the stuffing produced; the turkey prepared (surgical competence required!); and so on.

*Nevertheless, catering for the needs of an organisation with the aspiring vision of **safer patients**, and seeking to ensure continued delivery of high quality output, are challenges that demand attention on a different intellectual level than that needed to manage the household during a short and relaxed period in the company of close relatives – although I believe that the fundamental management principles are the same.*

My management philosophy is simple. It can be summarised in three words – responsibility, thought and action – within a framework of a shared vision and trust; and a genuine will and ability to listen, learn and collaborate.

First, you have to be given the right level of responsibility to carry out your assignment. Perhaps more importantly, you have to feel, and take, responsibility, sometimes beyond the mandate that you have been given, and possibly without the appropriate support and tools one may require in order to do a really good job. It is not only the needs of the customer (as in the end-user of a product or service that you are responsible for) that you must consider; having a managerial role means that an important responsibility is to lead and develop your team of co-workers, with provisions made for their needs, both as individuals and as part of the team. Does my team have the right competence, resources, and will, to do a great job? If not, it is your job to see to that the gaps are filled, or, at least, that the obstacles to success are reduced as much as possible. It is very easy to underestimate the need for a considered, and balanced, mix of abilities and personalities in a group working together. On a couple of occasions, we have done a Belbin Team Inventory¹ at the UMC. Although a test like this

should not be taken too seriously, it does give some insight into individuals' strengths and weaknesses when it comes to behaviour in the workplace (irrespective of professional competence and skills), which can be helpful in the composition of a winning team. For instance, wonderful ideas coming from thoughtful 'plants' or enthusiastically networking 'resource investigators' need diligent 'finishers' to be implemented successfully and on time.

*Second, for the successful realisation of an idea, each new project has to be carefully thought out and planned, and each phase – from preparation to development, implementation and follow-up – needs to be properly resourced and managed. A common mistake – yes, I know from my own experience! – is to set out, full of enthusiasm, on a new endeavour, fuelled by endless optimism and belief in the **idea** – without having thought it through properly. Why are we doing this? For whom? What are the consequences if we do this – and what would happen if we don't? Have we considered the long-term effects in terms of maintenance and support requirements? Much effort and money, I am sure, would be saved if we seriously seek to answer these questions before every new development, rather than having to face them as an afterthought. The same thinking should be applied also to regular work assignments aimed at maintaining a particular product or service, or administering work-flows and routine processes. Just because 'we have always done it this way' does not mean that it is the right way of doing it (I have previously referred to what my father calls the two notions that stop progress 'we have always done it this way' and 'we have never done it this way').*

*Third, it is the result that counts in the end. There is a time for thinking, and there is a time for doing. The world's best planning efforts would be wasted if they were not followed by the appropriate action and delivery of useful output. It is my job, and that of my management team, to get the priorities right – both in doing things right, and, most importantly, doing the right things. We believe that all UMC actions should be driven and inspired by the ambition to improve worldwide patient safety. My sincere wish for 2013 is that all of us around the world who share the same ambition engage in lively dialogue and productive collaborations so that we, together, can move closer towards the vision of **safer patients**.*

A handwritten signature in dark ink, appearing to read 'Marie Lindquist'.

¹ The Belbin Team Inventory is a personality test, also called the Belbin Self-Perception Inventory, Belbin Team Role Inventory, SPI or BTRSPI. It was devised by Meredith Belbin to measure preference for nine Team Roles. The Inventory assesses how an individual behaves in a team environment.

Source:http://en.wikipedia.org/wiki/Team_Role_Inventories. Accessed Jan 2, 2013

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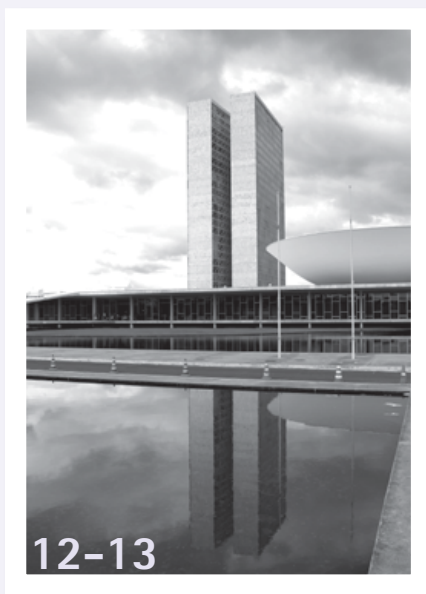
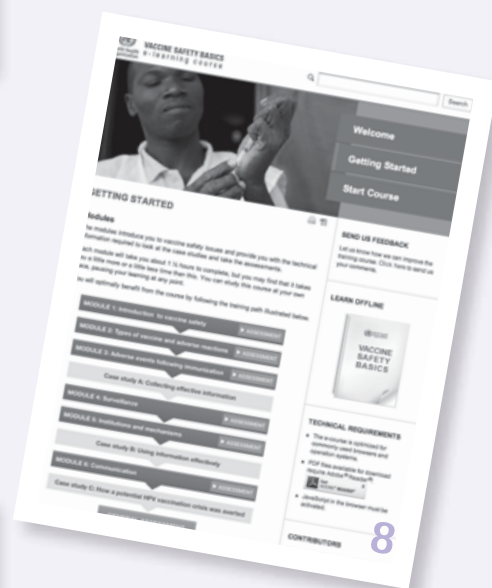


Vaccines safety

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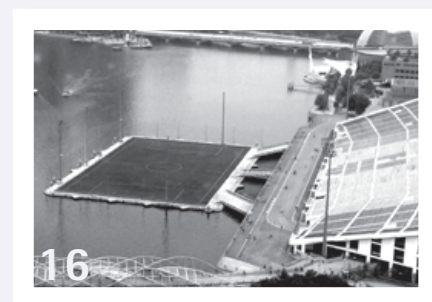


A global view

Surveying the pharmacovigilance scene from around the world

Reflections from Brazil

The WHO Programme met for its annual conference in Brasilia



Cape Verde joins the WHO Programme

The Cape Verde pharmacovigilance team

Background

The Republic of Cape Verde is a Small Island Developing State, comprising ten islands and five islets, divided into windward (Barlavento) and leeward (Sotavento) groups, and located in the mid-Atlantic Ocean at the latitude of Senegal, some 450 kilometers off the west coast of Africa. Cape Verde lies next to the major north-south sea routes and is an important communications station as well as a major sea and air refueling site.

In 2010, the Cape Verde population was estimated at 491,575 (half of which live on the main island, Santiago). Around 32% are under 15 years old and life expectancy is 71. Per capita income was about US\$ 1,200. The 2010 UNDP Human Development Index for Cape Verde was 0.534, which ranks it 118 out of 169 countries. Cape Verde's economy is service-oriented, and focuses on the tourism sector. Its vulnerability due to the scarcity of natural resources and shortfall of production capacity means the country has to rely on the international market to satisfy its domestic needs.

Promoting medicines monitoring

The need for a fully functional pharmacovigilance system was set out in June 2009. A workshop organized by the Food and Drug Regulatory Agency in Cape Verde (ARFA) led to the adoption of a strategy for post marketing drug surveillance and the creation of a working group.



Training session at Hospital Agostinho Neto, Praia.

In March 2010, ARFA, in collaboration with the medicines agencies ANVISA (Brazil) and Infarmed (Portugal) promoted training sessions on pharmacovigilance, risk management and rational use of medicines. A pilot-project was launched, and the first risk management group was established.

2011 was the first year of participation of Cape Verde in the training programme

organized by UMC. The Health Ministry's formal assignment of ARFA as the National Pharmacovigilance Centre for Cape Verde happened in June 2011. On 30th of October 2012, Cape Verde became the 110th full member of the WHO Programme.



Cape Verde Pharmacovigilance Team 2012: Dr. Lenira Centeio, Ms. Victória Robalo, Dr. Eduardo Tavares, Dr. Cálida da Veiga, Dr. Djamila Reis.

During that period ARFA promoted further sensitization and training sessions in detecting and reporting ADRs, at the Hospital Agostinho Neto, Hospital Batista de Sousa, Hospital Regional de Santiago Norte and the University of Cape Verde.

The Cape Verde centre

Cape Verde Pharmacovigilance Centre is based at the ARFA agency. It aims to develop: a national pharmacovigilance action plan, data collection/analysis and management, coordination and articulation of the information flux between the members of the National Pharmacovigilance System (SNF), coordination and supervision of medicine safety measures, releasing information about medicines safety and quality, and promotion of pharmacovigilance training sessions.

The Future?

The challenges for the next two years include the legal basis for the National Pharmacovigilance System (SNF), through a Law Decree proposal submitted during the first semester of 2012. This would promote notification next to private and public health professionals, management of ADRs and drug-related problem notifications, consolidation and improvement of the quality of those notifications, as well as setting-up the National Pharmacovigilance Committee.

For more information: visit our website www.arfa.cv or follow us on Facebook, Twitter or LinkedIn, or subscribe to our channel on YouTube! (ReguladorARFA)

Three new members

At the end of September **Jamaica** fulfilled the necessary requirements to become the 109th member of the WHO Programme (see report on page 16), and following Cape Verde, **Cambodia** joined at the beginning of November; the Cambodian Pharmacovigilance Center is part of the Department of Drug and Food in the Ministry of Health.

Also during the last quarter the United Arab Emirates has become an Associate member of the Programme.

Programme name

Last year it was decided by WHO Headquarters that in future the WHO Programme would be called the WHO Medicines Safety Programme instead of the WHO Programme for International Drug Monitoring.

UMC is currently finalizing the implementation of this change on the UMC website and introducing it in other materials. The formal title of the Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, however, remains.

DRC races ahead

Cecilia Biriell

Yves Lula Ntamba has recently written to us with news of the implementation of Drug Therapy Committees (DTC) in general hospitals, both rural and urban, in four provinces of the Democratic Republic of the Congo (DRC), where they are already sending in ICSRs. The aim is to improve rational use of drugs, and in addition DTCs could become a core of future regional pharmaco-vigilance centres.

Global Fund round 10 malaria project funding has given the centre the opportunity to carry out sensitization throughout the vast country – staff have travelled to more than ten cities to train health professionals. For routine activities, a steady stream of ICSRs

are arriving. Over the last two years 1,600 reports have been sent to the UMC via VigiFlow, with an equal number in the pipeline. Yves, who attended the UMC pharmaco-vigilance course in 2012, is one of three senior assistants in charge of reviewing reports submitted by junior assistants before they are finalized in VigiFlow. A CEM pilot programme ended successfully at the end of June and they hope to start using the CemFlow management tool during the coming year.

For a developing country with limited infrastructure DRC is leading the charge on ICSR reporting, not only in Africa. Currently they are top of the table of all countries for completeness and quality of their reports,

according to the UMC's Documentation Grading score (see UR54, p14-15 for a full description of Documentation Grading).



Training in DR Congo

WHO safety issues merge

Sten Olsson

WHO decided to merge two of its previous administrative 'clusters' into a new cluster called Health Systems and Innovation (HSI), headed by Assistant Director-General Marie-Paule Kieny. As of 1 November 2012, the following core departments are located in the new cluster:

- Essential Medicines and Pharmaceutical Policies (EMP) – led by Cornelis De Joncheere
- Ethics and Social Determinants (ESD) – led by Ruediger Krech
- Health Statistics and Information Systems (HSI) – led by Ties Boerma
- Health Systems Policies and Workforce (HPW) – led by Wim Van Lerberghe
- Health Systems Financing (HSF) – led by David Evans
- Knowledge Management and Sharing (KMS) – led by Najeeb Al Shorbaji

- Public Health, Innovation and Intellectual Property (PHI) – led by Zafar Mirza
- Patient Safety Programme (PSP) – led by Ed Kelley
- WHO Centre for Health Development (Kobe) (WKC) – led by Alex Ross

As part of the reorganization the Quality Safety and Standards (QSS) unit for vaccines, led by David Wood, was moved from the Immunization Vaccines and Biologicals department to join the EMP department of the new cluster. The WHO Medicines Safety Programme is hosted with the QSM team of the same department. With the new organization safety aspects of both medicines and vaccines are now managed within one WHO department. The WHO Patient Safety Programme resides within the same cluster.

New doctors in Uppsala

As we go to press, two new medical doctors are joining the UMC: Pia Caduff-Janosa (Chief Medical Officer) and Geraldine Hill (Medical Doctor, CEM specialist). Both have considerable experience in the field of monitoring medicines safety – Pia principally in Switzerland as most recently the Head of the Vigilance Unit at Swissmedic (Swiss Agency for Therapeutic Products) and Geraldine as Teaching Fellow at University of Otago Medical School, Dunedin, New Zealand.

These appointments are aimed at strengthening the UMC's expertise in key topics such as cohort event monitoring and vaccines, as well as providing experience of working in pharmacovigilance with public health programmes and national centres. The UMC's signal review process will also benefit from this additional guidance from our new doctors. Full details will follow in Uppsala Reports 61.

Patient reports

A valuable editorial highlighting the importance of patient reporting was published a few months back in an authoritative mainstream medical journal.

Drug safety: reporting systems for the general public – WHO's latest guidance is relevant to developed and developing countries by Dr June Raine of the UK's MHRA, is an important boost for those involved in patient safety.

June Munro Raine. Editorial. Drug safety: reporting systems for the general public – WHO's latest guidance is relevant to developed and developing countries. *BMJ* 2012;345:e4916 doi: 10.1136/bmj.e4916.

Regulators discuss pharmacovigilance

Sten Olsson

WHO organizes an International Conference of Drug Regulatory Authorities (ICDRA) every second year. The 15th ICDRA was held in the historic city of Tallinn, Estonia, from 23–26 October 2012. Representatives of drug regulatory authorities from all parts of the world came together to exchange information and to learn from each other in the joint effort of achieving well harmonized rules and regulations for the global trade of high quality pharmaceutical products and their safe and effective use.

International visions

This time a full morning of the programme was devoted to the topic 'Pharmacovigilance: Visions for the future'. The session was moderated by Esnart Mwape from Zambia and Mary Lou Valdez of the USA. The first speaker was Peter Arlett, European Medicines Agency, who presented the new EU pharmacovigilance legislation and its opportunities for improving public health. Christine Ho then gave the Singapore's regulatory perspective on the topic: 'Towards better pharmacovigilance'. Her talk was followed by Adeline Osakwe of Nigeria, talking about 'Developing pharmacovigilance in an emerging economy'. Finally Karen Midthun from the USA presented 'A vision for advancing pharmacovigilance systems'. Recommendations from the session are shown in the box opposite.

better regulate blood products, herbal medicines, vaccines and medical devices had safety monitoring implications.



Peter Arlett

All presentations are available as pdf-files from the ICDRA web site www.icdra.ee/icdra-presentations

UMC reaches out

The WHO Medicines Safety Programme was represented in the foyer of the conference by a booth. Helena Wilmar, Johanna Stenlund and I had the opportunity to interact with many country representatives during the four days, including some from national pharmacovigilance centres. We also disseminated a lot of printed WHO and UMC material to visitors for their later perusal.

ICDRA recommends the need for:

- Broader interpretation of pharmacovigilance definition as appropriate to the local environment
- Better tools and capacity for effective:
 - risk minimization, benefit/risk assessment
 - surveillance, research and decision-making
 - integration and cohesive systems
- Product life-cycle pharmacovigilance for:
 - clinical trial development
 - post-marketing surveillance
 - embracing the evidence hierarchy
- Additional sources of data
- Common nomenclature
- Need for data standards and common reporting
- Data sharing
- Appropriate use of standards



Helen Byomire-Ndagije (Uganda), Lembit Rägo and Shanthi Pal (Quality Assurance and Safety: Medicines, WHO) in Tallinn

Touching on safety

The programme of the ICDRA conference had several other topics of interest for patient safety. One workshop was on 'New tools for effective collaboration in combating SSFFC medicines' and sessions on how to

Vaccine safety stakeholders in Egypt

Sten Olsson

We have earlier reported on the WHO Global Vaccine Safety Blueprint and its implementation mechanism, the Global Vaccine Safety Initiative (GVS, see UR59 p4). The GVS planning group had its first face-to-face meeting in August 2012, and the first general meeting of stakeholders was held on 20 and 21 November 2012 in Hurgada, Egypt.

GVS stakeholders

GVS stakeholders are intergovernmental organizations, international non-governmental organizations, academic institutions, governmental institutions and agencies involved in regulatory activities, international industry umbrella organizations and WHO Collaborating Centres. Observers are organizations, agencies or institutions involved in activities which are relevant to all or part of the mandate of the Initiative as well as individual vaccine companies. The objectives of the meeting were to report on national and global initiatives and experiences to strengthen vaccine pharmacovigilance, identify needs and opportunities to support countries in implementing an effective vaccine pharmacovigilance system and to provide a platform to develop collaboration in support of GVS. In all about 65 persons from all WHO Regions attended the meeting.

Meeting programme

The structure of the meeting agenda followed the eight strategic objectives of the Global Vaccine Safety Blueprint (<https://extranet.who.int/iris/restricted/handle/10665/70919> - open: WHO_IVB_12.07_eng.pdf).

The first session focused on enhancing the detection and reporting of AEFIs with reports from China, Sudan, Sri Lanka and Brazil. The second session on evaluating vaccine safety signals included presentations from Iran on lymphadenitis to BCG vaccines, a study from the USA on Guillain-Barré Syndrome in the 2009 H1N1 pandemic and a discussion of signal verification and hypothesis testing using large health care databases from Erasmus University, Netherlands. The third session referred to vaccine safety communication, with presentations from Uganda and the London School of Hygiene and Tropical Medicine.

Second day

The first session of the second day was on Harmonized tools and methods for vaccine pharmacovigilance. An overview was given by WHO/QSS (Quality, Safety and Standards), and I presented a UMC approach for a general case management system for AEFIs, compatible with VigiFlow and the E2B format. Automatic case classification to facilitate signal verification was presented from the Brighton Collaboration. The strategic objective five of the Blueprint refers to the promotion of a legal, regulatory and administrative framework. The WHO approach to strengthen the capacity of National Regulatory Authorities was presented from Senegal and Indonesia and an overview of approaches to pharmacovigilance in the American region was presented by the WHO Regional representative.

Regional and global technical support and training was the subject of the next session in which GVS training facilities were presented by the WHO secretariat and a representative of the International Vaccine Institute (IVI) outlined its facilities for training and technical support. A session on expert scientific advice at national, regional and international levels followed. Presentations were made by representatives from Albania and the WHO Eastern Mediterranean and American regions.

The final session covered the promotion of information exchange between regulators, manufacturers and multilateral agencies. CIOMS and the VACCINE-GRID private-public partnership was presented.

Before the meeting closed, a brief summary of identified needs and opportunities to support an effective vaccine pharmacovigilance system was provided, approaches for collaboration between the GVS stakeholders were suggested and recommendations feeding into the work of the GVS planning group were listed.

GVS planning group

Following the general GVS stakeholders meeting the planning group stayed on in Hurgada for two more days to digest the recommendations made and to prioritize/align the activities in the GVS portfolio with the identified gaps.



65 stakeholders ready to tackle global vaccine challenges

WHO e-learning course on vaccine safety

Sten Olsson

While there is no replacement for a well-run face-to-face training course, internet learning courses are vital as a means of offering learning opportunities to a wider audience.

A new online vaccine safety course has been launched by WHO which covers all the main elements of vaccine safety from baseline definitions, through an introduction of vaccines and Adverse Events Following Immunization (AEFI), to surveillance, vaccine safety stakeholders and communication. It is aimed at future WHO training participants, country regulatory authority and immunization programme staff, and any others working in areas related to vaccine safety. This could include professionals such as nurses, midwives or community health workers, as well as pharmacists, medical doctors and technical officers.

The course includes learning tools, such as assessments, an advanced search functionality, clear navigation, and a thorough glossary. In addition, user statistics will be collated to help evaluate it, and to individually support countries who wish to follow up on its implementation.

The link is www.vaccine-safety-training.org. Alongside the detailed and didactic material users can take short tests on their knowledge or look in more depth at a particular point. Students can work at their own pace and at the depth preferred, recognizing their prior knowledge. Although the US experience in the area is the main reference point, the content is sensitive to most international settings.

The course modules are:

1. Introduction to vaccine safety
2. Types of vaccines and adverse reactions
3. Adverse events following immunization
4. Surveillance
5. Vaccine safety institutions and mechanisms
6. Communication

The course includes three case studies, presenting a different set of challenges for students to work through, during which feedback is provided.

Case Study A: Collecting effective information

Case Study B: Using information effectively (where the student has to act as monitoring officer of an immunization programme in a day-by-day response to a reported cluster of serious adverse events)

VACCINE SAFETY BASICS
e-learning course

World Health Organization

Search

Case study A
Case study B
Case study C
Glossary

MODULE 1: Introduction to vaccine safety

Module 1 | Module 2 | Module 3 | Module 4 | Module 5 | Module 6 | General Assessment

OVERVIEW

Vaccination is one of the great public health achievements of human history. Vaccines used in national immunization programmes (NIPs) are considered safe and effective when used correctly. Vaccines are, however, not risk-free and adverse events will occasionally occur following vaccination. Public trust in vaccine safety is key to the success of vaccination programmes.

This module serves as an introduction to the whole course. You will learn about the importance of immunization programmes and how vaccines work. You will understand the relationship between vaccine coverage, adverse events and disease spread. You will also learn about the importance of vaccine regulations in ensuring the effectiveness of vaccine initiatives.

MODULE OUTCOMES

By the end of this module you should be able to:

- 1 Explain the importance of Vaccination in the control of infectious diseases,
- 2 Describe the basic principles of vaccination,
- 3 Explain how the public are less tolerant of the risks associated with vaccines (although very low) than they are of those associated with drugs used to treat disease,
- 4 List the main types of vaccine and illustrate them with examples,
- 5 Describe the importance of post marketing vaccine safety surveillance,
- 6 Identify some vaccines that have been associated with adverse vaccine reactions.

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CONTENT

- Overview and outcomes
- Importance of immunization programmes
- History of vaccine development
- Expectations towards safety of vaccines
- How the immune system works
- How vaccines work
- Vaccine-preventable diseases
- Types of vaccine
- Adverse events
 - Classification
 - Causes
 - Frequency and severity
- Vaccine safety in immunization programmes
- Vaccine regulations
- Pre-licensure vaccine safety
- Post-licensure vaccine safety
- Balancing efficacy and safety
- Summary
- Assessment 1

World Health Organization Copyright © 2013 WHO | Glossary | References | Course evaluation | Contact

Case Study C: How a potential Human papillomavirus (HPV) vaccination crisis was averted

The Glossary is comprehensive, with an audio pronunciation tool.

To take the various assessments the user must follow a simple enrolment procedure.

The course was put together by several leading vaccine experts from South Africa, USA, Canada and Indonesia, based on preliminary work by Molly Mort (project coordinator and writer of a pilot course).

PV + SFFC = Bright future in Belgrade

Johanna Stenlund

In September I left the cold autumn in Sweden for 30 degrees and a clear-blue sky in Belgrade, Serbia. I had been invited to a conference hosted by ALIMS (Medicines and Medical Devices Agency of Serbia), where pharmacovigilance and counterfeit-related issues were on the agenda.

We received a very warm welcome from Pavle Zelić, PR Manager of ALIMS, who took us on a sight-seeing tour in Belgrade. We saw some of the important landmarks of the city, such as the enormous Saint Sava Church, one of the largest churches in the world. We ended with dinner at the astonishing restaurant Lorenzo Et Kakalamba, famous for its food and spectacular interior design.

Broad audience

The conference caught the interest of more than 100 participants, and most pharmaceutical companies in Serbia were represented. ALIMS had put together an interesting agenda and several speakers were invited to give their view of global/European topics while staff from ALIMS presented issues of particular relevance for Serbia.

Sabine Walser was invited to talk about the Medicrime convention, Domenico Di Giorgio from Italian Medicines Agency (AIFA) spoke about the fight against falsified medicine in Italy and representatives from Sanofi-Aventis presented their work with falsified medicines both in Serbia and on a global scale. Miroslav Ilić from the company GS1 gave an overview of an interesting pilot project where the labelling and coding GS1 standards had been implemented in order to enable traceability in the health care supply chain.



Marko Erić (far left) and his staff, with Johanna Stenlund

Pavle Zelić and the National Centre Head Marko Erić, gave presentations regarding spurious/false-labelled/falsified/counterfeit (SFFC) medicines experiences in Serbia and risk management. Hans van Bruggen from eCTD Consultancy gave an overview of the complexity of all the documentation needed related to the regulatory aspects of pharmacovigilance.

The Director of ALIMS, Tatjana Šipetić talked about the national pharmacovigilance system, their use of VigiFlow™ as data management system for ICSRs and their contribution to the WHO Medicines Safety Programme. I was invited to talk about our work at the UMC related to global pharmacovigilance and SFFC.

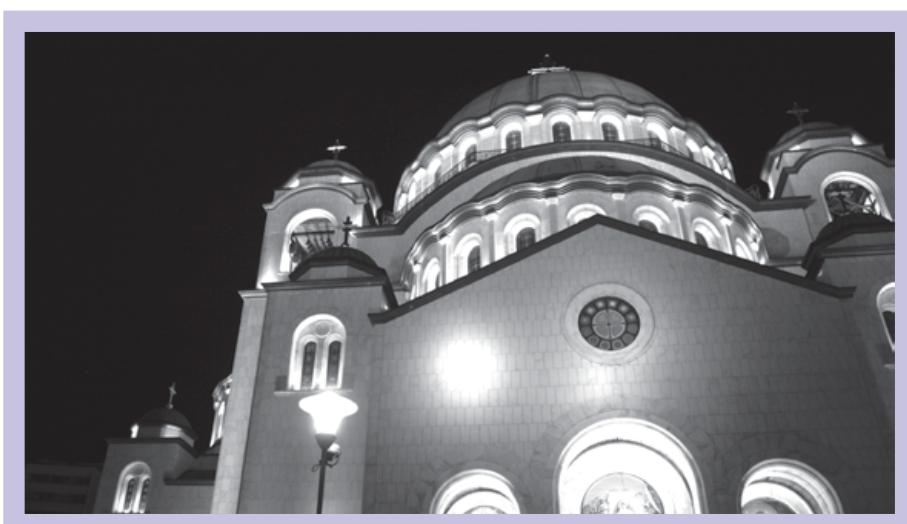
At ALIMS

The day after the conference, Domenico Di Giorgio and I were invited to visit ALIMS. Pavle Zelić, showed us his 'baby', an information terminal where the ALIMS visitors can discover facts about the centre and find their way through the building. A guided tour was arranged and we got to see the laboratories, various equipment used for identification of SFFC drugs and an insight to the work that is being performed at the centre.

I had a very fruitful meeting with Marko Erić and his staff at the National Centre, where despite their heavy workload they took their time to update me on their pharmacovigilance work. We discussed their reporting system and their plans of enabling online reporting both for patients and HCPs. Issues regarding their use of VigiFlow were raised and we discussed how they could improve their use of the system and simplify their work even further.

All in all, this was a very fruitful visit where the important connection between SFFC and pharmacovigilance became even more obvious. I also brought some very important insights with me back to the UMC which resulted in some new ideas for how to improve our work within the WHO Medicines Safety Programme.

Hvala Beograd and ALIMS for your splendid hospitality!



Saint Sava Church

A change blowing over Africa

Alex Dodoo

Pharmacovigilance in Africa is going through a rapid phase of growth and development thanks to several initiatives from WHO and UMC. The continent now has two WHO Collaborating Centres for Pharmacovigilance



Alex Dodoo and staff of UMC-Africa and Sante Afrique

– in Accra, Ghana (since 2009) and Rabat, Morocco (since 2011). In addition, the Uppsala Monitoring Centre's Africa office – UMC-Africa (UMC-A) has been operating since June 2009. In recognition of the important work being undertaken by UMC-A, UMC has renewed, enhanced and expanded the UMC-Africa contract in order to deliver enhanced pharmacovigilance services and products to all in Africa – principally to national pharmacovigilance centres but also to academia, industry and patient organisations where needed.

Head of UMC-Africa is still Professor Alex Dodoo with Sharon Ako-Aduonvo as Deputy Director. New recruits include Hagggar Hilda Ampadu (Director of Operations and Head of New Business) and Ken Agbodza (Head of Training and Quality Assurance) and Anita Anang (Project Manager). Abdul Malik Sulley is Chief Technology Officer whilst

Issifu Acheampong remains the head of finance and accounting. The team is supported by three consultants: family physician Roberta Lamptey and clinical pharmacists Ellen Sam and Stephen Corquaye. The UMC-A team will work very closely with the UMC Pharmacovigilance Services Department to develop joint programmes and activities. It is expected that there will be regular movement of staff between Uppsala and Accra for training, interactions and service delivery. UMC Consultants such as Bruce Hugman will continue to work with UMC-A in providing training and support in communication and crisis management. The UMC-A contract is managed by Sante-Afrique Limited whose other staff members will provide support for UMC-A work as necessary. Pharmacovigilance in Africa is on a positive move and the strong dedicated team in Accra is ready to move things forward.

Sustainable and functional pharmacovigilance

Shanthi Pal, Medicines Safety Programme Manager, WHO

Life-saving drugs and vaccines are reaching unprecedented numbers of people in low- and middle-income countries. With dozens of promising drug and vaccine candidates in development, millions of children and adults in these countries may soon receive novel, life-saving drugs and vaccines for malaria, dengue fever, and other diseases. Pharmacovigilance needs to keep pace with these expanding treatment and immunization programmes.

Monitoring new products

In recent years, many developing countries have adopted post-market safety systems with the help of numerous partners such as the World Health Organization (WHO), the European Commission, the Global Fund, PEPFAR, BMGF, GAVI and USAID. These efforts need to be sustained, to further strengthen the systems in low- and middle-income countries, to ensure they are fully functional and ready to monitor, at the very least, the new products that will be introduced in the coming years.

Gates Working Group

A Safety Surveillance Working Group was convened by the Bill and Melinda Gates

Foundation (BMGF) to develop practical and scalable strategies for supporting post-market drug and vaccine safety surveillance in low- and middle-income countries. The working group included representatives of the BMGF, biopharmaceutical company partners, product development partnerships, regulatory authorities, technical agencies, academia, and the global health policy community.

Report in the offing

The working group met thrice, over 7 months, between May and December 2012. The first two meetings discussed prioritization; leveraging regional approaches, existing infrastructure, and local governments and industry partners to improve sustainability. The last meeting, held in Ethiopia, in December 2012 discussed options for ensuring scalability and compatibility with existing international pharmacovigilance initiatives. The final product of the working group's efforts will be a policy report, to be disseminated publicly and published in shorter form.

Strengthening PV through Global Fund grants

Sten Olsson

Serge Xueref, Senior adviser, WHO Medicines Safety Programme, has published a valuable feature article in WHO Pharmaceuticals Newsletter No 5, 2012. He explains how grants from the Global Fund to fight AIDS, TB and malaria (GF) can be used to support pharmacovigilance activities in eligible countries. Such countries are urged to have a look.

ISoP beaches in Mexico

The UMC team in Cancún

In the last week of October, a UMC delegation attended the 12th Annual Meeting of the International Society of Pharmacovigilance (ISoP). The meeting took place in Cancún, Mexico, a tourist destination with a very nice beach. We did, however, manage to drag ourselves away to attend the meeting.

UMC present

The UMC was involved in many ways; Marie Lindquist and Ola Caster presented two topics each and Ralph Edwards and Marie each chaired a session. Interest in all UMC presentations was good, particularly Ola's presentation on Improved adverse drug interaction signal detection, after which there were many requests for Johanna Strandell's related thesis. In addition, we had six posters, three from the research department and three from the pharmacovigilance department and our printed copies of the abstracts, in both English and Spanish, were all taken on the first day. There was a table with UMC materials, and it was very much appreciated that members of our delegation were able to speak Spanish.

Some new landscapes

The theme of the Cancún meeting was "New Landscapes for Pharmacovigilance". Perhaps it was too much to expect that every item

would be unexplored territory, instead the lectures aimed to further explore new aspects of current pharmacovigilance initiatives across the globe. This should have given participants the opportunity to share best practices as well as common problems and challenges, but sadly there was very limited debate on presentations: this is a common challenge to be resolved in most international meetings. However, the three-day agenda was intense and covered several interesting areas such as:

- Signal detection
- Pharmacovigilance in paediatrics
- Role of pharmacists in patient's safety
- Studies in pharmacovigilance
- Pharmacovigilance in pharmacogenetic variations and in special populations
- Ecopharmacovigilance
- Pharmacovigilance in hospitals
- Communication in pharmacovigilance.

As well as the main programme, three different pre-conference training courses were held on the 30th October. The students could choose to learn more about the 'Basics in Pharmacovigilance', 'New EU-post licensing legislation' or 'Vaccines Pharmacovigilance'.

Journey through history

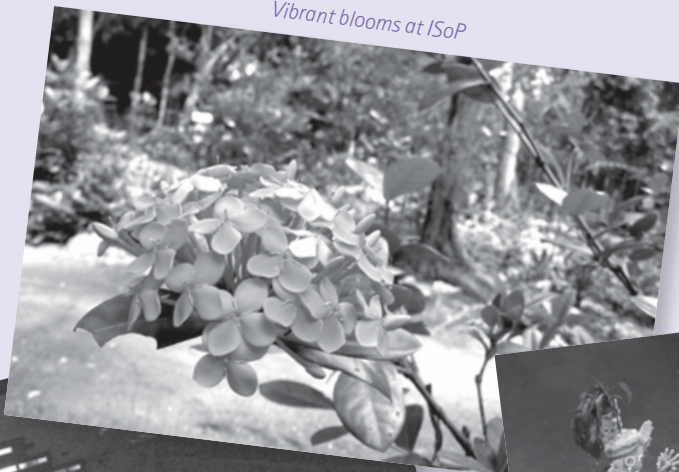
The Social Programme included both an opportunity to learn the basic moves in salsa and a course dinner in a 200-acre archaeological nature park. During dinner we enjoyed the "Xcaret México Espectacular" - a musical performance that took us on a journey through the history of Mexico.

A new Executive Committee was presented. Marie Lindquist as outgoing vice-president and Ralph Edwards as a previous President have both made much appreciated contributions to the Society. Ronald Meyboom was presented with an honorary membership. The 13th ISoP Annual Meeting will take place in Pisa, Italy with plans to focus on the younger generation of presenters and 'flash presentations' of 8 minutes plus 2 minutes discussion time. We're not sure that 2 minutes is enough, but we were convinced of the energy and determination to make the next meeting a great success!

Ronald Meyboom receives his honorary membership



Vibrant blooms at ISoP



The conference venue after dark



Entertainment for ISoP delegates

A vision of pharmacovigilance

Geoffrey Bowring

In November the Brazilian medicines agency ANVISA, welcomed around 100 representatives from 48 national pharmacovigilance centres to their young capital Brasília for the 35th meeting of the WHO Programme for Medicines Safety.

Lucio Costa (1902-98), the chief planner of this year's 50-year old host city, named three scales in his Brasília: the monumental, the residential and the gregarious. While the WHO Programme's annual meeting may not have sought the first Costa scale, it certainly offered a comfortable and warm place for national pharmacovigilance centre representatives to meet. Despite many new faces experiencing the event for the first time, and a few absent friends, the perennial spirit of international co-operation at these meetings was soon rekindled.

Regional emphasis

The choice of venue for 2012 was naturally intended to facilitate the participation of Latin American pharmacovigilance centre staff. In fact the annual meeting has only once before been held in south America. By working with the WHO Regional Office, PAHO, the hosts laid on simultaneous translation into Spanish and Portuguese during all plenary sessions. In spite of some technical problems, the work of the interpreters was a boon for lusophone and hispanophone sections of the audience alike. The facility was also appreciated by English speakers when presenters gave their talks in Spanish or Portuguese.

Being in Brasília was an opportunity for UMC staff to meet directly many of its primary contacts and colleagues. The day before the WHO meeting was taken up with presentations detailing recent progress in UMC services for national centres. A separate VigiFlow users group meeting was also held.

Major topics

Besides the vital networking taking place among those present, much serious and hard-thinking was evident on the programme. Unfortunately unable to travel to Brazil, David Martin, Director, Division of Epidemiology, Center for Biologics Evaluation and Research, US Food and Drug Administration spoke on *Balancing Pharmacovigilance priorities and resources* via a video link from his home. He set out the goals of drug safety surveillance and in particular the need in times of budget constraints to prioritize activities based on potential public health impact and practical considerations, and for national centres heads to critically re-evaluate priority activities and resource allocation. Quoting from the FDA Amendments Act 2007, he pointed out that safety monitoring priorities evolve from time to time, especially given changes in medicines usage in the population. He concluded that effective pharmacovigilance organizations are managed according to a set of goals, align their



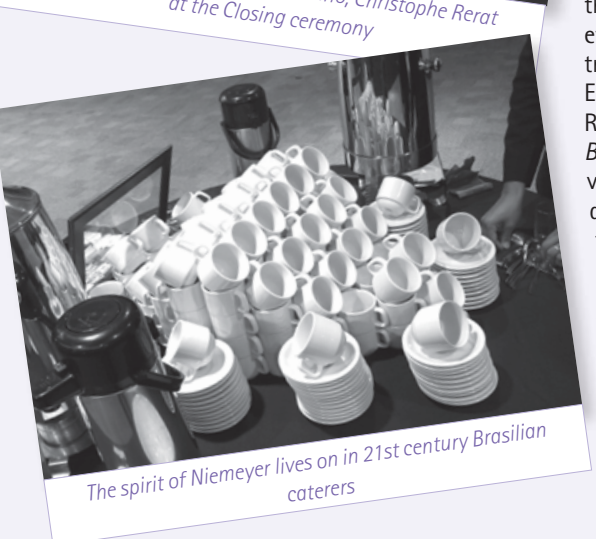
Networking in full swing



A poster discussion



Kees De Joncheere, Dirceu Barbano, Christophe Rerat at the Closing ceremony



The spirit of Niemeyer lives on in 21st century Brazilian caterers



Niemeyer's Panteão da Liberdade (Pantheon of L)



David Martin speaks



Everyone has a

activities and available resources with these goals and stay current with scientific and regulatory developments. They should also leverage assistance from partners and adapt their resources to shifting conditions, but still maintain the capacity to respond to drug safety emergencies.

Agnes Kant of Lareb, Netherlands looked at the recent *EU legislation and its consequences for national centres*. One notable change for the WHO Programme will be that ICSRs from EU countries will in future be forwarded automatically from EMA to UMC. The level of detail to be thus transmitted is not yet clear due to deliberations on privacy regulations; the Netherlands will continue in any case to send reports directly to UMC. She also considered the new prominence for patient reporting and its influence on patient safety, and examined the contribution of patient reporting to signal detection: patients are increasingly contributing to signals about drug-ADR associations.

Having recapped the reasons why patient reporting an important weapon in the armoury of the pharmacovigilante, Viola Macolić Šarinić, head of the Croatian national centre gave an exciting and enthralling case study (a mid-2012 campaign in Croatia) on how to promote your patient reporting means via national media, illustrated with a range of actual media clips from Croatian radio and television.

Heritage

The city of Brasília is unusual: a UNESCO World Heritage Site where construction only began 55 years ago (around the time modern pharmacovigilance was emerging) to create Brazil's third capital city (after Salvador and Rio de Janeiro). There are many stunning examples of modern urban design and architecture. Oscar Niemeyer and Dr Costa's 'bow and arrow' creation proudly showcases not only iconic buildings but also open spaces (green and urban), native flora and aquatic oases. A tour offered by ANVISA after the close of the meeting highlighted some of these. Oscar Niemeyer died on 5 December 2012 aged 104; his vision lives on.

International collaboration

The Closing Ceremony heard from Christophe Rerat of the WHO Regional Office, Kees De Joncheere, Head of Essential Medicines and Pharmaceutical Policies at WHO Headquarters, and Dirceu Barbano, Director of ANVISA. Dr Barbano emphasized the significance of international collaboration between complex and diverse regulatory situations, importance of a forward-looking vision, and working together.

Fernanda Ferrazin, on behalf of the Italian Medicines Agency (AIFA, L'Agenzia Italiana del farmaco) invited WHO Programme members to Rome for the 2013 meeting. In case anyone needed reminding, she illustrated her words with the famous images of the Eternal City which await the WHO Programme on 26-28 September 2013, with pre-meetings on 25 September.

Additional information from: McConnell, R Shean. Brasilia: city for the year 2000. Official Architecture and Planning, 34 (12), December 1971, 905-909.

Working Groups

The meeting had the customary two sets of working groups where the representatives could choose from several current topics and join together for a couple of hours to discuss them and make recommendations. Some of the matters raised in these will be taken further over the coming year(s).

Good Management Practices for national pharmacovigilance centres
To define and discuss skills and strategies to promote awareness and recognition and secure a stable and well-resourced place for pharmacovigilance in countries

Wider access to data in WHO database – optimizing data utilization: VigiLyze
To ensure that information and data extraction from VigiBase tool are optimally utilised by pharmacovigilance centres, today and tomorrow

Building capacity for safety monitoring of new vaccines
Discuss the importance of, need for, and opportunity to introduce pharmacovigilance of vaccines through monitoring of new vaccines

The ATC DDD system: tool that links drug consumption and ADR data
To raise awareness and promote use of this tool in the pharmacovigilance world

Pharmacovigilance Toolkit and its further development
To present the Toolkit, its features, current status and discuss future development plans

A central national pharmacovigilance centre or a decentralized system: pros and cons
To discuss pros and cons; examples of such models in countries, challenges they face in maintaining such systems, and proposed solutions

Role of industry in national pharmacovigilance programmes
To discuss the value of and challenges in collaborating with industry: resources and data versus issues of conflict of interest

Harmonizing pharmacovigilance with health economics for outcome measurements – setting the research agenda
To discuss savings to health expenditure through pharmacovigilance



Exterior view of the Tancredo Neves building, 1985 (Liberty and Democracy)



Participants attending via Skype



Participants in group work

VigiFlow™ still improving

Ulrika Rydberg

The aim of each new VigiFlow™ release is to make improvements – ensure it is better suited to the needs of the majority of its users, harmonize to international standards or add functions necessary for some users. This time, all of these goals have been met. VigiFlow 5.0, released on 27 November 2012 contains definitive improvements in the ICSR (Individual Case Safety Report) management system developed by Uppsala Monitoring Centre.

For those who want their data in their own language, search and statistics results are now translated into the chosen language as far as possible. This will definitely be a time saver for them!

Harmonization to standards

VigiFlow has been based on the international ICH-E2B standard since it was first launched in 2004. Nonetheless, standards have a

Of further interest

One improvement that will make a very big impact for users who import ICSRs in the E2B format is the new workflow for updates of previously received cases. It will now be much easier to handle and update cases if for instance a company that is obliged to report to the national authority sends a follow-up.

Two pilot projects are also part of VigiFlow 5.0 – these will be tested by a limited number of users and get a wider availability after a review. The first pilot is the possibility to see global combinations data from VigiBase directly in VigiFlow during data entry of the ICSR. This will support the medical assessor while evaluating the case without the need to perform a search in another system to get this information.

The second pilot is an automatic import from the patient reporting system developed by UMC as part of the Monitoring Medicines programme. This makes it possible for reports entered by patients in the patient reporting system appear directly in VigiFlow, thereby minimizing manual work for countries using both systems. More about the patient reporting system can be found in UR58, page 18; the Croatian experience with patient reporting was presented during the 2012 National Centres meeting (see page 12-13 in this issue).

Another functionality that is only available to a few users is an extra validation button that will check the entered ICSR for compliance to some additional requirements made by EMA in the EU. Others that would also like this functionality should contact UMC via the e-mail address below.

More information about these and all other changes included in VigiFlow 5.0 can be found in the Release Notes, which are available to all VigiFlow users on request. Users of VigiFlow can also download the updated User Guide from the VigiFlow interface.

Wishes for other improvements are always welcome. They can be sent by e-mail, the feedback function in VigiFlow or discussed with other users on the VigiFlow User Group site on the UMC Collaboration Portal.

VigiFlow contact: vigiflow@who-umc.org

reporter qualification	2009			2010			2011			2012					
	total	total	total	Jan	Feb	Mar	Apr	May	Jun	total					
physician	915	920	1319	44	38	92	90	96	40	400					
pharmacist	199	261	476	66	37	24	45	66	44	282					
other health professional	10	35	58	7	8	1	6			22					
consumer or other non-health professional	6	19	77	1		4	2	7	2	16					
value not set	45	69	107	1	4	2	1	3	2	13					
total number of reports	1175	1304	2037	112	86	130	139	178	88	733					

One of the new count profiles added to the administrative statistics section in VigiFlow™.

Showing off data

The Search and Statistics module in VigiFlow has been upgraded with a new type of administrative statistics that will save time for many users. These count profiles are meant to give a quick overview of the entered ICSRs. The data output is of the type often used in an annual report, while it is also possible to limit the search to a specified time period or include all years to get an overview. If the aim is instead to dig into the data, the expanded Excel export functionality from the Search and Statistics module is better suited. More than 40 new data fields have been added to this export so whatever a user's needs are, there is a great chance they will be covered. Expanding the Excel export has been asked for by many users so we are very happy to have done it.

tendency to deviate when they are interpreted by different people. With VigiFlow 5.0 an effort has been made to remove some deviations and harmonize to the E2B standard as used by EMA for instance.

Another standard that has now been more strictly implemented in VigiFlow is the WHO-UMC causality assessment. In addition, some values for reaction outcome have been removed since these were not found in the E2B standard. Users with ICSRs entered with values that have now been removed do not need to worry. The old values will remain on these reports unless they are manually removed and everything will work regardless of whether these values are kept or changed on these reports.

Best poster for grouping medical terms

Niklas Norén

UMC researchers have been awarded a Best poster prize for their analysis of grouping adverse reaction terms in signal detection. The PROTECT Conference in Copenhagen on 22 October 2012 was hosted by the Danish Health and Medicines Authority and drew together researchers from across European national pharmacovigilance centres, the European Medicines Agency, academia, and industry. PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium) is a collaborative European project that comprises a programme to address limitations of current methods in the field of pharmacoepidemiology and pharmacovigilance.

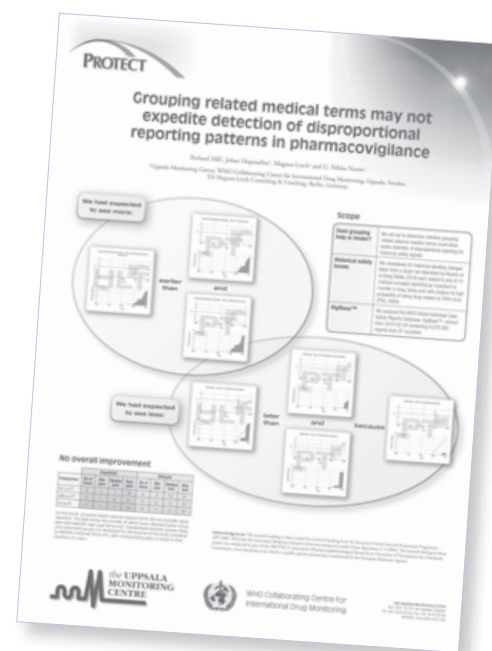
The meeting in Copenhagen marked the halfway point of this five year project and included presentations of progress to date. The Uppsala Monitoring Centre was

represented by its Chief Science Officer, Niklas Norén, who presented the accomplishments of the work-package on Methods for signal detection led by the UMC with active involvement and key contributions from national pharmacovigilance centres in Denmark, Spain, and the UK, along with academic groups and researchers at pharmaceutical companies.

Grouping related medical terms may not expedite detection of disproportional reporting patterns in pharmacovigilance Richard Hill¹, Johan Hopstadius¹, Magnus Lerch² and G. Niklas Norén¹.

¹ Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden.

² Dr Magnus Lerch Consulting & Coaching, Berlin, Germany.



The most comprehensive dictionary

Madeleine Krieg

More than a thousand pharmaceutical companies, CROs and regulatory bodies around the world are currently using UMC's WHO Drug Dictionaries in their day-to-day activities. Common uses are the coding, analysis and reporting of concomitant medications found in clinical trials, as well as for drug names appearing on Individual Case Safety Reports (ICSRs).

Optimizing coding

UMC's WHO Drug Dictionaries and related services optimize the global coding, analysis and reporting of medical product information from clinical trials and within drug safety. WHO Drug Dictionary Enhanced (WHO DDE) is the world's most comprehensive and widely-applied drug coding reference and is the core for an expanding family of related drug dictionaries and services, all seamlessly connect using the same working methods and terminologies. UMC Drug Dictionaries use the hierarchical system for ATCs (Anatomical Therapeutic Chemical classes), promoting aggregation of statistics in analysis and reporting.

WHO DDE's hierarchical product coding system, range of powerful analytical tools, and extensive global coverage make it a valued means of interpreting and reporting

medicinal product information. Most importantly, WHO DDE meets the need for a consistent drug dictionary and exact terminology. Users are able to code concomitant medication, better analyze and understand the resulting data, and accelerate submissions to regulatory authorities. Drug safety surveillance is also enhanced.

With its unique Herbal Anatomical Therapeutic Chemical (H-ATC) classification, WHO Herbal Dictionary (WHO HD) helps regulators and industry more fully understand herbal concomitant medications used by patients. Containing herbal drugs from all over the world, herbal drug names can now be translated into information used to code and analyse drug safety data.

Japan and China

Cross Reference Tool Japan (CRT Japan) directly matches Iyakuinmei Data File (IDF) codes with WHO DDE codes. IDF is Japan's national dictionary for reporting drug safety data to the PMDA (the Japanese drug agency). CRT Japan thus offers companies active in Japan a simple solution for coding and submitting concomitant medications to the PMDA.

Drug Dictionary China (DDC) translates Chinese character medicinal product names into the WHO DDE coding system. This gives users access to a broad array of up-to-date medicinal product information for products used on the Chinese market, including herbal medicines and Traditional Chinese Medicines (TCMs).

Standardised Drug Groupings

Standardised Drug Groupings (SDGs) simplify the creation of 'medications of interest' and protocol violation lists which can be used, for example, when identifying possible drug-drug interactions. All UMC SDGs are prioritized by our user community, developed by pharmaceutical experts, and peer-reviewed by counterparts in related fields.

For more information see www.umc-products.com, or contact sales@umc-products.com

Data Mining in the Lion City

Jeanette Johansson

Have you ever been to Singapore? If not, I can definitely recommend you go if you get the opportunity! The name Singapore is derived from Singapura, the Malay name for 'Lion City'. The island is located between Malaysia and Indonesia and has a land area of only about 700 square kilometers. Singapore's population is about five million people, and the official languages are English, Malay, Chinese and Tamil. The island does not have clear seasons like winter, spring, summer and autumn. Instead the weather is warm and humid all year round and a brief rainfall is more or less an everyday phenomenon.



Flower Dome and the Cloud Forest, with Super Trees (vertical gardens) behind.

Inter-regional training

In early October I had the pleasure of being invited there as a speaker, together with Professor Hubert Leufkens, Department of

Pharmacoepidemiology and Pharmacotherapy, Utrecht University, Netherlands and Dr Ruth Savage, New Zealand Pharmacovigilance Centre, University of Otago, for the WHO-HSA Inter-regional Pharmacovigilance Training Course. My first visit to Asia was a week full of happiness and joy, data mining and pharmacoepidemiology, together with more than 40 participants from 10 different countries!

The aim of the three-day course was to introduce the participants to concepts and principles relating to pharmacoepidemiology and data mining.

Concepts and methods

After the opening ceremony and words from Associate Professor John Lim, CEO of the Singapore Health Sciences Authority (HSA), the first day of the course started with updates on the HSA's pharmacovigilance and pharmacogenetics initiatives, presented by Ms Dorothy Toh, Director of the Vigilance Branch, Health Products Regulation Group, HSA, followed by an introduction to the Current landscape in drug development, regulation and usage by Professor Leufkens. During the session Data Mining and Signal Detection, the participants were familiarized with definitions and concepts as well as different approaches to signal detection. The first day ended with an overview of pharmacoepidemiological methods; e.g. basic

concepts of study design and available data sources. The participants were then divided into groups and given the opportunity to work with case studies and choose the most appropriate study design for a given topic.

The second day was dedicated to a range of topics including *Data Mining and Disproportionality methods and Dealing with the Results, Variability of drug exposure and exposure measurements and Confounding, bias and effect modification.*

Student feedback

During the last day we discussed different applications of data mining such as drug-drug interactions, time to onset analysis, and data mining in electronic health care records. Data quality and effects of stratification were other topics, together with regulatory aspects of benefit-risk decisions, data mining and absolute/relative risks in drug safety. One of the most enjoyable sessions was when each student group presented the outcome of their case study and had the opportunity to comment on and learn from each other's choice of study design.

After three intensive days in Singapore we all left the Lion City exhausted but with increased knowledge and lots of new ideas, and, maybe equally important, with new inspiration and friendships!

Pharmacovigilance of the Americas

Elki Sollenbring and Mariano Madurga

A meeting for Latin American and Caribbean countries was held from 8-10 November in Brasília to strengthen the pharmacovigilance work between them. Pan American Health

Organization, Agência Nacional de Vigilância Sanitária (ANVISA) of Brazil, Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) of Colombia and the Brazilian Ministry of Health were the organizers. These meetings have only taken place in Colombia, but from this year the joint the meeting will rotate; next year Colombia and 2014, Peru.

Large attendance

It was a big meeting, with more than 400 participants from 15 countries and a packed agenda. Over 30 plenary lectures covered a wide range of topics under the umbrella of three themes: Risk Management and Pharmacovigilance; Regulation and Notification, Challenges in Pharmacovigilance,

Public Policy and Pharmacovigilance Management. The programme's success due to the participants taking up points during the sessions.

A chance to mix

It was an excellent opportunity for us from Europe to talk with national pharmacovigilance representatives, some of whom we only knew through e-mail. It was invaluable to share experiences and discuss the progress in various countries and the difficulties that they face.



A large attendance at the Latin American and Caribbean meeting in Brasília

Sun, sea and safety

Marie Lindquist

The last week of October, Ralph Edwards and I took the opportunity to go to Jamaica after we had been to the Mexico ISoP meeting. I was particularly excited since Jamaica had just become a full member of the WHO Medicines Safety Programme!

Seminar on medical ethics

Sunday morning we were picked up from the lodgings in the Mona Campus by our host Dr Maxine Gossell-Williams and taken to the Medical Lecture Theatre where the ethics seminar 'Grey matters in Medical Ethics' was held.

The seminar was opened by Dr Rosemarie Wright-Pascoe. Ralph then talked about ethical considerations in pharmacovigilance, and discussed how our work impacts on ethics of regulation, medicine, nursing and pharmacy practice. Ralph emphasised that ethics change over time – what we regard as acceptable today often differs from views held in the past. For instance, there has been a general move away from a paternalistic approach in medicine to a more open and equal participation of patients in decisions about their treatment.

The ethical implications in the area of reportable diseases were covered by Dr Kevin Harvey, Director, Health Promotion & Protection, Ministry of Health. After an overview of how the reportable diseases surveillance system works, he proceeded with arguments for why this data collection for non-interventional purposes is ethical – provided that adequate safeguards are in place. He concluded that:

- there must be respect for the individual – a patient or a reporter should not be seen as a passive provider of data
- the risks of physical and psychological harm, and stigmatization of the affected individuals must be minimised insofar as possible
- the risks and benefits from surveillance should be distributed fairly and evenly in all population groups.

Nicole Chambers, an Attorney-at-Law from the Child Development Agency, talked about ethics in relation to the reporting responsibilities of health professionals under the Jamaican Child Care and Protection Act (CCPA).

Dr Michael Boyne gave a lively account of the pros and cons of doctors being active on social media. On the one hand, a presence on Facebook, Twitter and other sites may bring

doctors closer to their patients and provide a quick and easy communication. Dr Boyne gave some striking examples of how doctors may seriously jeopardise their professional relationship with patients. He also pointed out the importance of using the existing security features of Facebook – don't make all your postings publicly available! – although a patient can get the information anyway from being a 'friend' of one's own 'friends'.

Finally Professor Norma McFarlane Anderson, a molecular biologist, discussed the positive and negative aspects of the use of DNA technology. She provided an exposé of the developments in this field since the discovery of the alpha-helix in the 1950s; and gave an overview of the risks and ethical dilemmas involved in the applications of DNA technology.

Meeting the students

Ralph has for some time been the external tutor of a PhD student Dr Maxine Gossell-Williams at the Medical School Pharmacology Section of the University of the West Indies in Kingston. Our second day in Jamaica started with Ralph and I meeting a large number of her degree students. They seemed genuinely interested in hearing two 'old guys' talking about their personal history, the UMC and the WHO Programme, and pharmacovigilance in general. It is wonderful and reassuring to find that there are so many young enthusiasts out there, ready to change the world! If some of them decide to dedicate their career to patient safety work in one way or another, perhaps inspired by what we said – and definitely influenced by Dr Gossell-Williams contagious enthusiasm! – I'd be very happy.

After the main session, we had a chat in Dr Gossell-Williams' office, including a discussion with two very keen students about possibilities for further studies.

Round table discussion

The final point on our work programme was an informal round-table discussion with representatives from clinical medicine and university medical school, the local PAHO office and the national pharmacovigilance programme, PharmWatch. PharmWatch is a programme in the Ministry of Health, Standards and Regulation Division, under the leadership of Mrs Princess Thomas Osbourne. The programme, which is a collaborative effort between the Ministry of Health and the Pharmacology Section of the University of the West Indies, headed by Dr Gossell-Williams, has been created with a view of monitoring



Marie talks with the group at the University of the West Indies

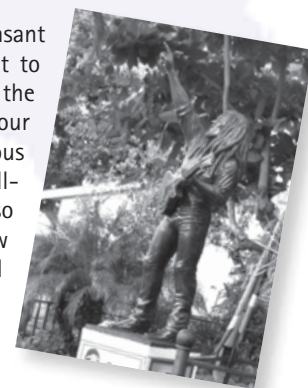
adverse events locally, through the reports of healthcare professionals.

In my introductory presentation 'WHO cares about pharmacovigilance', I gave an overview of roles and responsibilities of WHO and UMC, and also said something about the expectations we have on the member countries. Stressing the importance of audit and impact analysis in pharmacovigilance, I took the opportunity to introduce a summary of the coming WHO pharmacovigilance indicators.

We had interesting discussions about the many challenges in pharmacovigilance, with emphasis on the situation in Jamaica. The difficulties in collecting reports of suspected adverse reactions from health professionals are problems Jamaica shares with most countries. This key group of stakeholders stressed the importance of making the pharmacovigilance system accessible, and the need for informative feedback to those who report.

We also discussed the broader scope of pharmacovigilance today, compared with 10-20 years ago, and the new challenges; and touched upon the issue of blame as an impediment to reporting, in particular when reporting medication errors leading to patient harm.

All in all, a very pleasant and stimulating visit to this lovely island in the sun! Big thanks to our kind and generous host, Maxine Gossell-Williams, who also made sure that we saw some of the local scenery and visited some Kingston tourist 'musts' – like the Bob Marley museum!



A Jamaican icon

Masters in Costa Rica

Elki Sollenbring

During a recent visit to Latin America I took the opportunity to accept an invitation from Victoria Hall, deputy dean of the Pharmacy Faculty of the University of Costa Rica, to help them with some pharmacovigilance-related topics in their Master's of Pharmaceutical Care course.

Victoria and I held a three-day training course for 27 Master's students in the first week of November. These are pharmacists who work in hospitals, clinics, industry, private practice and so on. It was very impressive to see how they attend the classes on a Saturday from 8am to 5pm after a night working hard at the hospitals.

My presentations were about the WHO Programme, How to develop a pharmacovigilance centre, Terminologies for coding, Signal detection (including some causality assessment), Patient Reporting, and VigiFlow (with hands-on practice).

The agenda also had working groups:

- Analysis of different national centres' websites – assessing the best parts to improve their own country's web page
- Development of a patient reporting form
- Review of the country ADR reporting



Masters students working together in Costa Rica

form; input from this will also be sent to the individual's national centre

- Development of a plan to improve the national centre work.

I would like to thank Victoria Hall for the invitation, the attention offered and all the students who interacted so fully in all sessions.

Visit to the Centre

I also met the team at the National Pharmacovigilance Centre of Costa Rica on 6 November. It was impressive to see that after two years the group had grown, from 'one and a half' persons that I met two years ago to seven people this year. The majority of new personnel attended the training course.

Multi-training around Chile

Mariano Madurga

Requirements in the field of pharmacovigilance were established in Chile by National Decree in 2010, (Regulation of the National System of Control of Pharmaceuticals for Human Use of the Public Health Institute (ISP)), and the 'General Technical Norm No. 140 on Pharmacovigilance in Chile'. The ISP is also expected to conduct training, and strengthen the knowledge and skills of the pharmacovigilance team of National Medicines Agency (ANAMED) in periodic safety update reports (PSUR) and risk management plans (RMP). On 24–25 September 2012 a workshop was held at ANAMED in Santiago with pharmacovigilance staff (Dr Juan Roldán, Director) and clinical assessors from the Evaluation Department, with the Catholic University of Chile (Prof Rosemarie Mellado). Verónica Vegara (ANAMED) and Mariano Madurga (AEMPS, Spain) were the speakers (see <http://www.ispch.cl/noticia/17025>).

Looking wider

Following this, on 26–28 September the IX Meeting of National Competent Authorities from Ibero-Latin-American Countries (EAMI; www.portaleami.org), was organized by ANAMED with 14 Latin-American countries, Portugal and Spain attending. The theme was *Regulatory Challenges of Globalization and Access to Quality Medicines*. At the opening ceremony, Minister of Public Health Dr Jaime Mañalich encouraged participants to achieve the objectives of the meeting, http://www.aemps.gob.es/informa/notasInformativas/laAEMPS/2012/NI-AEMPS_09-2012.htm.

Inter-professional training

Then, on 1–2 October, there was a hospital pharmacovigilance workshop for medical doctors, pharmacists and nurses. The Sub-department of Pharmacy and the Training Unit of the 'Hospital Base de Valdivia' (HBV)



*Courses in Santiago...
... and Valdivia, Chile*

along with ANAMED organized this in the city of Valdivia, in a collaborative effort that brought together a total of 86 healthcare professionals from several regions of Chile. The objective was to strengthen the knowledge and skills of healthcare professionals and help them acquire the skills to implement a programme of institutional pharmacovigilance and establish a network with uniform concepts and criteria to identify, quantify, assess and prevent suspected ADRs detected in everyday work.

General pharmacovigilance concepts, medication errors causing ADRs, current legislation, and intensive monitoring in specific patient groups formed part of the Valdivia programme. The event brought together leading practitioners and experts from Chile and abroad.

The director of the workshop, Monica Kyonen, pharmacist from the Sub-department of HBV, said that the passive pharmacovigilance system operated since 1999 has been transformed into an active

one centred on patients. This course examined methods that complement voluntary reporting, such as intensive supervision of patients, useful for the ADR diagnosis, awareness, education of health professionals and ADR prevention.

Pharmacovigilance in Eritrea – promise and potential

Iyassu Bahta and Mulugeta Russom

The Eritrean National Pharmacovigilance Centre (ENPC) was established in 2003 in which year the country became an Associate Member of the WHO programme for international drug monitoring. However, despite the good intentions of the pioneers, several factors prevented the attainment of the true potential of the ENPC. Like other countries in Africa, Eritrea has had to deal with limited human and financial resources as well as the brain-drain of qualified professionals. For progress to occur, the country needed to innovate and achieve its aims despite the constraints. This the country has done with remarkable efficiency thanks to support from the Eritrean government and its development partners, especially the Global Fund.

Recognition for regulation

In 2012, the Eritrean government reorganised medicines regulation in the country and converted the Pharmaceutical Services Department into the National Medicines and Food Administration (NMFA). The NMFA is now the agency responsible for the regulation of medicines and food and is headed by Mr Iyassu Bahta, a very keen pharmacovigilante. The NMFA has 18 staff members with six units including the Eritrean National Pharmacovigilance Centre, (ENPC) which is the national pharmacovigilance centre, headed by Mr Mulugeta Russom. Thanks to funding from the Global Fund Against AIDS, TB and Malaria, Mr Bahta and Mr Russom undertook a three week pharmacovigilance attachment at the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, Accra, Ghana. The training equipped the participants with the technical expertise needed to handle individual case safety reports and Eritrea submitted enough reports to be admitted as

the 107th full member of the WHO Programme on 23rd April 2012.

Progress and Promise

Upon return to Eritrea, the NMFA and ENPC realised that the most sustainable and cost-effective way of promoting pharmacovigilance in Eritrea is through the establishment of medicines and therapeutics committees in health facilities. In addition, the National Medicines and Therapeutics Committee was given added responsibility of being the national pharmacovigilance advisory committee. This strategy has worked remarkably well, leading to several positive outcomes including:

- Training in pharmacovigilance of 1,851 healthcare professionals (78 physicians, 93 pharmacists, 91 pharmacy technicians, 328 nurses and 1261 auxiliary health workers including medical assistants and medical laboratory technicians and assistants)
- Establishment of Medicines and Therapeutics Committees in 13 health facilities
- Production of new, revised ADR forms
- Printing of medicines information bulletin.

Results

These measures have led to increased reporting with over 50 ADR reports received in 2012 alone compared to 46 reports in the previous 9 years! In order to consolidate these gains, the Government of Eritrea (with funding from the Global Fund) invited the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance and UMC-Africa to undertake a pharmacovigilance



Members of the Eritrean National Medicines and Therapeutics Committee after an orientation by Alex Dadoo. In the picture are Iyassu Bahta (kneeling left) and Mulugeta Russom (kneeling right), as well as Dr Berhane Gebretensae, Director General of the Ministry of Health and Chairman of the NMTC.

mission in December 2012. The mission took place from 10th – 19th December 2012 and included pharmacovigilance training for the National Medicines and Therapeutics Committee (the Pharmacovigilance Advisory Committee), site visits, training of the national centre staff and advocacy visits to key stakeholders. A report of the Eritrean PV Mission will be carried in the next edition of Uppsala Reports.

2013 Uppsala course

UMC's Education & Training team

The 2013 UMC Pharmacovigilance Training Course will take place in Uppsala, Sweden, from 20 May to 4 June 2013.

The course is open to health care professionals, e.g. physicians, pharmacists, nurses, who have recently become engaged or soon will become engaged in the practical

operation of pharmacovigilance programmes in a hospital, community, regulatory, university or industry setting.

Module I covers an introduction to ADRs, spontaneous adverse reaction reporting and effective communications in pharmacovigilance.

Module II offers an introduction to pharmacovigilance in public health programmes, vaccines, herbals and pharmacovigilance methods; an introduction to pharmacoepidemiology and application of pharmacovigilance to U.S. FDA regulatory decisions for vaccines.

Theoretical and practical aspects of ADRs and pharmacovigilance are covered. Theoretical parts include lectures, workshops and group discussions; practical sessions include recording of case information and computerised retrieval of information from the database of the WHO medicines safety programme. The course language is English. The application form for the 2013 course is available from the Education and Training page of the Pharmacovigilance section of the UMC website. The deadline for applications is 17 February 2013.

Train the Trainer

Johanna Stenlund

In early September two of our colleagues from the UMC-Africa office arrived in Uppsala for a one-week pilot 'training the trainers' course. This was the first step towards capacity-building on a global scale, where the aim is to have UMC-trained trainers in various regions of the world. Sharon Ako-Adounvo and Malik Sulley from UMC-A received further tuition in both basic pharmacovigilance and UMC tools. They also got to practice both their knowledge and presentation skills in various sessions where input was given from both the UMC Education & Training team, Bruce Hugman and other staff.

The pilot is still on-going and the next step will be for Sharon and Malik to host a national or regional training in Africa, which will take place during 2013.



Taking steps to better training: Johanna, Sharon, Elki, Bruce and Malik

Collaborating towards Chinese signals

Tomas Bergvall

During the autumn of 2012 UMC had the pleasure of working for two months full of information sharing and knowledge exchange side-by-side with two members of the China National Centre for Adverse Drug Reaction Monitoring (NCADRM). Dr. Wu Guizhi works for the Pharmaceuticals Monitoring and Evaluation Division where she is responsible for ADR monitoring and safety evaluation of pharmaceuticals. Her colleague Mr. Hou Yongfang currently works in the IT and Data management Division where he is responsible for the national ADR monitoring information system and the standardization of ADR data in the database.

The main purpose of the visit was to share knowledge of how to set up an efficient signal detection framework in a large database setting. Most of the activities related to hands-on work with new signals emerging from VigiBase™, but visits both to the pharmaceutical industry and the local

regulatory authorities were arranged to offer a broader view of how to handle safety issues related to pharmaceutical products. The visit also included discussions and training of advanced analytical methods as well as the updated WHO-ART, among many other things.



Hou Yongfang and Wu Guizhi

New publications

A paper based on the master thesis prepared by [Lars Melskens](#) and [Paw Petersen](#) from the University of Copenhagen in collaboration with Johanna Strandell at the UMC Research department has now been published in Drug Safety. The aim of the study was to characterize ADRs reported to the WHO global ICSR database, Vigibase, and to relate data to national income.

ADR reports submitted to Vigibase from 2000 to 2009 were analysed with respect to reporting rate, age and sex of patient, type, seriousness and medications. Reports were also analysed with respect to national income level, classified in accordance with the World Bank definition: low, lower middle, upper-middle and high.

[Aagaard L, Strandell J, Melskens L, Petersen PS, Holme Hansen E.](#)

Global Patterns of Adverse Drug Reactions Over a Decade: Analyses of Spontaneous Reports to Vigibase™.

Drug Safety. 2012 Dec 1;35(12):1171-82.



Screening of the WHO global individual case safety report database (Vigibase) has recently identified case reports with lipid-lowering HMG CoA reductase inhibitors and muscle symptoms co-reported with spinal stenosis. In some reports spinal stenosis appears to have been listed as a coincidental finding.

Reports with sufficient information were assessed to ascertain if they suggested that

there may have been diagnostic confusion between muscle symptoms attributable to HMG CoA reductase inhibitors, with or without concomitant use of ezetimibe, and symptoms of spinal stenosis.

The reports illustrate two safety issues: the need to consider HMG CoA reductase inhibitors as a cause of severe lower limb muscle symptoms even in the presence of spinal stenosis and normal CK levels, and the need to measure serum creatine kinase when these symptoms occur to detect the start and progression of a drug related myopathy with potentially serious outcomes.

[Savage RL, Star K and Hill R.](#)

Severe muscle symptoms with lipid-lowering agents may be confused with neurogenic claudication associated with spinal canal stenosis. *International Journal of Risk & Safety in Medicine*, 24 (2012), 215-219.



This article presents novel methods for quantitative benefit-risk assessment. It describes how qualitative statements that relate the utilities of clinical outcomes to each other can be incorporated into a fully quantitative framework of probabilistic decision analysis. This allows for a relatively cheap and fast benefit-risk assessment methodology, apt to scenarios where a drug safety issue is emerging, or reliable numerical utility data are unavailable. The analyses of three different case studies are presented, from which it is concluded first that the methodology is overall concordant with a standard alternative that requires more information, although one important and

justified discordance was identified; and secondly that widely agreed upon, clinically straightforward qualitative relations can be sufficient to obtain a conclusive result.

[Caster O, Norén GN, Ekenberg L, Edwards IR.](#) Quantitative benefit-risk assessment using only qualitative information on utilities. *Medical Decision Making*, 2012. 32(6):E1-E15.



A new paper has been published in collaboration with the group of Paediatric Medicines Research from the University of London School of Pharmacy. It describes the clinical circumstances in children and adolescents with rhabdomyolysis induced by antipsychotic medicines using published case reports and ICSRs from Vigibase. The original ICSRs free-text fields included much valuable added information. The paper aims to increase awareness of the features of this rare ADR in children and adolescents to enhance the chances of capturing early symptoms of rhabdomyolysis in order to prevent the serious consequences of this ADR.

Rhabdomyolysis reported for children and adolescents treated with antipsychotic medicines: a case series analysis.

[Star K, Iessa N, Almandil NB, Wilton L, Curran S, Edwards IR, Wong IC.](#)

Journal of Child and Adolescent Psychopharmacology.

2012 Dec;22(6):440-51. doi: 10.1089/cap.2011.0134.

View abstract: www.ncbi.nlm.nih.gov/pubmed/23234587

Fresh insights into causality assessment

Assessing and interpreting the strength of evidence in favour of a causal association between one or more drugs and an adverse reaction affects the future lives of patients and the viability of drugs. Not surprisingly, therefore, the debate surrounding causality assessment – what it can tell us, and what it cannot – continues unabated. In an attempt to shed light on this important topic, and to predict its future directions, the UMC 2012 Research Conference *Causality Assessment in an Evolving Pharmacovigilance Landscape* was held in Uppsala on May 24-25, 2012. The printed report is now available.

Many topics aired and discussed

The conference programme, speakers and audience reflected the broad scope of interest

in causality assessment. Views spanning the scientific principles to the practical perspectives of patients and health professionals were presented by international experts.

Professor Samir Okasha, University of Bristol, UK, began with a philosophical survey of causality in the sciences. This was followed by expert views covering the determination of causality on a case-by-case basis, assessing causality from clinical trials and observational studies, and on automated causality assessment for longitudinal observational databases, the latter by Dr. Patrick Ryan, Johnson & Johnson Pharmaceutical Research and Development, USA. UMC's Ola Caster spoke about accommodating causality considerations in benefit-risk assessments.

Societal challenges, as well as industry, regulatory, legal and media viewpoints were also highlighted, and a unique, no-fault compensation scheme for injuries caused by legal medication use was described.

Conference report now available

An illustrated conference report containing summaries of all the presentations has recently been published. For more information about how to obtain your copy, please contact UMC: order@umc-products.com



An illustrated report of the UMC 2012 Research Conference Causality Assessment in an Evolving Pharmacovigilance Landscape is now available.

New faces at the UMC

We asked some new staff at the Centre to introduce themselves:

Gunilla Osmund

Since the beginning of October I'm working in the Project Management Office (PDQ Department) refining UMC's Project Management Method.

Before UMC, I have all my 'working life' been an IT consultant in different positions within various stages of the systems development cycle. To make use of my knowledge and experiences of systems development within an organization where it is possible to take part and follow the results of the work, is something I've been longing for. I'm really looking forward to have that possibility at the UMC.

Originally I'm from Västerås, the fifth biggest town in Sweden. My family of three kids, husband and dog all enjoy skiing in the Swedish mountains, so when we got the opportunity we started a small company with two cottages for rent in Bruksvallarna, in Jämtland.

Johan Ellenius

I am employed as a researcher and belong to the Research department. My background is in medical informatics, and my most recent project at my previous employer Karolinska Institutet aimed at finding ways of supporting clinicians in decision-making regarding pharmacological treatment for HIV care. So medical informatics will be one of my focus areas. I also have experience in machine learning which should be useful in my new job here at UMC.

Uppsala born, I enjoy barefoot running and Ashtanga yoga, and have been impressed by both work and social sides of UMC life!

Anki Hagström

At UMC I am the Section Manager for Training, Education and Consulting in the Pharmacovigilance Services department. My responsibilities include leading and managing the operations of the section, to ensure that we support the WHO Programme via country support, education and training, as well as achieving the objectives and deliverables in

the 1-year and 4-year plans. What especially attracted me to UMC was working for an organization with a global perspective, and focusing on pharmacovigilance again.



Malin and Gunilla standing, with Paul, Johan and Anki in front of the UMC Christmas tree

I'm a pharmacist by training, born and brought up in Uppsala. My first employment was with the Medical Products Agency in Uppsala, six years working in both regulatory affairs and pharmacovigilance. From 2004 I worked as a study coordinator in phase I and phase II trials for a Contract Research Organisation (CRO) in Adelaide, South Australia. Back in Sweden I eventually became the Head of the Nordic Regulatory Affairs department in a pharmaceutical company.

I am married and have a young son. With a busy schedule work-wise and as a mum I still make an effort to squeeze in exercise a few times a week; strength training, running, boxing. I like cooking (or maybe even more, eating) nice meals, and I am lucky having a family that enjoys trying foreign dishes and experimenting with new ingredients.

Malin Fladvad

I'm responsible for quality assurance at UMC, including planning and management of UMC quality system and compliance of computerized systems. Since 1st of August I'm also acting section manager of the Drug Dictionary section.

I grew up in a calm suburb close to Stockholm but moved to Uppsala to study an MSc in Molecular Biotechnology. I worked at the Karolinska Institute for five years, studying the structure and binding capabilities of cancer related proteins. After getting my PhD I worked with quality assurance and quality control in the pharmaceutical industry.

I enjoy winter sports such as skating and skiing and take Zumba classes. During the summer I spend most of my time in the Stockholm archipelago, renovating an old house and working in the garden.

Paul Franzon

I have been working here at UMC in PDQ-IT as a systems developer since August and I find it very pleasant in many ways. A normal working day for me typically involves C# and Javascript coding. I have been working with IT systems in one

or another way since 1990, and I have been employed at Scanditronix, Pharmacia Biotech (known as GE Healthcare today) and for the last 12 years as an IT consultant/contractor. In my spare time, I am currently very busy doing genealogy research, but over the years I have been mostly interested in singing and playing music in various ways. Speaking of genealogy and music, one of my ancestors wrote the lyrics to the traditional Swedish Christmas song, "Tipp tapp"!

Farewell

We have recently said 'goodbye' to two long-standing members of staff. Stefan Lewenfalk, who has worked for the Centre for many years, joining officially in 2002, has moved to Norway, while Johanna Strandell, after ten years with us is going to work for a CRO in Lund, southern Sweden. Our thanks for all their valuable contributions over the years and good luck for the future!

DATES	TITLE	PLACE	ORGANISER/CONTACT
13-14 February 2013	Monitoring Safety in Clinical Trials and Drug Development	London, UK	Drug Safety Research Unit Tel: +44 (0)23 8040 8621 www.dsru.org/trainingcourses E-mail: jan.phillips@dsru.org
26 February 2013	Pharmacovigilance Aspects of Licensing	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
28 February – 1 March 2013	Medication-errors workshop	London, UK	European Medicines Agency Tel: +44 (0)20 7523 7170 E-mail: MedicationErrors2013@ema.europa.eu www.ema.europa.eu
4-6 March 2013	25 th Annual DIA Euro Meeting	Amsterdam, Netherlands	DIA Europe Tel: +41 61 225 51 51 www.diahome.org E-mail: diaeurope@diaeurope.org
4-6 March 2013	Advanced Pharmacovigilance	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
12-13 March 2013	4 th Pharmacovigilance 2013 – Ensuring safer drugs to market by analyzing latest developments in pharmacovigilance	London, UK	Virtue Insight www.virtueinsight.com/pharma/4th-Pharmacovigilance-2013/ E-mail: niraj@virtueinsightuk.com
13-14 March 2013	Back to Basics in Pharmacovigilance	Southampton, UK	Drug Safety Research Unit Tel: +44 (0)23 8040 8621 www.dsru.org/trainingcourses E-mail: jan.phillips@dsru.org
19-21 March 2013	ISoP-Asia 2013 Symposium: Pharmacovigilance Across Borders in Asia	Singapore	International Society of Pharmacovigilance Tel: +44 (0)20 3256 0027 E-mail: administration@isoponline.org www.isoponline.org
11-13 April 2013	ISPE Mid-Year Meeting	Munich, Germany	ISPE www.pharmacoepi.org/meetings/ E-mail: ISPE@paimgmt.com
24-25 April 2013	Regulations and Guidelines for Pharmacovigilance	London, UK	Drug Safety Research Unit Tel: +44 (0)23 8040 8621 www.dsru.org/trainingcourses E-mail: jan.phillips@dsru.org
9-10 May 2013	XII Jornadas de Farmacovigilancia	Tenerife Island, Spain	Spanish Medicines Agency & Regional Centre of Canary Islands www.jornadasdefarmacovigilancia2013.org/
20 May – 4 June 2013	Pharmacovigilance – the Study of Adverse Drug Reactions and Related Problems	Uppsala, Sweden	UMC E-mail: pvtraining@who-umc.org www.who-umc.org > Pharmacovigilance > Education & Training
11 & 12-13 June 2013	7 th Biennial Signal Detection Conference	London, UK	Drug Safety Research Unit Tel: +44 (0)23 8040 8621 www.dsru.org/trainingcourses E-mail: jan.phillips@dsru.org
19-20 June 2013	Periodic Safety Update Reports (PSURs)	Southampton, UK	Drug Safety Research Unit Tel: +44 (0)23 8040 8621 www.dsru.org/trainingcourses E-mail: jan.phillips@dsru.org
25-28 August 2013	29 th International Conference on Pharmacoepidemiology and Therapeutic Risk Management	Montréal, Canada	ISPE www.pharmacoepi.org/meetings E-mail: ISPE@paimgmt.com
1-4 October 2013	13 th Annual ISoP Meeting 'The Renaissance of Pharmacovigilance'	Pisa, Italy	International Society of Pharmacovigilance www.isoponline.org http://isop2013pisa.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.

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About UMC > UMC staff – on our website.

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