

MUR56



Vaccines | Dubrovnik

Toolkit | 7 million reports



Marie Lindquist
Director
the Uppsala Monitoring
Centre

Stepping into the New Year – 2012 – I think a lot about the future; both on what is happening in the world at large, and what is in store for pharmacovigilance and UMC.

So far the UMC has been unharmed by the financial turbulence affecting so many parts of the world. It is wonderful that our services are sought by so many, and that we have been able to expand our contributions to global pharmacovigilance; but we face the challenges of any growing organisation, and increases in activities and staff have to be matched by corresponding increases in income. I am immensely grateful to my colleagues who do such a good job ensuring the financial viability of UMC and providing the necessary funds for our operations. But it is constantly on my mind that, being a self-funded foundation, we have no fall-back position; we have to constantly refine and adapt our income generating activities in a fast changing world, with many economical and political pressures and also potential ethical conflict.

Lack of funding is a constant problem for anyone working in pharmacovigilance, but I find it almost unbelievable that the normative responsibility of WHO QSM in this area is not given higher priority, and reasonable funds. Good ideas for how to remedy this situation are welcome!

My father often gives me good advice about work. There are two mindsets for opposing change, he says, against which the leader of an organisation must be vigilant – one is expressed as ‘we have never done this before’; the other as ‘that’s the way we have always done it’. I fully agree that the two statements above, when used to resist progress, indicate a detrimental view that, if widespread, is a sign of a failing organisation.

For me, this is a key issue: how to get the right balance between development work requiring organisational growth, dynamism and change – and the preservation of a solid foundation with a sense of stability and the capacity to maintain existing services and core operations.

Signal detection is one such core activity – it was the ‘raison d’être’ for the WHO Programme and is part of the statutory mandate for UMC in its role as a Collaborating Centre. After thalidomide, and in the decades to follow, the concentration was on finding problems suspected to be caused by the drug substance itself, based on its inherent characteristics. This is still an important aspect of pharmacovigilance: to quickly identify adverse drug reactions which are not known at the time of first marketing a new medicinal product.

But, and this is a big but, looking at problems related to chemical or pharmacological drug properties only is too narrow a gaze; to achieve the goal of better patient safety we need to tackle the broader issues related to how medicines are used: this includes anything that can go wrong throughout the whole chain from production to administration of medicines. As reporting systems over the world develop to handle a broader range of health professionals’ and patients’ concerns, our signal detection process must be developed accordingly.

A lot of work has already been done in our research department and by our signal team to prepare the ground – now is a good time to make a thorough overhaul of our signalling system to meet the needs of the future. I don’t like the idea of signal detection being a competition; there is no reason to repeat what others do equally well, or better. I do believe we have the resources to provide new knowledge that will benefit prescribers and patients – that should be what matters, not who first found the ‘signal’!

I wish all our readers a Happy New Year. Together we will be able to change things for the better!

A handwritten signature in dark ink, appearing to read 'Marie Lindquist', written in a cursive style.

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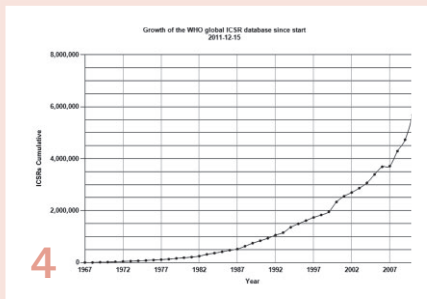
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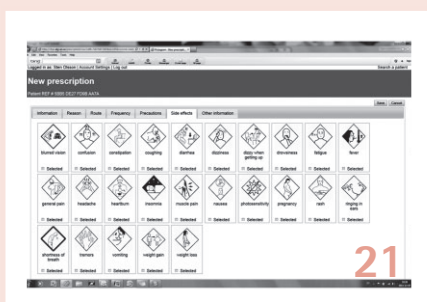


WHO Programme in Dubrovnik

A well-attended and warm 34th annual meeting

UMC out and about

Visits to build relationships with national centres continue – in Europe and South America



Pictograms come to fruition

The FIP project to help with patient communication is online



VigiBase now over 7 million

Sten Olsson

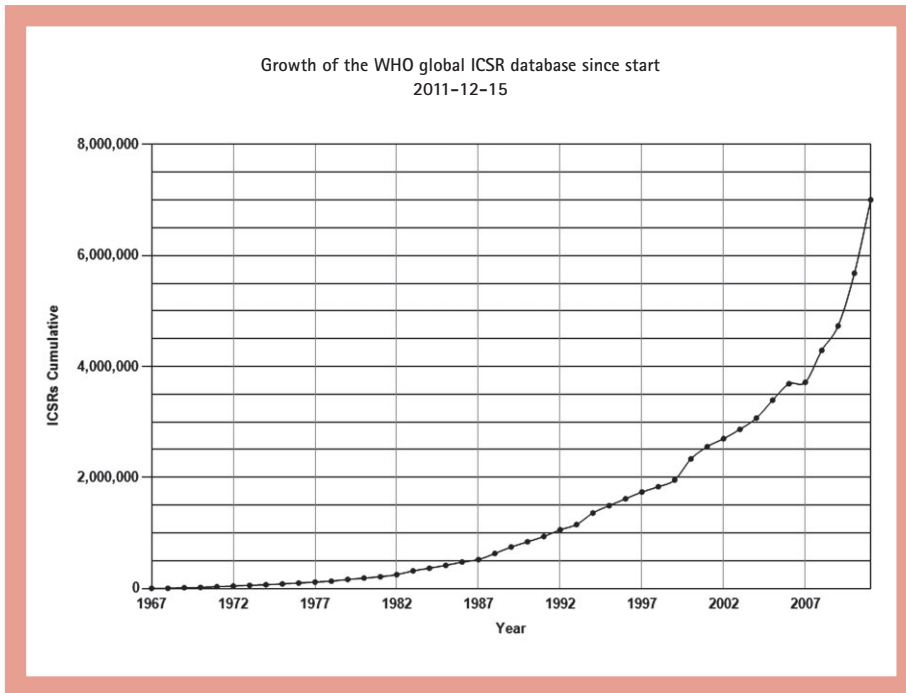
Thanks to the continuous submission of 'individual case safety reports' - ICSRs - from members of the WHO Programme for International Drug Monitoring, the milestone of 7 million reports in VigiBase was reached in mid December 2011. During the previous nine months the UMC received over 1,000,000 reports from member countries - an impressive figure!

Reports from health professionals

The 7 million ICSR reports from countries contributing to the WHO Global Individual Case Safety Report database, VigiBase, represent the concerns of health professionals around the world about possible harm caused to their patients by

medicines. Reports sent to national centres from pharmaceutical companies and from patients themselves are also in the database. All countries that belong to the WHO Programme for International Drug Monitoring commit to monitor the safety of medicinal products in their own countries, but also to share their information within the Programme.

Figure 1. Cumulative number of active ICSRs in VigiBase



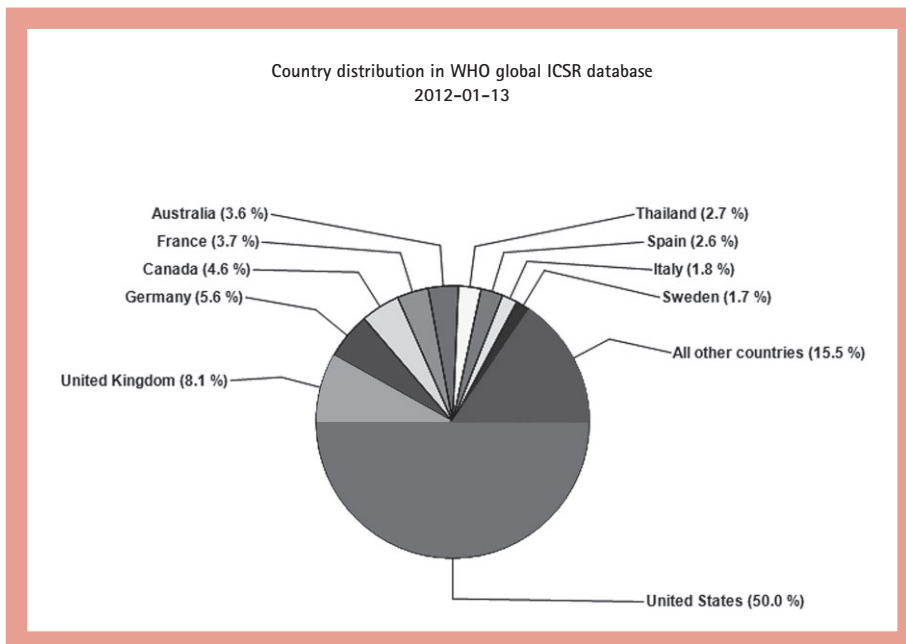
National level

Health professionals, pharmaceutical companies and patients report suspected adverse drug reactions and other problems related to the use of medicines to their national pharmacovigilance centre, which assesses them locally, and may then take action in the country concerned. The reports are also forwarded to the UMC which is responsible for VigiBase. Through membership of the WHO Programme one country can know if similar problems are experienced elsewhere.

Further analysis

After they are processed and entered into VigiBase, the 7 million ICSR reports are subject to further analysis. When there are a number of reports of a suspected new adverse reaction to a particular drug this may be circulated among Programme members as a 'signal' - a notice of a need for increased awareness of a possible hazard. This happens after preliminary evaluation and expert review at the UMC, prior to detailed work being performed by individual national authorities.

Figure 2. Country distribution in WHO global ICSR database



New pharmacovigilance Collaborating Centre

Sten Olsson

On the 1st of November 2011, a new WHO Collaborating Centre with a principal interest in pharmacovigilance was created. WHO nominated the Centre Anti Poison et de Pharmacovigilance du Maroc as a WHO Collaborating Centre for Pharmacovigilance, with the following proposed terms of reference:

1. To conduct and facilitate regional and national pharmacovigilance training courses for Francophone, Eastern Mediterranean and Arabic countries
2. To support the WHO normative functions related to pharmacovigilance and promote patient safety
3. To assist WHO in the pharmaco-vigilance assessments and in the provision of technical support to Member States in pharmacovigilance and patient safety.

Dr Shanthi Pal from WHO Geneva and Dr Mohamed Bin Shahna (see picture) from WHO Regional Office for the Eastern Mediterranean (EMRO) officially announced this nomination at the annual meeting of National Pharmacovigilance Centres in Dubrovnik, Croatia.

Well-established centre

This designation is recognition for all the work done by Professor Rachida Soulaymani as a head of the Moroccan centre and her active professional team who have played a major role in developing activities for the benefit of French and Arabic countries in particular and at regional and international level in general, in the field of pharmacovigilance and patient safety. Training and active collaboration in many international

forums have been part of their approach and many in the world of medicines and patient safety will be aware of the energy and commitment they bring our field.

Growing Network

This new centre will help to reinforce the existing WHO Collaborating Centre network

for pharmaco-vigilance (the UMC and the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance in Accra Ghana), and will be of great benefit for the development of tools and techniques of pharmacovigilance.



The Moroccan Collaborating Centre team with Mr Mohamed Bin Shahna from WHO EMRO during his visit to the centre. On Mr Bin Shahna's left is Professeur Rachida Soulaymani-Bencheikh, Directeur, Centre Anti Poison et de Pharmacovigilance du Maroc, and on his right is Dr Raja Benkirane, Responsable, Centre National de Pharmacovigilance (CNPV), Médecin Spécialiste en Pharmaco-Toxicologie.

Threat to WHO drug safety function

The need to balance the WHO's core budget is threatening work in the Essential Medicines Department, including pharmacovigilance. An important and substantial letter appears in the medical journal *The Lancet* as we go to press. Dr Mohga M Kamal-Yanni, Senior Health and HIV Policy Adviser, based at the UK international charity Oxfam, writes about WHO's financial predicament and the possible effect that cuts may have on crucial work in the field of medicines. This covers the Essential Medicines List (and the new version for children), Pain relief guidelines, guidelines for medicines

pricing and availability, WHO support to the International Narcotics Control Board, as well as its work in supporting the monitoring of drug safety (pharmacovigilance) with which *Uppsala Reports* readers are familiar; all these are in danger of being reduced or curtailed.

This core work impacts on public health involving medicines, has become partly reliant on voluntary contributions, and its component and inter-linking parts need firm funding, argues Dr Kamal-Yanni. Her article has been supported and commented on in other media.

Mohga M Kamal-Yanni. Action to preserve WHO's core functions cannot wait for organisational reform.

*(Correspondence) www.thelancet.com
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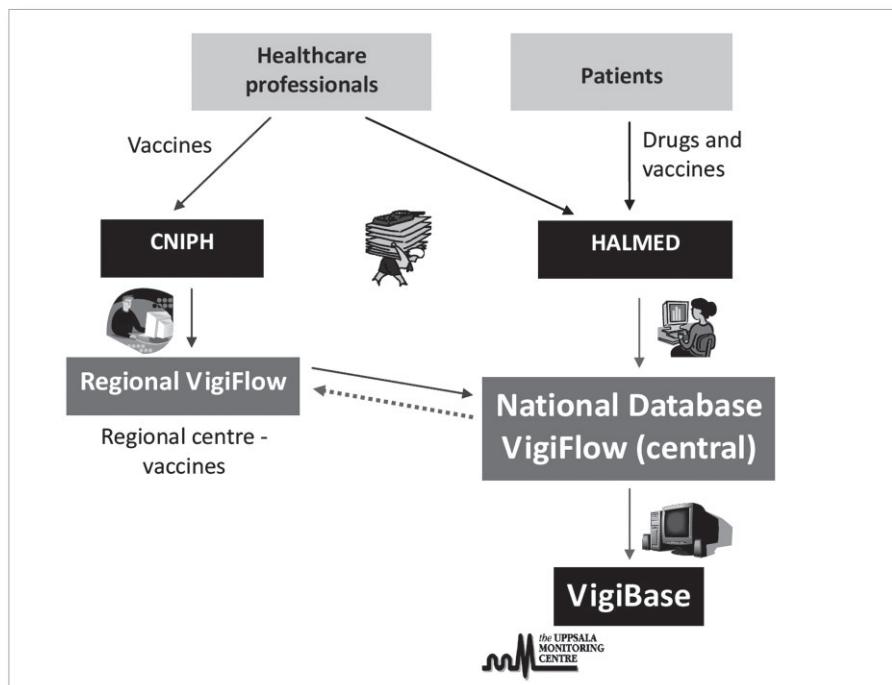
Working together to improve vaccine safety – the Croatian experience

Adriana Andrić, Viola Macolić Šarinić

Croatia has a long tradition of vaccination against infectious diseases, with the oldest records of vaccination against smallpox going back to year 1791. Today, planning and implementation of national immunization programme is conducted by the Croatian National Institute of Public Health (CNIPH). Adverse events following immunization (AEFI) reporting is traditionally considered as a part of epidemiological practice and healthcare professionals were sending AEFI reports solely to CNIPH until 2005. At that time, the National Pharmacovigilance Centre was working within the University Hospital in Zagreb, the capital of Croatia; the regulatory authority was the Ministry of Health.

Addressing problems

Within this setting, there were several problems regarding AEFI reporting: the copies of AEFI reports were sent to the National Centre only once a year, the Marketing Authorization Holders (MAH) weren't receiving the reports, the regulatory action was delayed (Summary of Product Characteristics and Patient information leaflet updates) and since both CNIPH and National Centre were managing the same reports individually, there were two coding systems used, two assessment processes conducted and two separate annual reports produced for the same data collected. In 2005 the National Centre became a part of the Croatian Agency for Medicinal Products



ADR and AEFI reporting in Croatia

and Medical Devices (HALMED). Since HALMED and CNIPH both recognized the issues of AEFI reporting, an Expert group for AEFIs was formed in November 2006.

Current Expert group tasks

The Expert group consists of the employees of the Pharmacovigilance department of HALMED and Infectious Disease Epidemiology Unit of the CNIPH. Its major tasks are:

- assessment of each AEFI individually
- classification of the AEFIs according to their causality and seriousness based on the internal document 'Official Guidelines for assessment of the AEFIs'
- identification of duplicate reports
- informing both parties on any action taken
- informing both parties on any follow-up reports
- decisions on the need for further action (investigation and regulatory), and
- production of a joint annual report on AEFIs.

Joint management of reports

The Expert group meetings are being held twice a month. The AEFI reports are exchanged, entered in the national database and sent to the UMC on daily basis. HALMED staff commit AEFI-reports to the UMC, while CNIPH has a status of a regional centre in Vigiflow. Regarding the other previously identified problems in the AEFI reporting

system, MAHs today receive all reports within 15 days; only one coding system is being used (MedDRA), there is a single joint assessment process conducted on each AEFI report, and a single joint annual report is being produced. This system enables immediate regulatory action to be conducted and information to the public to be sent in a timely manner. The Medicinal Products Act allows healthcare professionals to report AEFIs to both institutions. This means that health professionals both recognize the role of the National Centre and maintain a deeply-rooted practice of reporting AEFIs to CNIPH, while at the same time it enables the AEFI reporting system to be functional and more effective. The work of the Expert group was subsequently defined in Ordinance on Pharmacovigilance in 2009, making this positive practice obligatory.

The roles and responsibilities of both National Centre and CNIPH are precisely defined, the regulatory and epidemiology knowledge is being combined and a harmonized approach is being used when deciding on regulatory or public health actions and when informing the public. Both of our institutions are very proud of our successful collaboration which marked its fifth anniversary this year. Today we are confident that together we can face the challenges that the future holds in improving vaccine safety in Croatia.



Bottom row, left to right: Bernard Kaic (CNIPH) and Viola Macolic Šarinić (HALMED);
 second row: Armano Rajh (HALMED), Tatjana Nemeth Blazic (CNIPH) and Marin Banovac (HALMED);
 third row: Iva Pem Novosel (CNIPH), Gordana Cogelja Cajo (HALMED) and Adriana Andrić (HALMED);
 top row: Darko Krnić, Marina Flamaceta and Nikica Mirošević Skvrce (all HALMED)

Sharing AEFI reports: Pharmacovigilance Centres and National Immunisation programmes

Jerry Labadie

Review of AEFI (Adverse Events Following Immunisation) reports in VigiBase, submitted by National Pharmacovigilance Centres (NPC) of countries in the Global Network for PMS of Prequalified Vaccines (see UR46 p11 for project description) suggest that AEFI detected and reported within the National Immunization Programmes (NIP) are not shared with NPCs – and therefore not entered in VigiBase. To collect more specific and detailed information on NPC experiences a questionnaire was disseminated amongst the representatives of 57 countries who attended the 2011 Annual Meeting in Dubrovnik, Croatia. Completed questionnaires were returned by representatives of 50 countries:

Angola, Argentina, Armenia, Republic of Belarus, Belgium, Brazil (CEATOX & ANVISA), Bulgaria, Burkina Faso, Cambodia, Canada, Cape Verde, Chile, Democratic Republic of Congo, Croatia, Denmark, Egypt, Finland, Ghana, Indonesia, Iran, Iraq, Ireland, Italy, Japan, Kenya, Madagascar, Malaysia, Mauritius, Republic of Moldova, Montenegro, Morocco, Nepal, the Netherlands, New Zealand, Norway, Russian Federation, Saudi Arabia, Serbia, Singapore, Spain, Switzerland, Tanzania, Thailand, Togo, Uganda, Ukraine, USA, Zambia, Zimbabwe.

Method

Four questions were asked, questions 1 –3 used tick boxes (plus room for comments) and question 4 was free text.

1. Does your pharmacovigilance system receive AEFI reports from: NIP/EPI (public sector) / private sector / others (e.g. military) / none

2. Exchange of AEFI reports between NPC and NIP/EPI (specify send or receive): all reports / serious reports / non-serious reports) / no reports
3. Does your NPC have contact on AEFI with your safety surveillance colleague(s) in NIP/EPI: regular contact (specify frequency) / incidental contact / no contact
4. What do you see as major obstacles for collaboration between NPC and NIP / EPI in your country (e.g. different reporting forms?)

Results

Question 1. Five countries indicated that the NPC and NIP use a common, integrated database: Croatia, Denmark, the Netherlands, Thailand and the USA. From one country the results were unintelligible. Of the NPC of the remaining countries 15 (33%) indicated that they did not regularly receive AEFI reports from the NIP but 30 (66%) did receive AEFI reports from the NIP.

Question 2. Of the NPC which specified the nature of AEFI reports received, 21 (70%) indicated that all reports (both serious and non-serious) were received, while 5 (17%) received only serious reports. 15 NPC that receive AEFI reports also send reports to the NIP: 9 send all reports and 6 send only serious reports. But even among the NPCs that do not receive AEFI reports 8 do send their reports to the NIP! Eleven NPC do not send any of their AEFI reports to the NIP while 12 NPC did not give information.

Question 3. Most participants indicated that their NPC does at least have incidental, ad hoc contact with their NIP colleagues when safety issues occur; only five indicated that

there was no contact at all. The NPC of 30 participants has regular contact with their NIP colleagues with frequencies ranging from every week to once per year. The most frequently reported intervals were once every 3 months (n=7), once every month (n=6) and once every 6 months (n=5). Of the participants who gave only incidental contacts the pandemic H1N1 influenza vaccination campaign was mentioned by several as a recent example.

Question 4. A wide range of obstacles for collaboration between NPC and NIP was mentioned by the participants ranging from "the persons!" and "no communication" to a 4-point exposé identifying obstacles and possible solutions.

Conclusion

The results of this questionnaire indicate that many National Pharmacovigilance Centres and the National Immunization Programmes do share at least serious AEFI reports and have established some form of collaboration. But the extent of collaboration is variable and seems partly based on personal relationships rather than on formalized structures and procedures. Several participants indicated this in their answer to question 4. An example of formal successful collaboration was presented by the Croatian hosts (and is described on p6). It is obvious that the need for collaboration is widely recognized. Accessibility of all AEFI reports in a country is essential to be able to successfully assume the regulatory responsibilities regarding vaccines in the post marketing phase. UMC is thinking of ways to support NPC that want to pursue closer collaboration with the NIP in their country. You will find information in *Uppsala Reports* later in 2012.

'Blueprint' update

The stepwise endorsement process of the Global Vaccine Safety 'Blueprint' project, reported in UR55, steadily progresses. On 8 November 2011 SAGE discussed the final draft Global Vaccine Safety Blueprint. The Strategic Advisory Group of Experts (SAGE) on Immunization is the principal advisory group to WHO for vaccines and immunization. It is charged with advising WHO on overall

global policies and strategies, ranging from vaccines and technology, research and development, to delivery of immunization and its linkages with other health interventions. SAGE endorsed the Global Vaccine Safety Blueprint as the way forward for building capacity in vaccine pharmacovigilance for low- and middle-income countries. SAGE also indicated that

the Decade of Vaccine global action plan (www.dovcollaboration.org/action-plan/) should refer to the final Blueprint document for all aspects of vaccine pharmacovigilance. A pilot group will be assembled by WHO-IVB to start to move forward and implement the Blueprint.

UMC-A brings African nations together

Bruce Hugman

The UMC-Africa team in Ghana organised a communication skills training course in Accra on 11–13 October this year. Thirteen participants from five countries – Kenya, Zambia, Sierra Leone, Côte d'Ivoire and Ghana – took part.



International communications in Accra: course participants with members of the UMC-A support team.

Back row (from left): Nana Yaw Osei-Bediako (Ghana), Sheku Suma Mansary (Sierra Leone), Alimam Conteh (Sierra Leone), James Lartey (Ghana), Bruce Hugman (Thailand), Sahr Emmanuel Gbomor (Sierra Leone), Lyoko Nyambe (Zambia), George Muthuri (Kenya), Abdul Malik Sulley, Cyril Otieku-Boadu. Front row (from left): Thérèse Daubrey-Potey (Côte d'Ivoire), Sharon Ako-Adounvo, Adela Gwira (Ghana), Anita Anang, Amma Adomako-Bonsu, Abena Asamoah-Amoakohene (Ghana)

All the usual topics were covered – patient information, creating an ADR reporting culture, providing up-to-date safety information at the point of prescribing and dispensing, public health campaigns, and much more. The participants engaged actively and enthusiastically in the discussions and their evaluations suggested that they felt they had learnt useful, practical lessons for implementation back home.

Badly-managed meetings

In the session on running effective meetings, several participants revealed the astonishing fact that they spend between eight and ten hours a week in meetings, many of which they felt were pointless and demoralising: a quarter of their working lives, partly at least, seemingly wasted. There was lively debate about two of the principal rules for running good meetings: (1) having a clear purpose – is this meeting necessary at all?; and (2) having a definite (and short) time-limit for all meetings – meetings will expand to fill any amount of time allowed.

The skills of good chairing were also recognised as critical to productive and energising meetings. Many felt that reform in this area would revolutionise their working lives and their morale. (The group felt that a month's audit of personnel-hours and costs related to meetings might have an impact on senior managers' thinking.)

The course was run by UMC communications specialist, Bruce Hugman, with able support from the UMC-A team and excellent service at the Coconut Grove Hotel. Fifteen other participants, sponsored by the West African

attended this year's meeting in Singapore. The Secretariat of ASEAN (Association of Southeast Asian Nations), the European Commission, regulators and pharma companies participated in the Regulatory Update Forum on 17 October 2011.

Shirley Ramesh is leading the work in the ASEAN Pharmaceutical Products Working Group within the ASEAN Economic Community. She emphasized the importance of harmonization of standards, i.e. that Asian countries have to be in line with international standards such as ICH, while also coordinating with WHO.

Patrick Debooyer of the European Commission presented the EU's work to combat falsified medicines and control active pharmaceutical ingredients. A new Directive 2011/62/EU includes four important amendments related to safety features (to identify a single product), the supply chain (wholesalers, distributors, pharmacies, brokers), active substances and internet sales. For the latter, there is a proposal for a common logo, recognisable throughout the EU, to be displayed on websites selling legal medicinal products.

Participants from regulators and industry in China, Thailand, Taiwan and Japan reported on new national pharmacovigilance regulatory initiatives. Dr Du Wenmin of the Shanghai Center for Adverse Drug Reaction Monitoring gave the remarkable figures for reporting of his centre to SFDA: 692,904 ICSRs in 2010 and over 700,000 in 2011.



UMC staff and industry representatives during a pause in the Singapore Regulatory Forum Update day

Health Organisation (WAHO) should have joined the course, but unspecified last-minute administrative problems led to their attendance being cancelled.

UMC-A is hoping to run a range of courses, including communications, in the future. Individuals or countries interested should contact Alex Dadoo at alex000@yahoo.com.

Pharmacovigilance Asia 2011

Helena Wilmar

Since 2010 IQPC have organized the Pharmacovigilance Asia meeting as a platform to connect regulatory authorities and industry and share information in risk management, regulatory standardization and harmonization and systems compatibility in safety data management. Annika Wallström and Helena Wilmar of the UMC

Two conference days followed, with participation mainly from industry, but also from regulators. Enhancing collaboration between the two, to improve drug safety, align technology processes and improve pharmacovigilance practices in Asia was highlighted. The way forward seems to be harmonization, or more feasibly, adaptation to ICH, to improve all pharmacovigilance activities in the Asia region.

Enhancing tools to monitor Public Health Programmes

Ennita Nilsson, Jayesh M Pandit, Victoria Nambasa Bukunya

The Monitoring Medicines project has had a busy schedule conducting training in the past months. As well as the course in Kiev, Ukraine (see below), there have been two in Africa on CEM of antimalarial medicines, and Targeted Spontaneous Reporting (TSR) of anti-retrovirals (ARV). The countries represented in Africa were Uganda, Kenya, Botswana, Zimbabwe, Ethiopia and Burkina Faso. At the end of the training, each country was requested to write a proposal outlining how they wish to pilot the methods. Reviewers then decided which two countries could benefit from the seed money and implement the methods.



The Uganda team

The Pharmacovigilance at the Pharmacy and Poisons Board (PPB) in Kenya, and Pharmacovigilance at the National Drug Authority in Uganda both had very clear proposals, and will now receive financial support

from the European Commission through the Monitoring Medicines project. The two countries will initiate and establishing a system for Cohort Event Monitoring (CEM) of antimalarial medicines in Kenya and Uganda, implementing the Targeted Spontaneous Reporting of anti-retrovirals. The three countries trained in Europe (Moldova, Belarus and Ukraine) are currently working up their draft proposals.

Kenya – antimalarials

Kenya will initiate a CEM system to identify the real safety problems patients face with the recently introduced Artemisinin-Combination Therapy, namely Artemether and Lumefantrine (AL). Dr. Kipkerich Koskei, Registrar, PPB and Chief Pharmacist of Kenya says "This will enable us to provide better recommendations for its wide proposed deployment across the private and public sectors".

A cohort of at least 3,000 patients will be established over a period of 6 months beginning in April 2012. Patients will be selected from six sites across three malaria endemic provinces and will include adults, children, and pregnant women who present with symptoms of malaria (both presumptive and confirmed diagnoses). This will provide a better opportunity to understand AL better, identify the patient safety issues more

clearly, and work more closely with malaria programme and other collaborators.

Tenofovir & Zidovudine in Uganda

The project in Uganda will mark a major collaboration with public health programmes on the safety monitoring of medicines through work with the Aids Control Programme (ACP). The major goals for this pilot project are:

1. to improve care and safety of patients on antiretroviral therapy in Uganda.
2. to provide data for future reference on the safety of Tenofovir and Zidovudine.
3. to enhance pharmacovigilance in public health programmes and among health professionals in Uganda.

The programme will follow adults on a Tenofovir-based regimen and Zidovudine use. It will study both observational and interventional data. In the observational component, healthcare professionals will monitor and report solicited adverse drug reactions in patients who are initiating Tenofovir-based regimens and pregnant mothers initiating Zidovudine for Prevention of Mother to Child Transmission (PMTCT) in the two project sites. In the interventional component, a tool for assessing quality of reports will be developed and piloted at the sites and pharmacovigilance indicators developed for the STD/AIDS Control Program.

CEM training in Ukraine

Sten Olsson

A one-week training course on Cohort Event Monitoring of anti-retroviral (ARV) treatment was organized in Kiev, Ukraine, 21 – 25 November, 2011, initiated through the Monitoring Medicines project. Monitoring Medicines is coordinated by the UMC with WHO as the main partner and with funding from the FP-7 programme of the European Commission. The course was opened by Kees de Joncheere, WHO Representative to Ukraine, and Vasyl' Blikhar, Head, State Expert Centre, Ministry of Health, Ukraine. The objectives of the training were to bring together key representatives of the HIV/AIDS and pharmacovigilance programmes in Belarus, Moldova and Ukraine, and to stimulate a discussion on how to better study prevalent medication-related problems and improve the safety of patients treated with ARVs. The course was attended by 25 HIV and pharmacovigilance specialists from the three countries.

International speakers

The training started with an overview of commonly-used methodological approaches in pharmacovigilance. Trainers included Pia

Caduff-Janosa, Swissmedic, Switzerland, Shanthi Pal, WHO, Alex Dodoo, UMC-Africa and Sten Olsson, UMC. An overview of treatment options in HIV/AIDS and common and important patient risk scenarios were provided by Justina Kowalska from the HIV-Programme of Copenhagen University, a Monitoring Medicines partner. Training on the specifics of the Cohort Event Monitoring methodology and the CemFlow record management system was provided by Geraldine Hill, University of Dunedin, New Zealand, Henry Irunde, TFDA, Tanzania, Comfort Suku, NAFDAC, Nigeria and Magnus Wallberg, UMC. Steve Corquaye, an HIV patient counsellor from Accra, Ghana, shared his knowledge of patient perceptions of medication related risks and how to manage them. Lectures were carried out using simultaneous translation between English and Russian.

Next steps

At the end of the training the country representatives were requested to start working on a draft proposal for a pilot Cohort Event Monitoring programme of ARVs to be carried out in their respective countries. Once



Shanthi Pal, Olena Matvieieva (Head of Pharmacovigilance), Kees de Joncheere, and Vasyl' Blikhar at the Kiev training course

the proposals are completed and submitted to WHO in early 2012, one will be selected for a limited implementation grant from the Monitoring Medicines project.

Participants and trainers greatly appreciated the unique opportunity to discuss methods and approaches to improve the safety situation of patients on ARVs in the three countries: Belarus, Moldova and Ukraine. The local host, Ihor Perehinets of the WHO office in Ukraine, was given much praise for his efficient arrangements and the hospitality organized for the participants.

Five continents meet to discuss safety

The UMC team in Turkey

In its desire to be truly *international*, the International Society of Pharmacovigilance (ISoP) has in recent years spread its wings around the globe. 2011 saw it alight in a city straddling two continents, which only the most diligent conference delegate would have missed an opportunity to explore. The multi-layered city of Istanbul was an appropriate setting for an annual meeting of many levels, presentations moving from epidemiology, medication error, off-label use, to risk perception and communication, pharmacogenomics and more.



Harbiye Military Museum, ISoP 2011 meeting venue

Courses

The 11th annual ISoP meeting consisted of 2½ days (3½ including training courses) of around 50 presentations on various aspects of pharmacovigilance, as well as 250 posters. The massive earthquake in Eastern Turkey the week before provided a dramatic backdrop to the pre-conference course on crisis management. This was attended by twenty participants

keen to investigate how crises in healthcare could be anticipated, prevented or managed effectively. Local newspaper and TV coverage of the earthquake illustrated the generic challenges of crisis situations, especially with regard to prevention and communication. Other pre-meeting training covered causality assessment, good pharmacovigilance practice and basic concepts.

Large attendance

400 people attended the main meeting, of whom many were established pharmacovigilance professionals – offering excellent opportunities for networking. The quality of the presentations varied, though many were very well thought through and informative, stimulating further reflection. The scientific programme was good; in particular the plenary lectures starting each session were valuable and interesting. At least two sessions debated whether case reports can add more knowledge regarding an association than formal pharmacoepidemiological studies – an important and interesting discussion that will continue at the UMC.

Key-note lecture

John McEwen, former head of pharmacovigilance at the Therapeutic Goods Administration in Australia, gave the Bengt-Erik Wiholm lecture 'Pharmacovigilance of an anti-malarial and other tales'. This he presented in an informal style much in the way he might have chatted with his late Swedish colleague; the thread of the topics going from the saga of artesunate with amodiaquine in sub-Saharan Africa, effects of Zolpidem and publicity, the challenges of commencing pharmacovigilance in countries with limited health infrastructure, and some rare but severe adverse reactions.

Outstanding sessions

Professor Joerg Hasford of IBE University in Munich spoke on 'Ethics in clinical research and pharmacovigilance', underlining the principle of maximising benefits and well-being for the majority of patients, with as little harm as possible to as few as possible. Professor Hasford demonstrated that use of medicines in humans, when we are rarely if ever fully sure of the harm that they may cause, brings into sharp focus the importance of monitoring these medicines.

Another distinguished guest speaker was Professor Ragnar Löfstedt, of King's College, London, a major figure in the international field of risk and risk perception. He provided insight and research examples relating to the complexity and variability of risk perception across populations and the immense challenges of meaningful communication of risk in health and all human affairs.

Dr Mary Mease of Quintiles spoke on 'Measuring Risk Evaluation and Mitigation Strategy (REMS) effectiveness: time for program overhaul', commenting that three quarters of health care stakeholders believe that the REMS programme needs major overhaul, and it is virtually impossible to measure the benefits of a REMS, compared to

its burdens. She also examined the length of time needed to conduct an assessment effectively, and issues with medication guides not reaching patients (or not being comprehensible to them). The question of whether patients might even be exposed to more serious harm from alternatives, through REMS being a barrier to access was raised.

Several sessions covered the preventability of adverse reactions and medication error, and the contribution pharmacovigilance could make to identifying and reducing preventable harm. Work from Morocco, Turkey, Canada and the UK provided strong evidence of the solid progress being made in this field.

Posters

The poster exhibition was not very well-attended, partly because the area designated for poster presentations was quite small; still, there were a number of interesting posters, and as often happens, the judges struggled not to have more than three prize-winners (see box).

Social agenda

The gala dinner was held on a boat on the Bosphorus on a clear, chilly night. Participants sailed past a succession of grand palaces, forts, mosques and private houses which lined the coast, many of them magically illuminated and providing a romantic, historical backdrop to the food, music and dancing.

The UK/Ireland chapter of ISoP was officially launched, to join other regional chapters within ISoP.

In 2012 ISoP will meet in Cancún, Mexico, from 30th October to 2nd November.

From over 200 posters the prize-winners were:

1. Comparison of Safety Profile of Racemate Drugs and Their Enantiomers: Analysis of the French Pharmacovigilance Database, by C. Cailliet, L. Moachon, J. Montastruc and H. Bagheri (Toulouse, France)
2. Selective Serotonin Reuptake Inhibitors and Gastrointestinal Bleeding: A Meta-Analysis. A. Carvajal, C. Treceño, M. Sáinz, I. Salado, N. Jimeno, V. Velasco and L. Martín Arias (Valladolid, Spain)
3. Drug-Related Problems in Hospitalised Children in the United Kingdom and Saudi Arabia. A.N. Rashed, A. Neubert, S. Tomlin, J. Jackman, H. Alhamdan, A. Shaikh, A. Attar, M. Aseeri and I.C. Wong.

Pharmacovigilance Toolkit launched

Alex Dodoo

The *Pharmacovigilance Toolkit* – a unique collaboration within the WHO Programme to bring under one umbrella all resources and information on pharmacovigilance – has been launched. The Toolkit is a package of simple pharmacovigilance tools and a description of supporting processes for the conduct of pharmacovigilance. It is developed and maintained by the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, University of Ghana Medical School, Accra, Ghana on behalf of the WHO Programme for International Drug Monitoring and in collaboration with WHO-HQ, the Uppsala Monitoring Centre (UMC) and the WHO Advisory Committee on the Safety of Medicinal Products.

Trusted information

The main aim of the toolkit is to ensure that pharmacovigilance practitioners in low- and middle-income countries get access to information on the processes and activities involved in pharmacovigilance from a trusted source. All the material in the 'PV Toolkit' is endorsed by the WHO Advisory Committee on the Safety of Medicinal Products after the original text has been written by selected experts and then edited by an internal editorial team at the Uppsala Monitoring Centre, Sweden and Uppsala Monitoring Centre – Africa (Ghana).

Easy to access

The Toolkit can be accessed online at www.pvtoolkit.org and it will also be stored on USB drives in hyperlink format for use in areas where there is no internet connectivity. The Toolkit would be continuously updated with revisions of existing text occurring when necessary and inclusion of more topics as required and as available. The current version of the Toolkit is in English but there has been an offer from a national pharmacovigilance centre to translate the Toolkit from English into Spanish. Translation to other languages will happen based on the availability of funds and/or volunteers.

Fifteen chapters

This maiden version of the PV Toolkit comprises 15 chapters including a general introduction, functions of a national pharmacovigilance system; how to set up a pharmacovigilance centre and the WHO Programme for International Drug Monitoring. Other chapters are on methods, definitions and terminologies, relationship/causality assessment, signal identification, communication, crisis management and

The screenshot shows the homepage of the Pharmacovigilance Toolkit. At the top, there is a header with the WHO logo and the text 'World Health Organization Pharmacovigilance Toolkit'. Below this is a navigation menu with links for Home, PV Toolkit, Malaria PV Toolkit, About PV Toolkit, and Contact Us. The main content area is divided into two columns. The left column is titled 'Pharmacovigilance Toolkit' and contains introductory text about the toolkit's purpose and availability. The right column is titled 'What's New?' and features a section for 'The World Medicines Situation 2011: Pharmacovigilance and Safety of Medicines'. Below this, there is a section for 'Malaria PV Toolkit'. At the bottom of the page, there are logos for the Uppsala Monitoring Centre and WHO, along with text indicating that the toolkit is managed and maintained by the WHO Collaborating Centre for Advocacy & Training in Pharmacovigilance, University of Ghana Medical School, Accra, Ghana.

resources. The organisations involved in pharmacovigilance are listed as are training course providers. In addition to an Appendix with SOPs on spontaneous reporting and cohort event monitoring, there are also chapters on how to complete a Global Fund grant application for pharmacovigilance and Monitoring and Evaluation of pharmacovigilance systems including indicators.

Current news

The opening page of the Toolkit website contains information on what is new in pharmacovigilance; the current page features the release of the World Medicines Situation 2011 chapter on 'Pharmacovigilance and safety of medicines'. Pharmacovigilantes in low- and middle-income countries will find the Toolkit most useful as it provides all the resources essential for functional pharmacovigilance. It gives templates for pharmacovigilance activities, discusses the

technical and human resource requirements for pharmacovigilance and provides PDFs of essential publications in pharmacovigilance. There is also a detailed and comprehensive list of journal articles, books, textbooks, journals, and websites.

Comments, suggestions and queries on the website are welcome and should be addressed to info@pvtoolkit.org or to info@who-umc.org.

Warmth on the Adriatic

Geoffrey Bowring

Blessed with fine sunny weather, representatives of 56 countries from the WHO Programme, plus the European Medicines Agency, WHO Regional Offices and Collaborating Centres gathered on the Croatian coast for four days of discussions – formal and informal – from 30 October to 2 November. The conference venue, the Dubrovnik Palace Hotel, a modern building on the rocks outside the old city, boasted views over the Adriatic Sea – into which several adventurous souls dipped during the days of the meeting.

Busy sessions

On Sunday 30 October pre-meeting tutorials and interest group sessions took place, presented by UMC staff, alongside a seminar on use of MedDRA. VigiLyze, a new tool for VigiBase data, and CemFlow were outlined.

These sessions have become a key part of the meeting over the years, and were well-attended.

The main meeting started on the Monday. Plenaries consisted both of straight presentations and more interactive sessions. One of these was a discussion on 'Who carries the responsibility for pharmacovigilance in donor-sponsored treatment programmes?', with perspectives presented of a country receiving the medicine, WHO, and the donor, and with lively interventions from the audience. Other topics, which also featured stimulating responses from the floor, included:

- Internet and social media – boon or bane for patient safety?
- Detecting and assessing drug interactions from ICSR databases
- Training
- Integrating spontaneous reporting with other data sources
- WHO Blueprint project for safety monitoring of vaccines
- Anticipating potential medication errors in Risk Management Plans
- Experience of CEM in resource-limited settings
- Good practice in pharmacovigilance centre media relations
- Developing national pharmacovigilance systems by learning from past experiences.

Two sets of working groups completed the packed programme; there was also a good display of posters.

Working groups

- Assessing the preventability of medicine-related problems
- Optimizing communications between national pharmacovigilance centres (e.g., through Vigimed)
- Involving traditional medicine practitioners in pharmacovigilance
- How to demonstrate impact of pharmacovigilance activities
- Improving safety information to patients and their carers (parents, partners etc)
- Experiences of using documentation grading statistics to improve data quality
- Future role of PSURs: requirements for generic manufacturers
- Integrating national pharmacovigilance and public health programmes

Each group reported back to the plenary on the final morning, and work will proceed on the topics before the next meeting of the Programme.

Social activity

The old city of Dubrovnik, renowned for its beautiful historic buildings and unique atmosphere was only a short bus ride from the main hotels and many delegates took the opportunity to visit this UNESCO World Heritage Site. The pedestrianised old city was not too busy 'out of season' to enjoy the many sites and also for seeing the work of



Placa by night



User group



Dubrovnik

local artists, the historic pharmacy at the Franciscan Monastery and to eat and drink at the restaurants, many offering locally-caught seafood.

The Welcome reception at the old Restaurant Klarisa, and a dinner with traditional musicians and dancers at another coastal hotel, were both well attended. Close work between WHO, the WHO Regional Office in Europe and Halmed, the Croatian national PV centre, had allowed a 'visa on arrival' facility for a significant number of people from countries without a Croatian embassy.

Votes of approval

Among the many shared expressions of gratitude for an excellent meeting were comments such as:

"Permit me to add my voice to the unanimous chorus of agreement to the success of the Dubrovnik programme, the excellent organisation and the wonderful hospitality. The venue itself is magic but the personal touch, the detailed planning, the excellent scientific content and optimistic

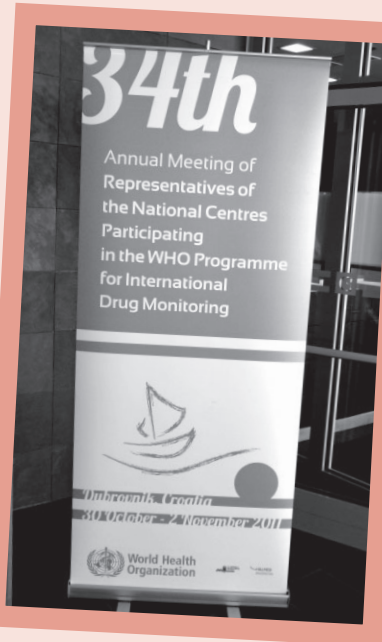
participation all added make this a most enjoyable and memorable meeting." Another representative wrote, "I too would like to thank WHO staff, UMC staff, and our Croatian hosts for a truly wonderful meeting. The National Centres Annual Meeting is a special gathering, because the dedication of the participants to our shared goal of improving patient safety is energizing."

Viola Macolić Šarinić, head of the Croatian pharmacovigilance centre added "Thank you very much for coming to Dubrovnik! It was an honour and a privilege to have you all.

These meetings are always full of positive energy and positive thinking... because you are all special and dedicated to people and their well-being. I am looking forward to implement all we have discussed and what we set as our key decisions in the coming year, and to see all of you in Brazil next year!"

Problems of Current Interest

- Atosiban and prolonged apnoea in a premature infant of 34 weeks
- The problem of evaluating the effectiveness of risk minimization measures
- ADRs related with the use of topical antiglaucoma drugs
- Retrospective observational study of ADRs caused by Drug Drug Interaction
- ADRs caused by drug-substrates of the metabolic enzyme cytochrome P450 CYP2C9
- NSAIDs-associated acute generalized exanthematous pustulosis (AGEP)
- New European legislation on pharmacovigilance and regional pharmacovigilance centres
- Five cases of hypoglycemia associated with antitubercular drugs
- Fennel essential oil
- Adalimumab and Merkel cell carcinoma
- Complementary medicines potentiated with pharmaceutical drugs
- Gemcitabine and infusion related adverse drug reactions
- Dabigatran related cardiac failure?
- Effective regulation of herbal medicines: safety monitoring in Nigeria
- Adverse event after using *Andrographis paniculata* containing product
- Increased reported lymphadenitis cases following BCG vaccination



Conference banner



Traditional music



from the air



Discussion group

Colombia congress

Elki Sollenbring

A three-day congress organized by the Pan-American Health Organization PAHO, Social Protection Ministry, Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA), National University of Colombia, Colegio Nacional de Químicos Farmacéuticos, took place in late November in Bogotá.

The first day concentrated on regulation of biotechnological products; speakers from Barcelona and Utrecht universities, the WHO Office in Colombia, the National University of Colombia, and others organized a working group around the subject. Colombia is trying to implement a new regulation for biotechnological products and the importance of pharmacovigilance was mentioned throughout the presentations.

The second and third days examined the role of pharmacovigilance in pharmaceutical policy and the rational use of drugs. Again, a wide range of speakers took part, from Pennsylvania University, Universidad Autónoma de Barcelona, Agencia Española de Medicamentos, PAHO, local experts and the UMC. The general view that emerged was that a pharmacovigilance system is essential in every country but needs to be a more intensive (active) element as the 'passive' form (spontaneous reports) does not capture in real time all the problems related to drugs – especially when new kinds of drugs are entering in the market.



The pharmacovigilance staff, from left to right: Freddy Yesid Ortiz, Jenni Andrea Murcia, Jenny Paola Perdomo, Daniel Alejandro Castiblanco.

At the Colombian National Centre I met the sub-director of the department of drugs, Francisco González, as well as six staff with whom I worked all that day. The staff are enthusiastic young people with much interest in learning more about pharmacovigilance. Despite all the difficulties in daily work they are trying very hard to develop and advance the pharmacovigilance system. The staff showed me their different tasks including the

tool they are using to enter ADR reports into their database. They are developing a more advanced entry tool to facilitate the entry of reports.

I presented for them basic information about UMC work and tools: documentation grading, VigiLize and VigiFlow. It was a good opportunity to discuss their needs and how we can work together to strengthen our collaboration.

In the Pyrenees

Elki Sollenbring



All the pharmacovigilance staff in Andorra, at the hospital in Andorra la Vella.

Background

The Pharmacovigilance National Centre of Andorra started 2007 and in 2008 became a member of the WHO Programme. They have a section in the Ministry of Health called 'Area de Recursos Sanitarios' (Healthcare Resources Area) and three of the six staff members work only a small percentage of their time with pharmacovigilance. Andorra has 60 pharmacies and one state hospital, where the majority of the ADR reports originate. Andorra has sent 170 reports to VigiBase and uses VigiFlow as its database. I visited the National Centre as part of the focus on strengthening the collaboration between the UMC and European countries.

The visit

Over two days I worked with the National Centre staff on entering reports into VigiFlow, explaining all the functionalities of the tool. VigiSearch was also discussed, along with documentation grading. By chance, the homepage of the ministry of health was launched that day, www.salut.ad, which includes a pharmacovigilance section and a web-based reporting form which will improve access and reporting response from the private sector.

I also visited the hospital pharmacy and met the chief of the pharmacy and his four staff. It was exciting to see the different strategies they have developed to improve the

reporting. The National Centre organized a conference in the hospital for staff and the private sector (pharmacies, clinics, etc), attended by around 50 people. The 'Director General de Salud y Bienestar', Josep Casals Alís, opened the meeting; Agustin Peris from the National Centre presented a report on the last three years of work, and I spoke on the need for pharmacovigilance and the WHO Programme.

Vienna visit

Hanna Pedersen and Cecilia Biriell

At the beginning of October, Cecilia Biriell and Hanna Pedersen from the Country Support team had the pleasure to spend a day at the Austrian national pharmacovigilance centre, part of the Austrian Medicines and Medical Devices Agency (AGES PharmMed), situated in the capital Vienna. Austria became a member of the WHO Programme for International Drug Monitoring in 1991.

We were welcomed by Dr Bettina Schade, Head of the Pharmacovigilance unit and her staff. Dr Schade started by presenting the set-up and activities of AGES PharmMed, the result of reorganization in January 2006. AGES is responsible for marketing authorization of medicinal products and assessment of medicinal products and medical devices already on the market regarding efficacy, adverse reactions and production.



Bettina Schade (to the left), centre staff and Hanna Pedersen (third from right) in Vienna.

The reorganized Pharmacovigilance unit at AGES PharmMed started with five staff members, but has now grown to 29. They are responsible for signal detection, risk management and communication. The main activities of the unit include handling Individual Case Safety Reports (ICSRs), Suspected Unexpected Serious Adverse Reaction reports, Periodic Safety Update Reports, Annual Safety Reports, Risk Management Plans and Labelling Implementation, and performing signal detection. The activities include pharmacovigilance for human and veterinary medicines, as well as vaccines. The unit

provides prescribers and patients with targeted information about drug safety.

Reporting rate

In 2010, the Pharmacovigilance unit received nearly 3,500 ICSRs – almost 500 reports/million inhabitants. The reporting from Marketing Authorization Holders accounted for about half the reports and the rest were from hospitals, healthcare professionals and pharmacists. The unit plans to start consumer reporting and electronic reporting for healthcare professionals soon.

Hanna gave a presentation about UMC, the WHO Programme for International Drug Monitoring and the benefits and obligations of being a member of the Programme. Cecilia continued with presentations on the UMC tools VigiSearch™ and VigiMine™, and about signal detection work. We had a lunch break at a nearby restaurant serving traditional Austrian food, like Wiener schnitzel.

Austrian database

After lunch the staff demonstrated the VigilanceOne database, their E2B-compatible database system, implemented in 2010. From this database reports are extracted and sent to the WHO global database, VigiBase™, as well as to the EU database, Eudravigilance. In the afternoon we discussed documentation grading, which staff found most useful, providing us with some really good feedback to take away and consider. We ended the day by showing some screen shots from VigiLyze, the new analysis tool in VigiBase currently being developed at the UMC.

We thank Dr Schade and her staff for a very fruitful and interesting visit!

The scope of training in China

Zhurong Liu

In early November I had the privilege to visit the Chinese State Food and Drug Administration (SFDA) Institute of Training and Education, in Beijing. The Dean, Jiang Deyuan, had led the delegation to the three-week workshop held at the UMC in October 2011 (see page 19).

The Institute has an important task to train professionals for the SFDA and for work in pharmaceutical companies, and they are actively examining the content of their training and relevant course materials following the workshop at the UMC.

Institute of Executive Development

The Institute of Executive Development is the only training and education organization at SFDA with the duty of training professionals from the SFDA system and from pharmaceutical companies in China. The Dean explained its history (it was founded in 1985), along with its structure, roles, and function in relation to the SFDA. Currently the Institute has over 60 full-time employees, 300 guest professors and 500 training programmes. These are housed in a large building, with a hotel for about 200 education course participants, a restaurant for them, together with classrooms, conference rooms and meeting rooms. He estimated that 300,000 professionals have been trained in the different disciplines in the Institute.



The SFDA Institute of Training and Education, Beijing

In recent years, the Institute has focused on training and education of adverse drug reaction reporting and monitoring, as SFDA issued new regulations on drug safety for the pharmaceutical industry in 2010. In these regulations, one of the requirements is that all pharmaceutical companies in China have a number of trained professionals responsible for ADR reporting and monitoring of their products. Due to the new regulations, the Institute has extensive programmes on drug safety to meet the companies' needs.

While in China, the UMC had a stand at the CHINATRIALS 2011 Summit, demonstrating the UMC's China drug dictionary to delegates. More than 300 people attended the meeting from all over China and east Asia.

On a mission to Russia

Geoffrey Bowling

A symposium on Safety Assurance of Medical Products was organized in Moscow on 27 October, 2011, in connection with the Council of Europe 'High-Level Conference on a Convention on Counterfeiting of Medicinal Products and Similar Crimes' (Medicrime



Vladimir Lepakhin and Alla Astachova

convention). The symposium was hosted and chaired by Dr Sergey Glagolev, chief of the division for monitoring of safety and effectiveness of medical products in the Russian regulatory authority Roszdravnadzor. Perspectives of the Russian pharmacovigilance system were provided by Dr Glagolev and by representatives of the pharmaceutical industry, academia and contract research organizations. Sten Olsson from UMC presented services offered by the WHO Programme and discussed contributions made to the Programme from Eastern European countries. Other international perspectives were given by Olena Matveeva from the national pharmacovigilance centre in Kiev, Ukraine and by Sabine Walser of the European Directorate for the Quality and Safety of Medicines & Healthcare (EDQM).



Sergey Glagolev and Sten Olsson

After the symposium Sten Olsson had the opportunity to discuss ways in which the UMC and WHO Programme might support the development of pharmacovigilance in Russia with Sergey Glagolev and, separately, with Vladimir Lepakhin, Alla Astachova and Anton Pereverzev of the Russian Scientific Centre of Medical Device Expertise. This latter centre is currently responsible for assessment of Russian ICSRs and for their submission to VigiBase. It was concluded that there is scope for closer collaboration in capacity building and research.

Talking to the neighbours: an unexpected outcome

Sten Olsson

I was invited to present the WHO Programme for International Drug Monitoring on 4 November 2011 at the annual conference of the Norwegian Pharmaceutical Society. After the session I was approached by a member of the audience who was on a temporary visit in Oslo from Malawi. He had a colleague at University of Malawi who was looking for ways of getting support for the development of pharmacovigilance in that country. Business cards were exchanged. Through the encounter in Oslo, UMC and UMC-A have now established a contact point in Malawi that was previously a blank spot on our pharmacovigilance map.

Society of Pharmacovigilance of India

Ronald Meyboom

This year's annual meeting of the Society of Pharmacovigilance of India (SoPI) took place in the ancient town of Patna, formerly known as Pataliputra, in Bihar, northern India. It was organized by SoPI together with Professor Harihar Dikshit and colleagues of the Nalanda Medical College and the Indira Gandhi Institute of Medical Sciences.

The three-day meeting was a success, thanks to its rich programme, including many excellent presentations covering a wide range of safety-related matters, often presenting original work, and as testified by the more than 200 participants. The programme, with speakers from Kolkata, Mumbai, New Delhi, Moga, Aligarh, Hyderabad and many other towns, also shows that SoPI has succeeded in spreading the interest and concern regarding pharmacovigilance to many corners of this vast country.

Monitoring on a wide scale

Examples of the many notable presentations were Professor Sharma's review of serious adverse events occurring in obstetric practice, Dr Manisha Singh who elaborated on the monitoring of oncolytics, Dr Sandeep Agarwal with a presentation on Medical Errors in Surgical Practice, Dr Zaki Anwar Zaman who focused on his experiences with the use of amphotericin in the treatment of Kala-azar, and Dr RN Acharya from Jamnagar University, who reviewed the achievements of the new national pharmacovigilance resource centre for Ayurveda, Unani and Siddha drugs that will monitor treatments used in ASU.. Professor KC Singhal highlighted impediments in monitoring drugs of the Indian system of medicine, including the concept of Al-Abdal in the Unani system and Pratinidhi Draya in the Ayurvedic system. Professor CP Thakur (former Union Health Minister) presented the John Autian Oration, entitled 'Medicine Safety – The Lifetime Experience of a Veteran Practitioner'. Speakers from Europe were Saad Shakir and Ronald Meyboom. Professor Shakir reviewed the important issue of Risk management in

pharmacovigilance, and Dr Meyboom gave the KC Singhal Oration, focusing on 'Signal Detection from a Clinical Pharmacological Perspective'. Professor Hari Dayan from the UNTHSC School of Public Health of Texas, USA, emphasized the increasing importance of pharmacoconomics and cost-effectiveness issues in health care policy.

PAHO course in Panama

Mariano Madurga

Panama hosted a course 'Pharmacovigilance of medicines, vaccines and biologicals: a proactive focus', organized by the PAHO (Pan-American Health Organization) from 12 to 14 December 2011. During the past six months, 50 healthcare professionals from 11 Latin-American countries have taken a web-based course in the virtual classroom of the PAHO web portal 'Virtual Campus of Public Health', an example of collaborative action between PAHO and the Spanish Agency of Medicines and Health Products (AEMPS).



During the pharmacovigilance workshop in Panama.

15 participants from six countries (who had followed the previous internet programme), and three facilitators attended the course in Panama. With a practical programme of 25 hours, specific aspects of the online course were reviewed, and there were workshops on evaluation of suspected ADR reports, including AEFI (adverse events following immunization). Students worked in groups, coding in dictionaries such as WHO-ART, WHO-DD, MedDRA, and practising with the databases VigiBase and FEDRA (database from the Spanish pharmacovigilance system). Queries were made in these databases, with explanations on signal detection (with VigiMine), on risk analysis and health issues, and ways of risk communication.

Finally, we discussed several proposals for applied research projects to be completed: among others, it was agreed to co-ordinate three related to ineffectiveness or therapeutic failure. This is a common problem in Latin-American countries and affects spontaneous reporting systems of suspected ADRs: a great reason to undertake an investigation.



Speakers and organizers arrive for the SoPI meeting in Patna

A new doctor at the UMC

Sten Olsson

Johanna Strandell of the UMC's Research department has been awarded a doctorate in clinical pharmacology by Linköping University (Department of Medicine and Health Sciences). She defended her thesis 'Drug interaction surveillance using individual case safety reports' in an academic dissertation on October 6, 2011. The faculty opponent was Professor Robin Ferner of the University of Birmingham, United Kingdom.



Professor Robin Ferner with Dr Johanna Strandell

Johanna has worked at the UMC since 2003. She started off within the Signal detection and Analysis team from 2003 to 2006, after which she has been working in the Research department. Her doctoral studies were carried out from 2008 to 2011 with Professor Staffan Hägg, of Linköping University, as the main supervisor, and firstly Dr Andrew Bate, UMC, as co-supervisor from 2008 to 2009 and then from 2009 to 2011 Dr Niklas Norén, UMC, as co-supervisor.

Drug interactions

Johanna's thesis is based on six original scientific contributions that explored the potential to identify drug interactions using individual case safety reports (ICSRs) and to develop a method to facilitate the detection of adverse drug interaction signals in the WHO Global ICSR Database, VigiBase. The thesis demonstrated that drug interactions can be identified in large post-marketing pharmacovigilance reporting databases. Both pharmacokinetic and pharmacodynamic interactions are reported on ICSRs and the surveillance system that UMC implements during spring 2012 will therefore aim to detect both types of interactions. To facilitate the identification of novel adverse drug interactions, a strategy combining different types of information (clinical reported information, pharmacological data and disproportionality measure) available on ICSRs and in VigiBase were proposed. In a first evaluation the proposed strategy had higher performance in comparison to current methods available for detecting adverse drug interactions.

A copy of the thesis can be obtained by writing to the UMC. The six papers are listed in the box.

- I. Strandell J, Bate A, Lindquist M, Edwards IR; Swedish, Finnish, Interaction X-referencing Drug-drug Interaction Database (SFINX Group). Drug-drug interactions – a preventable patient safety issue? *Br J Clin Pharmacol* 2008; 65(1):144–6.
- II. Strandell J, Bate A, Hägg S, Edwards IR. Rhabdomyolysis a result of azithromycin and statins: an unrecognized interaction. *Br J Clin Pharmacol* 2009;68(3):427–34.
- III. Strandell J, Wahlin S. Pharmacodynamic and pharmacokinetic drug interactions reported to VigiBase, the WHO Global Individual Case Safety Report Database. *Eur J Clin Pharmacol* 2011;67(6):633–41.
- IV. Strandell J, Caster O, Bate A, Norén GN, Edwards IR. Reporting patterns indicative of adverse drug interactions – a systematic evaluation. *Drug Safety* 2011;34(3):253–266.
- V. Strandell J, Norén GN, Hägg S. Key Elements in Adverse Drug Interaction Safety Signals. Submitted to *Drug Safety*.
- VI. Strandell J, Caster O, Hopstadius J, Edwards IR, Norén GN. Triage algorithms for early discovery of adverse drug interactions. Submitted to *Drug Safety*.

US FDA Vaccine Safety Seminar

The U.S. Food and Drug Administration (FDA) will run a two-day free training seminar, 'Application of Pharmacovigilance to U.S. FDA Regulatory Decisions for Vaccines'. The FDA two-day seminar is open only to paid participants attending the WHO Uppsala Monitoring Centre (UMC) course, Pharmacovigilance: the study of Adverse Drug Reactions and Related Problems.

The FDA Center for Biologics Evaluation and Research (CBER), Office of Biostatistics & Epidemiology (OBE) are to host a two-day seminar on Saturday, June 2 – Sunday June 3, 2012 in Uppsala, Sweden.

Representatives from multiple national centres will apply principles learned in the UMC course as they explore the methods

used by FDA scientists to assess postmarketing safety data and inform subsequent regulatory actions taken for vaccines and other biologics. FDA CBER Division of Epidemiology (DE) staff will describe the strengths and limitations of FDA data sources and analytic methods. Subsequently, CBER DE staff will illustrate the application of FDA analyses to specific regulatory decisions and communications that are now public. Specific topics will include vaccine passive surveillance report review, data mining, safety signal hypothesis generation, interpretation of controlled epidemiologic studies, review of reporting from manufacturers, review of pharmacovigilance plans, postmarketing requirements, and public reporting of DE's findings.

Registration is required, at no cost (no walk-in attendees). Airfare, lodging, and meals are the sole responsibility of the attendee for this two-day US FDA free seminar. Contact Marie Wallin at the UMC (marie.wallin@who-umc.org) for details of and application forms for training in Uppsala during May and June 2012, including this two-day seminar.

In the centre of pharmacovigilance

Mariano Madurga's reports on training activity are much appreciated by Uppsala Reports readers. However, we have never introduced the man, his career in Spain and the background to the training he has undertaken for several years in Latin America.

Mariano graduated in Pharmacy over 35 years ago at the Complutense University of Madrid. He then studied Biology for 4 years, and also obtained a Masters degree in Public Health. Later, in 1994-1995, he obtained a Diploma in Pharmacoepidemiology and Pharmacovigilance (Autonomous University of Barcelona).

In the 1980s Mariano helped create the first Drug Information Centre in a professional college of Pharmacy, serving 5,000 pharmacists and 2,500 community pharmacies in the Madrid Region. He was also a director of a pharmacotherapy journal *Mundo Farmacéutico (Pharmaceutical World)*. In 1985 he joined the 'Institute of Health Carlos III' (ISCIII), supervising information about new medicines, Patient Information Leaflets, and Summaries of Products Characteristics. In 1990 ISCIII assumed the role of co-ordinating centre of the Spanish pharmacovigilance system and became the pharmacovigilance department of the new Spanish Medicines Agency (AEMPS) in 1999.



Mariano, 3rd from right, with the Peruvian pharmacovigilance team at Machu Picchu.

"I started working full-time in pharmacovigilance in 1990. With our knowledge and skills we initiated the co-ordination of the Spanish Pharmacovigilance System for Human Use Medicines (SEFV-H). There are 17 regional centres in the SEFV-H, and we created a database, FEDRA, with online access from each region. Once we had undertaken training in the regional centres, the Ministry of Health proposed the first pharmacovigilance course in Latin America

in 2000. This was a 40-hour course in Santa Cruz de la Sierra, Bolivia (the training centre of AECID – the Spanish Agency of International Cooperation for Development) with 25 students from several countries."

"Since then, I have participated in or directed more than 12 courses of pharmacovigilance for Latin American healthcare professionals in AECID training centres in Antigua, Guatemala and Cartagena de Indias, Colombia. With my friend Albert Figueras, professor at the Catalan Institute of Pharmacology, we have worked hard to disseminate knowledge about pharmacoepidemiology and pharmacovigilance. I also participated in several meetings run by OFIL (Organization of Pharmacists from Ibero-Latin American countries), and have been part of working groups of Drug Utilization Research Group, Latinoamérica, www.durg-la.uab.es." One result has been the document 'Buenas Prácticas de Farmacovigilancia para las Américas' ('Good Pharmacovigilance Practice for American countries') published by WHO/PAHO in 2010.

Mariano has been invited to conferences on pharmacovigilance by agencies in the region such as CECMED and CDF in Cuba, DIGEMID in Peru, COFEPRIS in Mexico, the Institute of Hygiene 'Rafael Rangel' in Venezuela, INVIMA in Colombia, the National Directorate of Pharmacy and Drugs in Panama, among others.

"I have collaborated in developing pharmacovigilance regulations in Costa Rica, Cuba, Ecuador, Nicaragua, Peru, Venezuela, among others. I have also trained healthcare professionals from these countries, but there have often been complete changes in the pharmacovigilance team so then you have to start again." At present, AEMPS supports the development of a Regional Pharmacovigilance Programme in Central-America and Dominican Republic, comprising Belize, Guatemala, Nicaragua, Honduras, El Salvador, Costa Rica, Panama and the Dominican Republic. "AEMPS is working with SICA (Central-American Integration System, www.sica.int) providing training in each country. In these activities, the Panama national centre acts as the project co-ordinating centre."

So what drives Mariano? "Pharmacovigilance is a broad and heterogeneous activity, as it includes all kinds of medicines, and requires continuous learning in several subjects: pharmacology, epidemiology, and the regulation of medicines. After so many years, my personal commitment is continually being reinforced. In relationships with Latin America, language and similar cultures are unifying

factors. It is a way of making friends, establishing networks; it is easy to find people concerned about public health and interested enough to devote their professional life to this purpose. I feel that healthcare professionals owe a debt to our societies, and we must use our knowledge to promote public health."

As for the main lessons learned from these activities, Mariano again stresses the broad scope: many types of medicines, more data arriving each day. "In addition, healthcare professionals usually have little knowledge about pharmacovigilance, and it is necessary to teach basic concepts, such as relative risk, incidence, prevalence, interactions, medication errors, causality assessment, risk communication, etc. Pharmacovigilance as an activity impacts on public health and involves many disciplines; it should be condensed into thematic lessons, supplemented with case studies in workshops. New technologies can be used: on-line courses with virtual platforms, videos, and discussion forums. The new on-line pharmacovigilance course with the Moodle® platform organized by PAHO, in collaboration with AEMPS, is a first step to multiply the pharmacovigilance training courses in Spanish.

He identifies some obstacles to development of pharmacovigilance in Latin America:

- lack of resources to finance activities
- high turnover of professionals and teams
- lack of continuity in governmental projects, due to political changes that impact on technical issues,
- insufficient training of professionals,
- limited books and manuals in Spanish,
- lack of collaboration between countries,
- too few leaders.

Of course countries with established monitoring systems can learn from countries just embarking on the journey: "they must ensure the professional pharmacovigilance teams, resources, workplaces are maintained, with courses and continual training. Simple and effective pharmacovigilance rules must be established".

"Sometimes I've felt gratified when I have met strangers in Latin American countries and they have thanked me warmly for the information, data and opinions which I have expressed during the many years that I have been commenting in discussions list such as [e-farmacos] (www.essentialdrugs.org/efarmacos/), the Spanish version of [e-drugs]. It's very exciting to see how so many people are united with one click of the mouse!"

Sending off ADRs

Geoffrey Bowring

At the ISoP meeting in Istanbul our eye was caught by some striking and original posters and leaflets produced by the Turkish Pharmacovigilance Center (TUFAM) to raise awareness about the agency and about ADRs, particularly among health professionals. The cartoons are created by Dr Ercan Aydinkarahaliloğlu, a radiation oncologist and the husband of the Director of TUFAM, Demet Aydinkarahaliloğlu.

The referee (TUFAM) blows his whistle – Zıırt! and says to the offending player (Adverse Effect) "Dışarı" (Get off!)

Lying on the ground is Mr Patient Rights (Hasta = patient; Hakkı : rights Bey = Mr).



SFDA training course

Anna Hegerius

As a result of the collaboration between UMC and the Chinese State Food and Drug Administration, SFDA, a big Chinese delegation visited Sweden during three weeks in October. The purpose of the visit was a pharmacovigilance training course based on lectures, discussions, hands-on computer sessions and study visits. The delegation consisted of senior staff representing ADR monitoring centres in provinces of China.

The participants had already gained a lot of knowledge prior to the course, which meant challenging questions and engaging discussions. The group paid visits to the Swedish Medical Products Agency, the Karolinska Institute, ReAct (Action on Antibiotic Resistance), Strama (the Swedish Strategic Programme against Antibiotic Resistance) and the Akademiska Hospital (Uppsala university hospital), where a wide

range of exciting topics were covered. The study visits were very much appreciated, both by the Chinese group, the hosts and the UMC staff who also attended.

In addition to the general programme, Gang Cheng, from the National Center for ADR

Monitoring, had a presentation about Pharmacovigilance in China. At the closing ceremony, participants were given course certificates and Deyuan Jiang, President of the SFDA, Institute of Executive Development, expressed their gratitude for the successful execution of the course.



Representatives of regional monitoring centres in China pose during the course in Uppsala

Pharmacovigilance Department head



Antonio Mastroianni was born in New York City, New York, but grew up living in various cities on the East Coast of the United States. He studied History at the University of Vermont and later received a Master's of Science degree in Telecommunications Management from Oklahoma State

University, Spears School of Business. He worked in government affairs in Washington DC following college. Through his work representing the interests of IT companies, he moved to website development and was recruited to work in a small IT company that helped organizations with grassroots campaigns by harnessing the power of the

internet. In 2000 he went to work for a large networking company called UUNet and began managing automation and system integration projects to bring more on-line services to customers. Through UUNet (ultimately part of Verizon), he was able to join his wife (then girlfriend) Kristina, when she moved back to Sweden in 2003. In Sweden he worked on large global customer projects and moved into global programme management and finally was the head of a large global outsourcing programme for one of Verizon's premiere customers.

After 11 years of working in IT management and outsourcing, Antonio began to look for other ways to apply his skills that were more meaningful. A book written by Steven Johnson called the Ghost Map described the use of mapping technology to discover the cause and eventually the cure for cholera. This book served as a motivation to find another job, and within one week of this decision he was talking with Marie Lindquist about a new role at the UMC.

The UMC is the start of another chapter for Antonio as he is now Head of Pharmacovigilance Services, and looking forward to helping the UMC grow as an organization. In addition to the opportunity to learn more about patient safety, pharmacy, and medicine, he is excited about getting to learn more about Uppsala as he always worked in Stockholm. For Antonio, the intellectual stimulus, constant curiosity, and truly motivated and dedicated people are the most appealing characteristics of the UMC.

Sweden introduced Antonio to many new activities and he is now an avid Nordic skier and long-distance Nordic skater, and has adopted the Swedish tradition of working on one's house during every vacation, evening and weekend. In his quest to better understand Sweden and participate in key traditions for his children he is a trained outdoor teacher with Friluftsförbundet (The Swedish outdoor association) and teaches about the outdoors in English (Skogsmulle) to children between 3-6, including his two sons, Theo and Kalle.

PDQ

The Production, Development and Quality department at the UMC has been strengthened over recent months by three new staff members: **Andreas Zetterström**, **Gunnar Dahlberg** and **Mikael Gustafsson**.

Andreas and Gunnar are both originally from Uppsala and are currently working as systems developers in the VigiBase team within the PDQ department. Before joining the UMC Andreas worked as a lecturer in Computer Science at Uppsala University. During this time he started an IT consultancy firm together with Gunnar, who was then doing his master thesis work at UMC on a tool that can be used to automatically find

ADR terms within free text. After working part-time in the PDQ department they started working full-time at UMC in September.

Andreas is working mainly with development of VigiLyze - UMC's new ICSR analysis tool. "With VigiLyze we have applied a Business Intelligence perspective on analyzing ICSR data, thus leveraging on the recent progress of technical solutions in this area. This will help maintain UMC in the very forefront of signal detection using ICSRs." Gunnar is responsible for the development of tools to facilitate the import and analysis of ICSRs in VigiBase. "The goal is to provide a web service to national centres so they have the ability to send new ICSRs continuously. This should become a complement to the existing process of sending large files of ICSRs per e-mail. This will make it possible for us to receive the ICSRs from the national centres faster, automate the import process and improve analysis and signal detection in the future."

colleagues working at UMC and through them I became interested in applying for a position here. My first months here have been really interesting and stimulating and I have enjoyed every day."

Mikael was born in Mariestad but spent six of his early years in South Africa. Returning to Sweden he lived in Dalarna, moving to Stockholm after school. "Since 1992 I live in Knivsta south of Uppsala. Dogs and old vehicles tend to find their home in our house so at the latest count I found two small white dogs, two motor cycles and two vintage cars."

Gunnar is interested in sports, particularly soccer and golf, which he enjoys playing during the summer season. He appreciates the enthusiasm of people working at UMC. "I very much like the atmosphere at the workplace. My colleagues really embrace change and are willing to develop and provide new tools to make processes become more effective."



Mikael Gustafsson, Andreas Zetterström and Gunnar Dahlberg

Mikael, as a systems developer and architect, is currently working with the China version of the Drug Dictionary Browser. Before joining UMC he worked as a consultant for many years, including a period at the Swedish Medical Products Agency, Läkemedelsverket, where he helped develop their central system LVIS-C and the public product service NPL. "I have a few former

Before studying Computer Science Andreas worked as a professional violinist; he still plays the violin and the piano. He very much likes the ethos of curiosity and invention at UMC. "I like to work in a cutting-edge environment that embraces constant change to improve our methods and processes. I find it rewarding to work in an organization that has such an important mission as UMC has."

More on Pictograms

Sten Olsson

Following our report on the use of pictograms in pharmacy practice (UR54, p10), there have been further developments in the International Pharmaceutical Federation (FIP) initiative to develop pictograms to assist pharmacists when there are communication barriers with patients which might affect compliance and safety. Luc Besancon, Manager, Scientific and Professional Affairs FIP has circulated the details.

As a result of comments received on the initial edition (mainly from pharmacists), a second version has been developed. This updated version can be run either online (with internet connection) or offline (downloaded on the pharmacy computer).

New features enable the pharmacist to work in their own language and then select the language of the patient, so that the material

and instructions are printed in the patient's language.

Instructions can be printed in three formats:

- a label, with size able to be customized
- a Medication Information Sheet - the patient medication instruction for a particular medicine
- a prescription calendar, which combines the medication instructions for all medicines dispensed to the patient.

Further improvements are promised.

To use this software you just need to go online at: <http://www.fip.org/pictogramssoftware>

New EU guidelines

Good Pharmacovigilance Practices (GVP) will be the name of a new set of pharmacovigilance guidelines in the European Union (EU), which will ultimately replace the current Volume 9A of the Rules Governing Medicinal Products in the EU. The development of GVP is part of the implementation of the new pharmacovigilance legislation passed by the European Parliament in 2010 which comes into force in July 2012. GVP will be organised by key processes described in its various modules.

The modules are developed jointly by the European Medicines Agency and the EU Member States, and the first draft modules will become available at the Agency's website (www.ema.europa.eu/) for public consultation over two months - watch the site from February for details.

These first modules cover quality systems, pharmaco-vigilance system master files, risk management plans, individual case safety reports, periodic safety reports, post-authorisation safety studies and signals. The

draft modules will give insight in the future pharmacovigilance processes in the EU, and the public consultation is open to all individuals and organisations worldwide.

Further draft modules are planned to be released for public consultation later in 2012.

Visitors

Postgraduate students

Ermelinda Viola, a student in Chemistry and Pharmaceutical Technologies of the University of Palermo, Sicily, has been undertaking a placement at UMC for several months. She is currently undertaking a postgraduate Masters course in Pharmacovigilance and Regulatory Affairs at the University of Verona. During the first part of the Verona course the lectures about signal detection, and the suggestion from Professor Giampaolo Velo, led her to apply to undertake a project at UMC. She worked in the UMC Analysis team, as part of a project on the follow-up of old signals.



Ermelinda



Maria

Maria Lindgren, a Masters student in Pharmacy at the Division of Toxicology in the Department of Pharmaceutical Biosciences at

Uppsala University has spent time in the UMC Research department in the second half of 2011. Her studies centre on Dose Information on Individual Case Safety Reports in VigiBase.

WHO HQ Vaccines

In November three visitors from WHO Headquarters Geneva, Department of Immunization, Vaccines and Biologicals (IVB) came to the UMC for meetings, VigiFlow training and demonstrations of VigiLyze and CemFlow. Dr Christine Maure, Technical Officer Global Vaccine Safety, Quality, Safety and Standards (QSS), Dr Madhava Ram Balakrishnan, Medical Officer, QSS and Dr Philipp Lambach, Technical Officer, QSS spent time with Jerry Labadie and other UMC staff.



Madhava Ram Balakrishnan, Philipp Lambach, Christine Maure and Antonio Mastroianni

SFDA directors

Anders Viklund

Together with the first snow in Uppsala on November 28th, a Chinese delegation from SFDA visited the UMC. The group consisted

of four directors from different centers at the State Food & Drug Administration, SFDA, in China. One of the main objectives of the visit was to investigate in depth signal detection, data mining and analysis. Marie Lindquist, Ralph Edwards, Johan Hopstadius and Anders Viklund from UMC presented the UMC work-flow and related tools and research projects. Zhurong Liu, also from UMC, facilitated the communication as interpreter.



Many steps to strengthen pharmacovigilance in China have been taken. Recently an electronic tracking system has been implemented using barcodes when administering around 350 medicinal products categorized as 'essential medicines'. Planning regarding training and education for staff at the regional centers is ongoing. The delegation is pleased with the collaboration between UMC and SFDA and looks forward to see how it will evolve in the future.

From left: Anders Viklund, Ms. Du Xiaoxi, Deputy Director-General, Drug Re-evaluation Center, SFDA, Ralph Edwards, Marie Lindquist, Mr. Sun Xianze, Director-General, Information Center of SFDA, Ms. Ye Guoqing, Deputy Division Director, Dept. of Drug Safety & Inspection, SFDA, Ms. Cao Lili, Division Director, China Center for Pharmaceutical International Exchange, SFDA

DATES	TITLE	PLACE	ORGANISER/CONTACT
13-17 February 2012	DIA Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing Training Course	London, UK	DIA Europe Tel.: +41 61 225 51 51 Fax: +41 61 225 51 52 Email: diaeurope@diaeurope.org
22-23 February 2012	Monitoring Safety in Clinical Trials and Drug Development	London, UK	Drug Safety Research Unit Tel: +44 (0)23 8040 8621 www.dsru.org/ E-mail: jan.phillips@dsru.org
26-29 February 2012	Drug Safety Middle East Conference	Dubai, UAE	IQPC Middle East http://www.drugsafetymiddleeast.com/Event.aspx?id=634224
3-4 March 2012	Future Perspectives in Pharmacovigilance	Bangalore, India	DIA http://www.diahome.org/DIAHOME/Home.aspx
14-15 March 2012	Back to Basics in Pharmacovigilance	Southampton, UK	Drug Safety Research Unit (see above for details)
14-16 March 2012	Advanced Pharmacovigilance	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
28-29 March 2012	Understanding Laboratory Results and Other Investigations (e.g. X-Ray, ECG) in the context of Adverse Drug Reactions	Southampton, UK	Drug Safety Research Unit (see above for details)
4-6 April 2011	7ème congrès P2T	Dijon, France	Société Française de Pharmacologie et de Thérapeutique http://www.congres-p2t.fr/
21-23 April 2012	International Society for Pharmacoepidemiology 2012 Mid-Year Meeting	Miami Beach, Florida, USA	ISPE www.pharmacoepi.org/meetings/ E-mail: ISPE@paimgmt.com
25-26 April 2012	Regulations and Guidelines for Pharmacovigilance	London, UK	Drug Safety Research Unit (see above for details)
21 May - 1 June 2012	Pharmacovigilance - the Study of Adverse Drug Reactions and Related Problems; followed by a two-day training seminar Application of Pharmacovigilance to U.S. FDA Regulatory Decisions for Vaccines.	Uppsala, Sweden	UMC E-mail: marie.wallin@who-umc.org www.who-umc.org > Pharmacovigilance > Education & Training
24-25 May 2012	Causality Assessment in an Evolving Pharmacovigilance Landscape - Uppsala Monitoring Centre Research Conference	Uppsala, Sweden	UMC Register directly at: conference2012@who-umc.org
26-29 May 2012	The Asia Pacific Conference on National Medicines Policies (APCNMP)	Sydney, Australia	APCNMP http://www.apcnmp2012.com.au/
23-26 August 2012	28th International Conference on Pharmacoepidemiology & Therapeutic Risk Management	Barcelona, Spain	ISPE (see above for details)
17-28 September 2012	Cours Francophone Inter Pays de Pharmacovigilance	Rabat, Morocco	Centre Anti Poison et de Pharmacovigilance du Maroc Tel: +212 537 77717467; Fax: +212 537 77717479 E-mail: rsoulaymani@gmail.com
30 October - 2 November 2012	12th ISO P Annual Meeting	Cancún, Mexico	International Society of Pharmacovigilance www.isop2012.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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