

MUR57



Quality of reports | Media relations

Publications | Patient reporting



Marie Lindquist
Director
the Uppsala Monitoring
Centre

When I go for my daily (well, almost daily) early morning walk, I usually listen to the news on the radio. Yesterday, one of the featured news items was a report referring to a recent study showing that almost half of the medicines used in Swedish children's hospitals have insufficient documentation for pediatric use. A representative from the Swedish Medical Products Agency commented that there has been a change in attitude, from the view that it is complicated and ethically dubious to perform clinical trials in children, to the current attitude that it is unethical not to test medicines on the patients who are going to use them. This stance is supported in recent legislation in the EU and in US FDA acts, with stricter requirements and incentives for studying the safety and impact of medicines in children, before and after market launch.

I think it is an important step forward to make sure that children are not neglected when approving and monitoring medicines; all those who have worked for improved legislation and guidance in this respect deserve praise! However, there are considerable ethical dilemmas surrounding pediatric clinical trials, and we should not forget that ethics depend on the context; what is seen as acceptable today may change over time.

Thinking about vulnerable populations, what do we do for those who are at the opposite end of the age spectrum? Even if old age is not an exclusion criterion per se in clinical trials, most elderly potential study subjects fall victim to the common exclusion criteria - elderly patients aren't perfectly healthy; they have multiple chronic diseases, often including dementia; they take lots of drugs and are physically fragile. This means that we know very little about what is likely to happen when a new medicine is used by the elderly.

I wasn't exactly surprised to find that 19% of the reports in VigiBase concern patients over 65, to be compared with 8% of the world's population being 65 years or older. Today, many 65 year olds are not really old at all, in terms of physical and mental shape – something that I'm glad about – I'm at an age when being 65 is not something that will happen in a long distant future! Looking at data for those over 80 (around 1% of the population today), I find that more than 4% of VigiBase reports concern this age group. The corresponding figures for children (0-14 years) are 26% (of the population) and 10% (of VigiBase reports). The relative over-representation in VigiBase of older patients further supports the need for improved pre- and post-marketing safety monitoring in senior citizens.

This year, the topic for the World Health Day is Ageing and Health, with the theme 'Good health adds life to years'. Although a higher proportion of us than ever before will continue to lead a happy and healthy life well into our 80s, the predicted global increase of those aged 80 and over – from less than 100 million today to almost 400 million by 2050 – is a call for everyone concerned about patient safety to ensure, as far as we can, that we are willing and able to tackle the special needs of an ageing population. There is no doubt that many, many people have medicines to thank, at least in part, for their reaching old age; but there will still be a growing number of people with multiple illnesses, and also taking multiple medicines, who will need the support of a dedicated pharmacovigilance community.

A handwritten signature in black ink that reads "Marie Lindquist". The signature is written in a cursive, flowing style.

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Final assembly of Monitoring Medicines

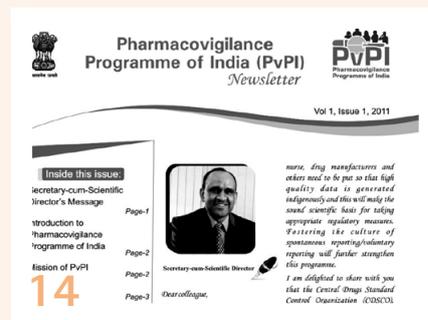
The project, funded by the European Commission, met together in Amsterdam to sum up achievements and look forward to more

Publications

All kinds of new publications of interest to everyone working in pharmacovigilance



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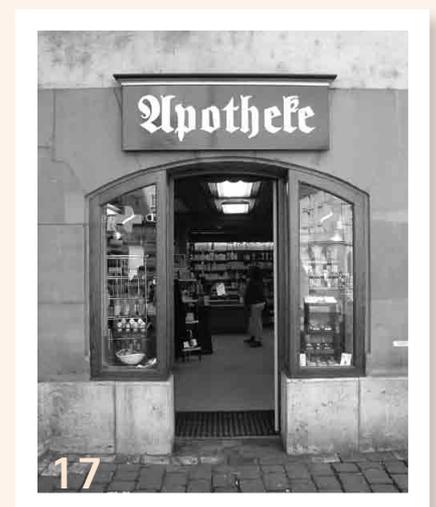
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News from India

The Pharmacovigilance Programme of India reports solid progress over the past year

UMC out and about

Switzerland, Turkey, Netherlands – some places where UMC staff have been meeting people and making presentations over recent months



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Brasília beckons

Geoffrey Bowring

Dirceu Barbano, director-president of ANVISA, the Brazilian National Health Surveillance Agency, sent a message at the end of the 2011 WHO Programme meeting in Dubrovnik to invite national centres to the 35th Annual Meeting of Representatives of the National Centres Participating in the WHO Programme for International Drug Monitoring.

Return to South America

This 2012 meeting, only the second time the WHO Programme has held its deliberations in Latin America, will be a key opportunity for the national pharmacovigilance centres

and boosting economic development while promoting social growth.

Meeting invitation

Official invitations to heads of national pharmacovigilance agencies will soon be sent out, inviting countries in the WHO Programme to join together in the modern city of Brasília, from 12-14 November 2012 (pre-meeting tutorials and other courses on 11 November). There will also be the usual agenda questionnaire to elicit suggestions for topics national centre heads would like to have discussed.

Cityscape

The Brazilian capital, noted for its modernist architecture, took over from Rio de Janeiro in 1960. It became the only city in the world built in the 20th century to be awarded the status of Historical and Cultural Heritage of Humanity by UNESCO in 1987. Major landmarks in Brasília include the Juscelino Kubitschek bridge (named after the country's president from 1956 to 1961), the Praça dos Três Poderes (Square of the Three Powers), the Palácio do Planalto (offices of the President of Brazil) and Palácio da Alvorada (official residence of the President). Some of these buildings are near the 'Monumental



to learn about health and patient safety in Brazil. A fast-growing country, Brazil already has 80,000 pharmacies, 450 drug companies, 3,702 producers of cosmetics, 3,248 producers of medical devices, 3,849 clinical laboratories, 15,491 radiology services, 6,627 hospitals and 2,056 haemotherapy services. In this vast picture, ANVISA focuses on protecting health, promoting innovation

Brazil

Brazil is the largest country in South America and the world's fifth largest economy. With a population of over 192 million, it is a multi-cultural and ethnically diverse nation. Brasília, the capital city hosts 124 foreign embassies. It is located in the Central-West Region, with a population of 3.6 million and is the 4th largest city in Brazil.

Axis', the central avenue in Brasília's city design.

The surroundings of the city include the national park Chapada dos Veadeiros, the Caldas Novas hot springs, and the old cities of Pirenópolis and Goiás Velho.

SIGNAL opens up

Geoffrey Bowring

SIGNAL, published several times a year by the UMC, covers potentially interesting pharmacovigilance problems, referred to as signals. It is based on information derived from individual case safety reports (ICSRs) available in the WHO Global ICSR Database, VigiBase™, containing over 7 million ICSRs of suspected adverse drug reactions (ADRs) submitted by national pharmacovigilance centres.

WHO has defined a signal as:

'Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.

An additional note states:

'Usually more than one report is required to generate a signal, depending on the seriousness of the event and the quality of the information.'

Before signals are published, they are clinically assessed by pharmacovigilance experts at UMC and reviewed by the UMC Review Panel of experienced international scientists and clinical experts.

Articles in SIGNAL represent varying levels of suspicion resulting from this assessment. Topics discussed in SIGNAL may need further action (eg. further evaluation of data from other sources, including studies for testing of

hypotheses). The topics presented in SIGNAL inform regulatory authorities who are responsible for deciding on further action, including communicating the information in SIGNAL to relevant health professionals and responsible market authorisation holders.

Up to now SIGNAL has only been sent to a restricted audience: the UMC's Review Panel and staff at national centres. Signal articles are also sent to international pharmaceutical companies which can be identified as uniquely responsible for the drug concerned. However, from February 2012 signals will also be subsequently published in the *WHO Pharmaceuticals Newsletter*.

Following the announcement Shanthi Pal and Marie Lindquist responded on E-DRUG to comments from the International Society of Drug Bulletins (ISDB), that "the intention of WHO is that the more than 7 million reports in VigiBase... be made accessible in a responsible, stepwise fashion in order to assist early detection of problems with medicines. Publishing SIGNAL in WHO Pharmaceuticals Newsletter is the first step."

The recommendations from the Advisory Committee for Safety of Medicinal Products (ACSoMP) in April 2011 describe the process of opening access; the full ACSoMP statement is on page 2 of their report: http://www.who.int/medicines/areas/quality_safety/safety_efficiency/recommendations.pdf



UMC organises an international research conference on causal association evidence

Causality Assessment – what can it tell us and what can it not? This is the theme of the UMC 2012 Research Conference Causality Assessment in an Evolving Pharmacovigilance Landscape, soon to take place in Uppsala, Sweden, where international opinion leaders will gather to present and discuss the current challenges and future directions of this important topic.

Interpreting evidence for a causal association between drugs and adverse events is complex. Whether determining effect in an individual patient or at the population level, multiple factors need to be considered. Furthermore, information from sources as diverse as case reports, observational studies and randomized trials must be weighed together, assessed and then motivated.

Affects the future lives of patients and the viability of drugs

The challenges of causality assessment affect patients as well as a wide body of professions. The questions are many and wide-ranging: What can case reports, studies and trials tell us? Can the evidence be incorporated in benefit-risk assessment? Will it stand up in court? What reporting responsibilities do the media have?

The answers can influence our future lives plus the viability of drugs. UMC's 2012 Research Conference seeks to provide some of them.

Places still available

Join us in this open research forum to debate what causal association evidence can and cannot tell us. Places are still available.

Causality Assessment in an Evolving Pharmacovigilance Landscape

May 24–25, 2012, Uppsala, Sweden

For the latest program information and details of practical arrangements:

www.who-umc.org/research

Register at: conference2012@who-umc.org



Reporting statistics – importance of quality

Helena Wilmar and Lovisa Sällstedt

The WHO Global Individual Case Safety Report (ICSR) database, VigiBase, is the source of worldwide post-marketing case safety reports. More than 100 countries are currently contributing to the database by submitting ICSRs collected at their national pharmacovigilance centres (NCs). VigiBase data is accessible to all NCs participating in the WHO Programme for International Drug Monitoring and periodic analysis of VigiBase data is performed, in accordance with UMC's current routine signal detection process, to find previously unrecognized adverse drug reactions (ADRs) and other patient safety issues.

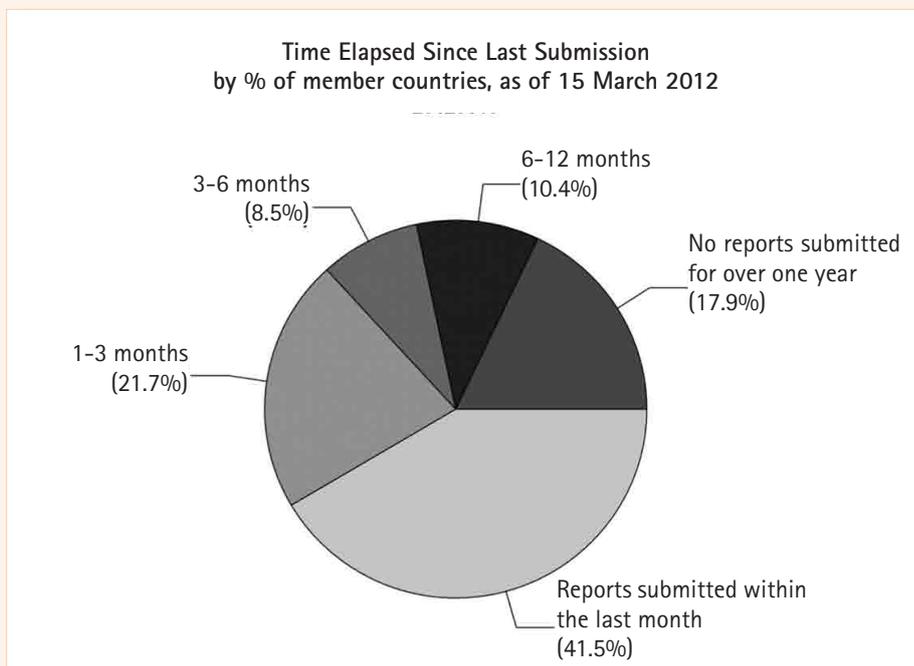
Following the passing of the 7 million landmark in January (UR56 p4), we have some time before the next one million reports are reached, so we are focussing this quarter's article on quality.

ICSRs constitute a key resource for the early identification of patient safety issues in relation to medicines. The quality of data in ICSR databases is crucial; the consequence of poor quality data is the risk of drawing wrong or delayed conclusions about a patient or a safety signal, which in turn could lead to patients being harmed unnecessarily.

Quality of VigiBase

UMC is constantly working on improving the quality of VigiBase, both when it comes to input of data and to output of data. A fundamental requirement for the quality of an ICSR database is that the data is up to date. As underreporting is a major problem in post-marketing reporting systems, each report is valuable. Both frequency of reporting and the number of reports submitted to VigiBase are quantitative measures. Just as essential is the quality of the data submitted.

- To ascertain the availability of high quality data in VigiBase, members of the WHO Programme are expected to transmit complete ICSRs to UMC, in compliance with the World Health Assembly agreement for founding the WHO Programme.
- Members of the WHO Programme are expected to submit ICSRs to VigiBase at least every quarter and preferably more frequently than once a month.
- Members of the WHO Programme are expected to submit all post-marketing ICSRs to VigiBase, irrespective of their origin, source/reporter type, causality, or seriousness.



UMC is actively promoting the international ICSR standard exchange format; International Conference on Harmonization E2B (ICH E2B). This format includes all relevant data fields, which allows for a comprehensive medical analysis of the data. The ICSR management tool VigiFlow allows new countries entering the WHO Programme and countries with limited resources to use the ICH E2B format. This means that more countries have the prerequisites for managing and transmitting high quality ICSRs. UMC recently reintroduced a tool for indicating how complete the data is given on a report; the 'Documentation grading – completeness' score (see UR54, p14-15). This score is used to identify problems of missing data in reports received from NCs and aims to help countries improve their methods for collecting, managing and transmitting complete ICSRs.

Essential ICSR information

Certain minimum information is needed on a report to qualify as a valid ICSR and to be included in VigiBase. The required information includes administrative data, e.g. a case identification number, together with essential case information, e.g. at least one reaction/event and one drug.

In addition to the minimum information, further information is crucial for making a valid medical assessment of an ICSR. The consequence of missing information is the risk of an incorrect conclusion about a single patient or a potential drug problem, or that a

relationship between a drug and reaction/event cannot be confirmed. For instance, missing information on the time interval from start of drug to onset of reaction may prevent confirmation of any time relationship between drug and reaction/event and hinder causality assessment, especially if information on dechallenge and rechallenge is also missing.

In the area of patient information, lack of details on age and sex, medical history as well as indication for use of drug, may result in an incorrect conclusion about a patient; confounding factors should always be considered. Of course, precise and correct description of the medical product, including trade name, is of utmost importance for evaluation.

Data Quality versus Data Protection

UMC is subject to, and complies with the EU data protection law, and adheres to the guidance in ICH E2B for protecting patient and reporter confidentiality.

High quality data and completeness of information are critical factors for UMC's ability to live up to its core mission of assessing new patient safety issues on behalf of the WHO Programme. All ICSR information has its purpose, either administratively or medically. With the exception of confidential patient and reporter details, preferably no information should be left out if available on the original report.

- UMC does not make free-text information from medical history and case narrative available to third parties. Instead, the national pharmacovigilance centre from which the information originated is referred to when that information is requested.
- UMC only publishes anonymised data in Signal and other scientific publications.

ICSRs and VigiBase - the vital importance of quality

The above information is an extract from the new-published document 'ICSRs and VigiBase - the vital importance of quality', recently added to the UMC website. The document emphasizes the significance of good quality data in VigiBase, by describing the scientific value of complete information from mainly a medical analysis perspective. The full document is available for download in pdf form at the UMC website: [Pharmacovigilance > WHO Programme > VigiBase](#)

Reporting statistics

Submission frequency

At the time of going to press for Uppsala Reports there were 7,160,190 reports in VigiBase. However, 30 out of 106 current member countries of the WHO Programme had not submitted any reports for over six months (see graphic, p6). UMC has noticed that regrettably some countries join as official members of the WHO Programme after initially submitting the required 20 cases, but after that there is no regular ICSR reporting to VigiBase. In addition, looking at the overall ICSR submission frequency a striking proportion of member countries have not submitted any reports for more than one year.

An overall goal for the UMC is to enhance countries' involvement in the WHO Programme; we greatly welcome input from member countries on how UMC can reach this goal.

India

In recent months reports have started to flow into VigiBase from India, from under 100 a year to 20,000 at the time of writing. This is partly due to the adoption of VigiFlow by the Indian national centre, which allows also for better quality of reports. This is an important development, as this large population has much to contribute to our knowledge of patient safety. (See also page 14).

ASEAN

Two Association of Southeast Asian Nations (ASEAN) countries recently switched from the old WHO-format (INTDIS) to VigiFlow: the Philippines and most recently Viet Nam. The Food and Drug Administration in the Philippines have used VigiFlow as their ICSR management system since early 2011. The National Centre of Drug Information & Adverse Drug Reactions in Viet Nam switched to VigiFlow in early 2012, and are currently training their staff to use the system. In Viet Nam there is also, so far, one regional centre connected to VigiFlow in addition to the national centre.

AEFI Causality Assessment workshop in Nanjing

Jerry Labadie

In the second part of the road map for strengthening the National Regulatory Authority (NRA) in China, the World Health Organization (WHO) committed to provide technical support to strengthen post-marketing surveillance of vaccines. As one of the agreed activities, a workshop for monitoring adverse events following immunization (AEFIs) and causality assessment was scheduled from 27 February to 1 March 2012 in Nanjing, capital of Jiangsu Province.

This workshop brought together four international experts to facilitate and 25 participants from the Ministry of Health, China Center for Disease Control and Prevention (CDC), The State Food and Drug Administration (SFDA), Chinese Medical Association and provincial CDCs and FDAs from all over China.

This workshop depends heavily on participation and input by the participants in order to achieve the objectives, which



One of the working groups trying to assess an exercise AEFI case

include being able to: ensure consistent case investigation and causality assessment practices, analyze AEFI data and report on them, use this data for improving the safety of vaccines, and communicate properly about vaccine safety.

The participants are expected to use the acquired knowledge and experience to educate and train their colleagues and for this purpose all course materials have been translated into Chinese.



The Nanjing AEFI workshop

In the capital of Kiril

Cecilia Biriell, Jerry Labadie

As the last in the UMC series of country visits in European member countries, we visited Bulgaria in March. For various reasons this visit had been postponed several times, so staff at the Bulgarian Drug Agency (BDA) and ourselves had been looking forward to this visit for a long time. We got to experience the great hospitality from the Bulgarian team already at the airport, where we were met by Julian Eutimov and a driver who took us to our hotel close to the Bulgarian Drug Agency. The next morning we were taken on foot to the Agency where we were met by Dr Maria Popova-Kiradjteva, Head of the Medicines Use Control department, and the staff of the Pharmacovigilance division. The Pharmacovigilance division has six staff members and is headed by Dr Kapka Kaneva. Cecilia presented current UMC activities, including the development of VigilLyze and the experiences using Documentation grading, showing how well ADR reports are filled in. Jerry explained UMC's signal analysis work and we discussed how analysis work at the Bulgarian centre may be improved.



Staff of the Bulgarian centre, from left: Anna Ivanova, Hristina Slavezkova, Ina Georgieva, Julian Eutimov, Petko Bankov, Maria Popova-Kiradjteva, Kapka Kaneva

Dr Kaneva presented the activities of the Bulgarian pharmacovigilance centre, which is governed by a law from 2007. Despite great efforts to increase ADR reporting, for example by lecturing to students at the faculties of pharmacy and medicine, reporting is still very low. We discussed how reporting can be improved, and Jerry Labadie referred to his experience working at Lareb, the pharmacovigilance centre in the Netherlands. Recently a reporting form for patient reporting has been introduced on the BDA website.

In the afternoon the two staff members Julian Eutimov and Petko Bankov were our excellent guides on a long walk through the city of Sofia, showing us all the main sites. Bulgaria has a long, varied, complicated and interesting history with liberations from many conquerors, and each liberation has a monument. The country was also home to Kiril (Kyrillos) and his brother Methodius, missionaries in Sofia in the 9th century, who created the Cyrillic alphabet, still used in many Slavic countries.



Kiril and Metodi outside the National Library.

The next morning we had a practical session on how the centre works with its ADR reports. As mentioned, reporting is low, and most reports come from industry, but each is thoroughly investigated and, for reference, searches in VigiBase are made regularly. We demonstrated how to make better use of the WHO database, in particular in using VigiMine. As Bulgaria is a member of EU, the centre will have to comply with the new European legislation for pharmacovigilance and we discussed how they can cope with this task.

Before heading back to Sweden we were taken to the Boyana Church in the outskirts of Sofia. The oldest parts of this church date back to the 11th century and it is on UNESCO's World Heritage list (mainly for its beautiful mural paintings). We wish to thank the staff of the Bulgarian centre for two intense and interesting days. We appreciated the open and frank exchanges and hope that this visit will facilitate cooperation in the future.

Sultanate of Oman revisited

Sten Olsson

Eleven years after my first visit to Oman I was again invited to speak at a pharmacovigilance workshop in the country in January 2012, this time organized by the University of Nizwa. The city of Nizwa is located about 1½ hour's drive west of the capital Muscat, on an excellent road through

a barren but spectacular landscape. Nizwa has an old history and was at one time the capital of the country; it has a fort well worth visiting.

The College of Pharmacy and Nursing of University of Nizwa had invited many international speakers for its pharmacovigilance workshop, including professor Saleh Bawazir from Saudi Food and Drug Administration and Syed Rizwanuddin Ahmad from Georgetown University and US-FDA. The African perspective was provided by Professor Ibrahim Oreagba, University of Lagos, Nigeria, and Professor David Woods from Dunedin, New Zealand gave many examples of risk situations and avoidable adverse reactions which occur in pharmacy practice. The perspective of the Ministry of Health of Oman was given by Dr Shirly Samson Varughese. My own presentation focused on education and training opportunities offered by WHO and its WHO Collaborating Centres. During one panel session and two parallel workshops many questions coming from the audience were discussed by the faculty members.



(from left) Mohamed Bin Shahna, Mohammed Hamdan Al Rubaie, Sten Olsson, Shirly Samson Varughese and Madiha Juma Almaskari

Prior to the Nizwa meeting I had the opportunity to visit the national pharmacovigilance centre at the Directorate General of Pharmaceutical Affairs of Ministry of Health. Discussions were primarily held with the technical experts in pharmacovigilance Madhia Almaskari and Shirly Samson Varughese. Oman was the first country from the Middle East to join the WHO programme in 1995. Reporting increased after a pharmacovigilance conference was held in 2001 and has further increased the last few years despite the fact that reporters are not given any personal acknowledgement or feed-back. An information bulletin from the Directorate is widely distributed however. There is an interest in expanding

pharmacovigilance activities into new domains such as medication errors but resources remain scarce. Substandard and counterfeit medicines are not considered a threat to public health in the country, partly because of good working relations with the customs. The pharmacovigilance centre is not directly involved in the collection of adverse events following immunization. New regulations are being considered that would make marketing authorization holders more directly involved in patient safety activities including prevention. After the discussion with the pharmacovigilance staff I also had the opportunity to discuss future opportunities for pharmacovigilance with the acting director of the Directorate, Mohammed Hamdan Al Rubaie and with Mohamed Bin Shahna, pharmaceutical advisor at the WHO Office for Eastern Mediterranean Region.

Thai briefing

Antonio Mastroianni

During the National Centres' meeting in Dubrovnik, I met many new friends and colleagues from across the world. While talking with Wimon Suwankesawong of Thai FDA I mentioned that I would be in Thailand over Christmas on a family vacation (to truly be Swedish I had to visit Thailand at least once). Wimon thoughtfully invited me to come to the Thai FDA and see how they support pharmacovigilance.

Wimon, her staff and her manager, Somchai Preechathaveekid, Director – Technical and Policy Administration Division, FDA, Ministry of Public Health met with me to discuss a variety of subjects important to the Thai FDA and how to collaborate further with the UMC. Her staff introduced the Health Product Vigilance Center (HPVC), from its inception in 1983 to the present. This was an instructive view of a national centre and highlighted the challenges centres face as they expand regionally, increasing coverage of activities and products, and move from hospital-based to community-based reporting. We discussed the current work of

the HPVC, including how the Thai FDA supports and encourages spontaneous reporting, performs cohort event monitoring and signal detection, and finally how the Thai FDA converts pharmacovigilance into regulatory action. We concluded with discussions around efforts in Thailand and across Asia to support the ICH-E2B standard, which will enable electronic transmission of patient safety data and ways in which the UMC might support Thailand in this effort.

The meeting was informative and provided new insights in how the UMC can better support countries in Asia and across the world. The generosity and kindness of Wimon and her staff in giving much time and energy to make a productive meeting also allowed me to learn more about Thailand and Thai culture.

FDA exchanges

Antonio Mastroianni

In January of this year Marie Lindquist, Antonio Mastroianni and Ola Strandberg were hosted by Gerald Dal Pan, Acting Director – Office of Pharmacovigilance and Epidemiology for a day's study visit to the Center for Drug Evaluation and Research (CDER at FDA) in Rockville, Maryland. This visit was an opportunity for the UMC and FDA to discuss joint efforts and learn more about key activities in both organizations that support patient safety.

Data strategies

It was a full day of exchanges that began with an examination of how the FDA collects data and manages the data entry process for adverse event reporting. This consisted of a behind-the-scenes look at how the AERS database is managed and provided valuable insight on data collection and mapping activities. After discussions on AERS there was a chance to meet with Gerald and his senior staff to discuss strategies on how the FDA can better utilize the advantages of the WHO Drug Dictionary when mapping terms in adverse event reporting.

Presenting the UMC

After lunch, to an audience of over 50 key staff members from both the CDER and the Center for Biologics Evaluation and Epidemiology (CBER), Marie Lindquist gave a presentation on the history of the UMC and our continuing mission to improve patient safety by reducing the risk of medicines. After the well received presentation the UMC delegation met with Director Dr Robert Ball, Director and Division Director Dr David Martin, from the Office of Biostatistics and Epidemiology to discuss current efforts to



Ola Strandberg, Antonio Mastroianni, Gerald Dal Pan, Janet Woodcock, Marie Lindquist at the CDER offices

improve vaccine safety, and the CBER course, 'Application of Pharmacovigilance to U.S. FDA Regulatory Decisions for Vaccines', which is being held in Uppsala this June.

Further collaboration

Following the meetings with CBER, the UMC delegation met the Division of Pharmacovigilance to look at data mining strategies and signal detection and how the UMC and FDA can collaborate further in both areas. Then the UMC delegation met with Ilisa Bernstein, Director – Office of Compliance and senior staff from the Office of International Programs to discuss WHO-FDA collaboration opportunities toward global monitoring and surveillance for substandard, spurious, falsified, falsely-labelled, and counterfeit drugs, which led to a lively discussion on how to combat this growing threat to patient safety and a critical effort to secure safe and effective medicines.

The day concluded with a meeting with Dr Janet Woodcock, Center Director for CDER to wrap up an exciting and informative day, and to lay the groundwork for future successful collaborations.

UMC around the USA

UMC staff used their time in the USA to visit other UMC partners. In Los Angeles Ola Strandberg and Mikael Nilsson gave a live demonstration of UMC's Hosted Services and the Cross Reference Tool (CRT). Mikael also had an informal meeting with one major customer to learn at first hand how they are using the WHO Drug Dictionaries.

Mikael and Ola then met up with Annika Wallström, Antonio and Marie in Arlington, Virginia to attend the DIA Pharmacovigilance and Risk Management Strategies Conference.



Somchai Preechathaveekid, Antonio Mastroianni, Wimon Suwankesawong with Thai FDA staff

Monitoring Medicines final General Assembly

Ennita Nilsson

Monitoring Medicines project gathered at Lareb pharmacovigilance centre in the Netherlands from 5-6 March 2012 for its third General Assembly. Kees van Grootheest, Director of Lareb, welcomed everyone both to the consortium meeting, and also the training workshop on patient reporting soon after the meeting (see full report below). Sten Olsson, the Project Coordinator highlighted that Lareb was the ideal host for such training due to its leading work in patient/consumer reporting.



Monitoring Medicines representatives during their General Assembly in the Netherlands

The General Assembly discussed the progress made so far and reviewed the work programme for the final months of the project. The partners had a chance to express their views on past work and pointed out areas for improvement. Key work package leaders gave a detailed update from their area. Elliot Brown

demonstrated an additional terminology tool that he had developed as part of the web-based patient reporting tool. Partners decided to field test the enhanced feature before making it part of the new tool. All work package updates showed significant results and demonstrated that the project is right on track.

Major remaining activities

Uganda has begun implementing the programme to monitor patients on antiretroviral therapy using the targeted spontaneous reporting method. In the coming months the project management team will visit the programme sites. Results will be shared, and the hope is to pilot the method in other countries outside the project.

Kenya will initiate Cohort Event Monitoring (CEM), aimed at identifying safety problems patients faced with the recently-introduced artemisinin combination therapy for malaria. Either Belarus or Ukraine will pilot CEM of anti-retrovirals in their country. External assessors are reviewing their proposals and the result will be communicated in the next month.

The Moroccan pharmacovigilance centre and the UK national patient safety organization, with WHO and UMC, are developing information guidelines on how to enhance medication errors detection within pharmacovigilance. The work will be presented at the next Advisory Committee on Safety of Medicinal Products (ACSoMP) and then shared with the ten countries who

participated at the initial training in Morocco in 2011 for further comments before wider dissemination.

Copenhagen HIV Programme (CHIP) has developed a website that currently summarises side effects on HIV treatment. The website links to videos, publications, e-learning and other tools. In the remaining months of the project, the team will work with a patient management tool that binds the tools together. This displays changes in risk over time, linked to literature, training material and guidelines. The site is linked from the Pharmacovigilance Toolkit: <http://www.hivpv.org/>.

Dissemination and promotion

European Commission rules set out how to handle 'foreground' material – documents and publications generated through the project. All members have ownership of the material and are required to share the results to a wider audience. The consortium discussed various ways to promote and disseminate the results from the project in order to empower patients and improve patient safety. The coming months will be spent writing journal papers, publications, sharing results at international meetings, such as the World Health Assembly, the WHO Programme annual meeting in Brazil and the International Aids Conference. The consortium also proposed to have a communication symposium in either Geneva or Brussels early in 2013, in order to influence policies and encourage patient safety concerning medicinal products use.

Workshop on direct patient reporting

Monica Plöen

The Monitoring Medicines consortium organized a workshop in the Netherlands from 7th-9th March to discuss direct patient reporting. It was hosted by the Lareb pharmacovigilance centre and held in conjunction with the General Assembly of Monitoring Medicines. The workshop was attended by 30 representatives of national regulatory agencies and consumer/patient organizations from around Europe. All participants, from 10 European countries and Morocco contributed actively in group work and discussions.

Development Process

Commissioned by the Monitoring Medicines project, the UMC product management team spent six months prior to the workshop developing a web-based reporting tool

intended for the general public. The software design was made in close collaboration with representatives of national medicines agencies and patient and consumer organizations. The web-based tool was developed by this user-group through several tele-conferences and site testing. The system was built in a way that any country accepting ICSR data in E2B format can use it. Language, style sheets and logos can be adapted to meet local needs. The tool is directly compatible with UMC's general ICSR data management system VigiFlow.

The UMC team enjoyed working closely with the potential end users in the development process. Their needs, ideas and suggestions were very valuable and taken into account in the design of the end product.

Growing significance

Welcoming participants, Lareb Director Kees van Grootheest referred to the special attention his organisation has given to the reporting of medicine related problems from the public. Major efforts have been made to scientifically assess the contribution to the knowledge of ADRs made by patient reporting, as demonstrated by the recent PhD thesis on the subject by Florence van Hunsel. Sten Olsson, Monitoring Medicines project coordinator, mentioned that WHO had been requested to develop a patient reporting guideline at the national centres' meeting in 2008. Through the Monitoring Medicines project it had become feasible to develop both a guidance document and a web-based reporting system.

Shanthy Pal, WHO and Linda Härmark, Lareb introduced a new WHO guidance document on 'Reporting system for the general public'. The guideline describes how to analyse spontaneous reports on medicine-related problems from the public, how to provide feedback, legislation, how to promote patient reporting and how to handle negative attitudes. The day ended with working groups discussing implementation of direct patient reporting.



Keen to move forward on patient reporting – the group in Amsterdam

Launching patient reporting

The next day focused mainly on the tool for public reporting developed by the UMC and the user representatives mentioned above. Information about the general structure of the system and the parts that are available for national adaptation was presented by Magnus Wallberg, UMC. It can be used only in collaboration with a national pharmacovigilance centre. Countries (national pharmacovigilance centres) wishing to use this system, need to contact UMC to discuss the set-up. The information created will be transferred to the respective national centre for analysis and possible feedback to the patient. Information will be made available outside the national pharmacovigilance centre only when it so decides.

The participants got the task of entering cases in the system and were asked for their views on its functionality and user-friendliness. A discussion led by Monica Plöen, UMC, around feedback to be given to the reporter generated a lot of comments. As a minimum, the reporter needs to know what will happen once the report is submitted. Some national centres do not have the manpower to contact all reporters individually. In this case it is important to let the patient know how (s)he can find out more and where to turn with questions. Meeting expectations from patient and consumers is critical.

Pia Caduff-Janosa, Swissmedic, discussed issues regarding analysis of the individual

case safety reports and Linda Härmark also contributed to the session on signal detection.

The third day looked at the consequences of the new European pharmacovigilance legislation. Other topics were how to promote patient reporting globally, and how to handle negative attitudes to patient reporting. It was agreed that scientific evidence is now available and continues to grow. This shows the positive contribution of reporting from consumers and patients to early signal identification and understanding of important

aspects of drug related harm, not necessarily identified by health professionals.

Next step

Some final adjustments will be made to the public reporting system as a result of feedback received from the workshop. From May 2012, UMC will pilot the system with four to five countries during the rest of 2012. The system is currently available only in English. Piloting countries will need to translate labels, help texts etc. and write the necessary country specific caveats themselves. For further information about the patient reporting system developed by UMC, please contact monica.ploen@who-umc.org

New WHO handbook on direct patient reporting

Sten Olsson

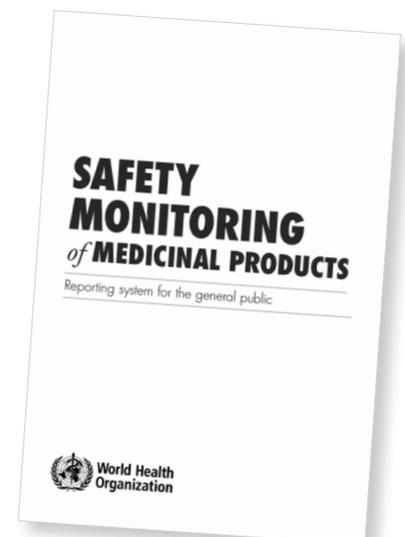
A new guidance document on reporting systems for the general public is now available from WHO.

In an increasing number of countries consumers are being encouraged to report adverse reactions to medicines to a spontaneous reporting system, and organizations such as WHO and the European Commission acknowledge the role of the consumer in spontaneous reporting.

At the meeting of representatives of national centres in Uppsala 2008, WHO was requested to develop a handbook on how to establish a reporting system for medicine related problems for the general public. The implementation of the task became feasible by introducing it as one of the objectives of the Monitoring Medicines project funded by the Seventh Framework Programme of the

European Commission. Anne Kiuru, Medical Products Agency, Sweden and Linda Härmark, Netherlands Pharmacovigilance Centre, Lareb, kindly assisted in writing the original manuscript. It was later reviewed by members of the WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) and selected national experts.

A copy of Safety Monitoring of Medicinal Products – Reporting system for the general public will be sent free of charge to national centres participating in the WHO Programme. The 26-page handbook can also be requested from Shanthy Pal, at WHO-HQ (pals@who.int) or from the UMC (info@who-umc.org), or downloaded in pdf format from WHO's website: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/EMP_ConsumerReporting_web_v2.pdf



Pharmacovigilance of Traditional Chinese Medicine drugs

Ronald Meyboom

Traditional Chinese Medicine (TCM) is widely practiced and has played an important role in health protection and disease control in China, and increasingly worldwide. Recently Dr Li Zhang from China and colleagues have presented the first article on pharmacovigilance of TCM drugs.

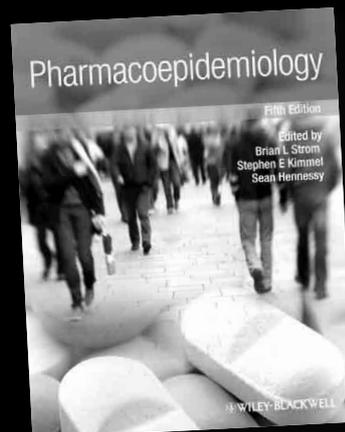
The authors propose that pharmacovigilance should be introduced into the safety monitoring and evaluation of TCM drugs; emphasize the importance of life-long safety monitoring of the TCM drugs – from good practice in the production through the entire treatment, which includes proper TCM diagnosis, therapy choice, follow-up and adjustment of treatment. In accordance with the characteristics of TCM drugs, examples of issues of particular concern in TCM pharmacovigilance are:

- Some of the raw materials of the TCM drugs (Chinese Materia medica) with the same generic Chinese name may implicate different plants or ingredients of different origins.
- Some of the TCM drugs may have been inappropriately processed, produced or stored, and thus may contain an undesired level of ingredients, heavy metals, or might be contaminated.
- Inaccurate TCM diagnosis or administration of a wrong medicine may complicate the condition of the patient and result in unexpected or unintended responses.
- Particular TCM ingredients may elicit characteristic reactions, for instance hypersensitivity to antigenic natural constituents.
- Incorrect combinations with chemical medicine, incorrect route of administration, dosing and timing.

The article will be published in the forthcoming issue of the *Journal of Ethnopharmacology*.

Zhang L, Yan J, Liu X, Ye Z, Yang X, Meyboom R, Chan K, Shaw D, Duez P.

Pharmacovigilance practice and risk control of Traditional Chinese Medicine drugs: Current status and future perspective. *J. Ethnopharmacol.* (2012), doi:10.1016/j.jep.2012.01.058, Epub ahead of print.



La Aldea Mágica

by Karina Hernández Mercado

A new book has reached the UMC called *La Aldea Mágica* the thesis work of Karina Hernández Mercado from Mexico. It is a story book with colourful pictures, like many children's books you can find in any bookshop. But it tells, in a very imaginative way, how adverse reactions are and teaches about pharmacovigilance. It is a magic pill. One day the pill goes wrong and the beach becomes a forest, the forest turns dry and the ice starts to melt. Three children contact Mr Farmacon-vigil-lancia to come to the village.

We won't give the end away, but look forward to a full print version. A creative and original way to introduce drug safety to you.



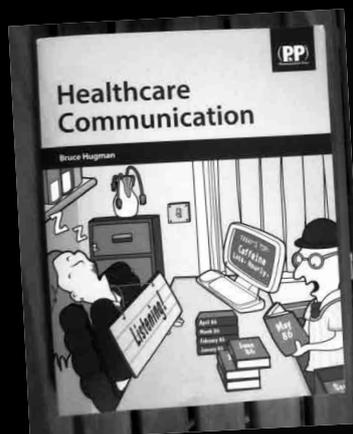
Atravessando fronteiras Talidomida,

by Rosângela Nascimento

The book, in Portuguese, is by Rosângela Nascimento and the publisher is TVB-N - Brazilian Association of Pharmacies.

We welcomed Rosângela Nascimento (see UR9) and we are proud to have her record.

160 pages ISBN: 978-85-7301-100-0



Healthcare Communication

First published in April 2009, UMC consultant Bruce Hugman's interactive and engaging guide to healthcare communication is now available both in a digital version: For individual, private or public libraries: <http://www.ebooks.com/444177/healthcare-communication-hugman-bruce/> or for public and academic libraries: [mylibrary.com/](http://www.mylibrary.com/) and in its hard copy book form, available from www.pharmpress.com and internet book retailers round the world.

It explores establishing professional, practical and positive relationships to support therapy and enhance patient health and morale. It will be of interest to everyone working in healthcare, especially doctors, nurses and pharmacists in training and will have relevance to all roles, medical and non-medical.

Epidemiology

Pharmacoeconomics, edited by Brian L Strom, and Sean Hennessy, has recently been published by Wiley (1: 978-1-1199-5992-2).

As this reference book continues its path with new pages and chapters on every aspect of the subject, the Lindquist contributes to the chapter on Spontaneous Pharmacovigilance Reporting Systems, and Kate Gelperin.

...ca – part of Mexico. It's a book you'd want to read, what a vigilance... a controlled by a comes cold, children need to and help...

...nting of this ng people.

Do Fronteiras: a impunidade continua

...ento
...ese, tells the story of the life of Rosângela, a fight for victims of thalidomide, as president of Association of Victims of Thalidomide.

...gela Nascimento to the UMC in February 1999 and delighted that she has put her experiences on

...85-99361-21-4

...e Hugman's ation is now purchasers: **Communication/** <http://www.> from: <http://> the world.

...rewarding health, safety healthcare, and in practice dical.

Recent publications from the UMC

Caster O, Edwards IR, Norén GN, Lindquist M. Earlier discovery of pregabalin's dependence potential might have been possible. *Eur J Clin Pharmacol.* 2011;67(3):319-20.

Bakare N, Edwards IR, Stergachis A, Pal S, Holmes CB, Lindquist M, et al. Global Pharmacovigilance for Antiretroviral Drugs: Overcoming Contrasting Priorities. *PLoS [Public Library of Science] Med* 8(7): e1001054. doi:10.1371/journal.pmed.1001054.

With increasing numbers of people worldwide on antiretroviral drugs, the need for improved and sustained global drug safety monitoring or pharmacovigilance is critical. Important but contrasting priorities and values among stakeholders — all of whom are dedicated to establishing global pharmacovigilance — were identified as barriers to progress. Recognition, understanding, and respect for these contrasts is a way of increasing collaboration and cooperation, to lead to a sustainable system involving all stakeholders including industry and experienced regulatory agencies.

Edwards IR. Conflicts of interest in medicines safety and regulation: how much conflict and how much interest should we allow? *Drug Safety.* 2011;34(8):617-21. Epub 2011/07/15.

An editorial examining situations in which conflicts of interest might affect pharmacovigilance.

Bahri P, Mol PG, Theophile H, Edwards IR, Hugman BR. Communication in drug safety: a report from an interactive debate held at the 10th annual meeting of the International Society of Pharmacovigilance (ISoP), 2010. *Drug Safety.* 2011;34(10):881-2. Epub 2011/09/02.

Isah AO, Pal SN, Olsson S, Dodoo A, Soulayami Bencheikh R. Specific features of medicines safety and pharmacovigilance in Africa. *Therapeutic Advances in Drug Safety.* 2012, 3: 25 (originally published online 17 October 2011).

Mass deployment of medicines in Africa poses additional challenges to the health system with notable safety concerns. Safety issues include substandard and counterfeit medicines, medication errors and quality of medicinal products. The pharmacovigilance systems operational in African countries are based essentially on spontaneous reporting facilitated by the introduction of the new tool VigiFlow. The individual case safety reports committed to the WHO global database (VigiBase) in Africa have grown from 2,695 in 2000 to over 25,000 in 2010.

Edwards IR. Prevention and pharmacovigilance: what should we do, what can we do? *Drug Safety.* 2012;35(2):87-90. Epub 2012/01/17.

The article discusses issues raised in four papers presented at the ISoP meeting in Istanbul, 2011.

Hopstadius J, Norén N, editors. Robust Discovery of Local Patterns: subsets and stratification in adverse drug reaction surveillance. Proceedings of the 2nd ACM SIGHIT Symposium on International health informatics 2012; Miami, Florida US; 265-274.

Labadie J. Vaccine safety. *Int J Risk Saf Med.* 2011;23(2):113-5. Epub 2011/06/16.

This paper looks at Swissmedic's experiences with PaniFlow (the UMC tool to monitor Adverse Events Following Immunization (AEFI) of pandemic influenza (H1N1) vaccines; WHO's Global Network for Post-marketing Surveillance of Prequalified Vaccines) with India joining the network; and the June 2010 meeting of the Global Advisory Committee on Vaccine Safety.

van Hunsel F, Härmark L, Pal S, Olsson S, van Grootheest K. Experiences with adverse drug reaction reporting by patients: an 11-country survey. *Drug Safety.* 2012;35(1):45-60. Epub 2011/12/14.

Willemen MJ, Mantel-Teeuwisse AK, Straus SM, Meyboom RH, Egberts TC, Leufkens H. Use of Dipeptidyl Peptidase-4 Inhibitors and the Reporting of Infections: A Disproportionality Analysis in the World Health Organization VigiBase. *Diabetes Care.* 2011;34(2):369-74.

The paper describes a nested case-control study using VigiBase, to identify suspected ADRs involving antidiabetic drugs. Reporting of infections was higher for patients using DPP-4 inhibitors compared with users of biguanides, and the authors call for further research to evaluate this suspicion and the underlying mechanism.

Hakkarainen KM, Olsson S, Hägg S. The scale and nature of adverse events in hospital – Is an event drug-related? <http://www.bmj.com/content/344/bmj.e832/rr/575178>. Rapid response to Wilson RM et al. Patient safety in developing countries: retrospective estimation of scale and nature of harm to patients in hospital. *BMJ* 2012; 344 doi: 10.1136/bmj.e832 (Published 13 March 2012)

A rapid response to an article published in the *BMJ*. Katja Hakkarainen, of the Nordic School of Public Health in Gothenburg, Sten Olsson (UMC) and Staffan Hägg discusses the low figures given in the results of the Wilson article for medicine-related events.

Olsson S. The right prescription. *Public Service Review: European Union* (issue 23), 28 March 2012. Online: http://www.publicservice.co.uk/pub_contents.asp?id=556&publication=European Union

Communicating safety issues – the Croatian experience

Jasminka Tadin, Viola Macolić Šarinić

Communicating safety issues with the public, including media representatives and healthcare professionals and patients, is generally very sensitive and risky. We in the Croatian Agency for Medicinal Products and Medical Devices (HALMED) nurture close cooperation between the Public Relations Office (trained journalists) and the Pharmacovigilance Department (doctors and pharmacists) because we believe our joint work and investment of joint efforts in this area bring the best results.

Informative and easy website

The basic premise for high-quality public relations is an informative and easy-to-read website. A few years ago HALMED invested in a complete redesign and development of a new website and we have been working since on its continuous improvement. The goal was an intuitive, user-friendly site which would be simple and easy-to-read, but also as rich as possible in content. On the home page, included in the header itself, are links for sending enquiries and subscribing to the HALMED newsletter, Rapid Alert System contact details for adverse drug reactions and quality defects of medicinal products and medical devices, and five main headings one of which is Pharmacovigilance.

Immediately underneath the homepage's banner is a large field entitled 'For Patients' linking to a database of all approved medicines in Croatia, containing detailed information about the medicines and the SPCs and PILs for each, as well as an invitation to report any adverse drug reactions, instructions and forms for making the report, and information on public education campaigns in which HALMED participates. New safety information, 'Dear Healthcare Professional' letters, workshops and events and other news is published on the homepage. The homepage also has links to annual reports on spontaneous reporting of ADRs and on drug consumption.

Proactivity

HALMED has a proactive approach to public relations. We do not just wait to be asked; we take it upon ourselves to provide news, announcements, informational and educational articles, adverts and similar content. If necessary we seek corrections and send official denials. One of the first daily tasks of HALMED's PR office is to review press cuttings and the electronic media concerning activities within HALMED's scope. If we think certain information needs to be added to, better explained or corrected, we react immediately and contact editors with our proposals. In cases where our announcements or statements are incorrectly

presented or interpreted, we seek a correction. In this way, the correct and truthful informing of the public and prevention of rumours and disinformation which could have an adverse effect on public health is ensured, and at the same time we help to enhance HALMED's reputation.

Speed

Speed is a crucial element in communication with the media and public. Therefore HALMED's priorities are to ensure fast exchange of information, fast replies to questions from journalists and the patients and fast publication of information on our website. We sought an appropriate IT solution to make changes to our website easier and faster. Members of our PR Office and Pharmacovigilance Department administration have access to our website interface so they can add new content and activate its publication directly without any delay or going through the IT department. In this way we can publish new safety information and announcements as well as Dear Doctor letters as soon as we learn about them.

We respond to journalists' questions immediately; we inform them that we have received their questions and tell them when they can expect an answer. We always try to reply to journalists within a few hours so they can prepare their article for the next edition or include a statement in the next news broadcast. What is a current topic for the media today may not be tomorrow, so we try not to miss an opportunity to present our opinion. We believe that failing to respond to journalists is never a solution because they will seek answers to their questions elsewhere, making the quality of the information they receive questionable. By providing answers, even to uncomfortable questions, HALMED is actively participating in creating public opinion and in informing and educating the public.

As a rule, we try to reply to questions from the patients and healthcare workers within 24 hours. By providing information quickly not only do we solve their current problem and reply to a specific situation but also build a long-term stable and positive relationship in which the public can gain and maintain confidence in our institution and its employees.



Viola Macolić Šarinić and Jasminka Tadin

Priority for patients too

We treat all patients who contact us in the same way as journalists with 'breaking' news. We provide an answer as good as possible in the shortest time. In the context of the development of so-called 'citizen journalism' via the Internet and digital technology, it is necessary to consider every member of the public a potential editor and publisher, because they can be within a few minutes (which is all it takes to start a blog). Answers sent by HALMED to patients have appeared on their blogs, although when we replied we did not know they had a blog and that our response might be published there. Fortunately, as we give every answer our maximum attention, these comments are very positive. These patients praise us on their blogs and cite us as an example of a state institution which does its work well.



When we conducted a Google search on a member of the HALMED PR Office who had given numerous statements to the media and written many responses to journalists as well as announcements, the first result was an individual's blog. This person quoted the entire response received from HALMED and commented: "Many of us complain that we live in a country which does not care about its citizens. This story is proof this is not always the case. We do have responsible people in our institutions who can set things in motion." HALMED is very proud of such a positive public image and believe this to be evidence that we are 'on the right track'.

As an additional incentive to invest in PR and to cooperate with their PR colleagues, we would like to remind all those wishing to follow our example in developing communication and public relations of the words of Bill Gates: "If I was down to my last dollar, I'd spend it on public relations."

West Africans explore communications skills

Sharon Ako-Adounvo



The communications course participants during a break in Accra.

February saw participants from eleven West African countries making their way to Ghana for a West Africa Health Organisation (WAHO)-sponsored communications skills course run by the UMC-Africa team and UMC's communications specialist, Bruce Hugman.

With more than half the group from Francophone countries, for the first time in a course of this kind, simultaneous interpretation was provided. Language differences, however, did not inhibit lively discussion and a very sociable atmosphere in the comfortable ocean-side La Palm Royal Beach Hotel, which was also the venue for ISO in 2010.

Through an interactive teaching style, multiple communication topics were covered, including: principles of effective communication; managing meetings; risk communication, crisis management and communication with patients. Working groups were tasked with presenting innovative communication projects; ambitious and entertaining modes of healthcare communication were developed. Highlights of the teaching sessions were the video clips from a

variety of sources which kept participants stimulated, interested and drew attention to the fact that humour can play a valuable role in presenting vital healthcare information.

Stimulating ADR reporting

In the session on developing an ADR reporting culture, participants discussed developing smart phone applications for reporting, relationship-building with health professionals, and the use of focal/local persons to act as champions, amongst others, as ways of encouraging ADR reporting. It was unanimously agreed that ultimately ADR reporting methodologies have to be created that shift the burden of reporting

from busy health professionals to other support staff or the pharmacovigilance centre.

Implementation plans

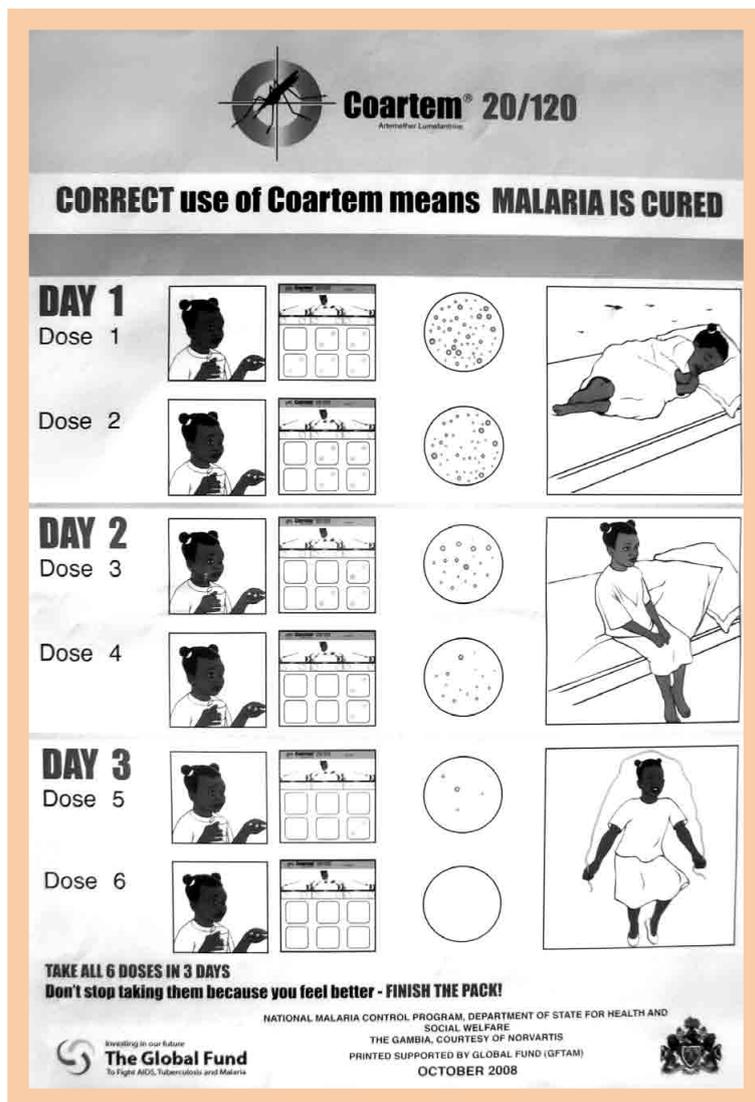
A lively discussion took place to ascertain what participants planned to implement on their return home. Crisis management planning stood out as a key area that needed to be developed. Participants also envisaged how forming stronger alliances with the media could benefit key audiences and stakeholders in pharmacovigilance. Other areas mentioned included: improving patient communication using a more empathetic approach and conducting more effective meetings. (A quick poll again indicated just how many, sometimes seemingly fruitless, hours, participants spent every week in meetings.)

Sharing Information

Mr Easa Marenah from the Gambia showed a number of excellent campaign posters for HIV and Malaria illustrating how to translate and present complex health messages in simple ways. These aroused enormous interest and prompted a call for greater resource and information sharing among West African countries. The UMC-A team has now taken on the challenge to develop an internet repository for African countries for sharing of communication information such as newsletters, ADR form designs and other communication aids. (More information will be available on this at - www.pvafrica.org)

Spreading the word

Following this event, Bruce and the team also provided a two-day course covering similar issues, for senior officials and academics from Government departments and universities. This programme also included discussion of the creation of an open and dynamic organisational culture, and the skills of teaching and training.



Reaching the patients: Among impressive posters from the Gambia was this ambitious one explaining how to take antimalarials, and what effect they had day by day on the parasites and the patient. A fine example of making medicine intelligible to a popular audience, encouraging rational use through better understanding.

SALUS lift off in Istanbul

Tomas Bergvall

It is generally agreed that pre-approval clinical trials cannot guarantee that drugs will not have serious side effects after they are marketed. Although post-approval drug safety data studies aim to address this problem their effectiveness is being examined closely following recent examples of drug withdrawals. This is mainly because current post market safety studies largely depend on submission of spontaneous case reports, where under-reporting is a major problem. A more proactive approach is needed, where safety data from multiple sources are actively monitored, linked and analyzed. Effective integration and utilization of electronic health records (EHR) can help to improve post-market safety activities.

A new project, SALUS (after the Roman goddess of health and Latin for salvation) aims to automatically detect adverse drug events (or reactions) in EHR, highlighting the detected events to the treating physician and creating procedures for sending the reports to regulatory authorities. Another main objective is the development of methods to enable

exploratory signal detection in EHR data. The focus will be on exploratory analysis in EHR data based on signals found in VigiBase data to enhance the signal detection procedure with the data available in different EHR sources.

and Systems (OFFIS, Germany), Agfa (Belgium), Electronic Record Services (Netherlands), Lombardia Informatica (LISPA, Italy), the Institut National de la Santé et de la Recherche Médicale (INSERM, France), the Dresden Institute of Technology (Germany), and F. Hoffmann – La Roche (Switzerland).



The SALUS project team in Istanbul

The project partners are Software Research and Development and Consultancy Ltd (SRDC, Turkey), the European Institute for Health Records (EuroRec, France), the UMC (Sweden), the Oldenburg Research and Development Institute for Information Technology Tools

The outcome of the project will be an open source software tool which will be possible to implement on top of any EHR system with web services that communicate between the different parts of the system.

For more information regarding the project please visit <http://www.salusproject.eu>

The inaugural meeting, organized by SRDC, the project coordinators in Istanbul, had a bit of a rocky start, with all the meeting delegates being delayed 12 hours due to heavy snow in Istanbul. The project finally got off the ground anyway and was topped off by a visit to the Nar Lokanta restaurant for a great dinner and a showcase of old Turkish art.

Lareb Day of Side Effects

Helga van Boxtel

The Netherlands Pharmacovigilance Centre Lareb organizes an annual continuing education day for doctors and pharmacists whose main theme is adverse drug reactions, and focuses on a certain aspect of ADRs. The theme for 2011 was drug use during pregnancy, chosen because of the thalidomide catastrophe 50 years ago, but also because Lareb is now the reference centre in the Netherlands for drug use during pregnancy (previously carried out by the National Institute for Health and the environment). 300 people attended the event, including general practitioners, gynaecologists, paediatricians, midwives and pharmacists.

During the day Kees van Grootheest, director of Lareb, presented the Meyler prize 2011 (named after the Dutch Professor Leopold Meyler who published his book the Side

effects of Drugs in 1951). The prize is awarded to an undergraduate student who wrote the best thesis or publication about side effects of drugs. Cynthia Nijenhuis, of the University of Groningen, won for her research on the use of SSRIs during pregnancy and the effect it has on the development of the gastro-intestinal tract of the child. Her research will be published in the British Journal of Clinical Pharmacology.

Björn Håkansson, president of the Swedish Thalidomide Society, gave an interesting and moving presentation about how thalidomide affected his life. He talked about surveillance of drug use in pregnancy from the survivor's point of view. After this, drug use during pregnancy in patients with epilepsy and diabetes was presented and discussed, as well as drug use during lactation.



Kees van Grootheest and Björn Håkansson at the Lareb continuing education day

The Teratology Information Service, which recently became part of Lareb, also introduced its activities. Agnes Kant, head of the Teratology Information Service spoke about the role of the patient in pharmacovigilance.

Surveying VigiFlow from on high

Ulrika Rydberg



Rosemarie Sift-Carter, Nicola Dürig and Pia Caduff-Janosa, near the top of Gurten, the Swiss capital Bern in the background

The country with the largest number of ICSR reports in VigiFlow is Switzerland, which also has the highest number of VigiFlow users. The Swiss national pharmacovigilance centre at Swissmedic (Swiss agency for therapeutic products), is also driving the development of E2B transmissions using VigiFlow.

Therefore, I spent one week in Bern visiting Swissmedic. The aim was to learn more of how they use VigiFlow and together plan new functionality needed to automatically exchange E2B messages with Market Authorisation Holders via a gateway. Some of these changes will appear in VigiFlow by the end of April, others in the autumn release – countries using VigiFlow can find more

information regarding upcoming releases on the VigiFlow User Group site on the UMC Collaboration Portal.

During my visit to Bern, we also had time to share information regarding our work processes and for an extracurricular hike up the Bernese 'Hausberg', Gurten, with spectacular views of both Bern and the Swiss Alps. My hosts Pia Caduff-Janosa, Rosemarie Sift-Carter and Franziska Kolb among others, took great care of me during my visit and made my stay both memorable and productive. A well-spent week learning and sharing information regarding VigiFlow and how it is, and can be used.

Iraq update

Manal Mohammed Younus

Iraqi Pharmacovigilance Centre activities over the last two years have been extensive, with much support and dedication from the pharmacovigilance team and the advisory committee. Draft pharmacovigilance guidelines are now in their final review stage, a 3-day training package is finalized and ready for implementation, there has been an advocacy campaign among stakeholders, especially the medical professions in health directorates, and direct co-operation with the epidemiology programme in Iraq is in place.

The team at the centre has been strengthened by new specialist staff to expand the areas of activity coverage. Jaffer Kurmanji, a clinical pharmacist with an MSc degree, has been appointed to supervise research work at the centre. Maytham Hadi, a specialist in biotechnology and genetic engineering with an MSc degree is assigned as the case analyst of the centre. In addition, Firas Ali, an expert in pharmaceutical analysis from the National Centre for Drug Research and Quality Control has joined.

In February 2012 Amjad Aziz Mahmmud has been assigned as head of the centre while Dr Manal Younus undertakes a PhD in clinical pharmacy. Pharmacist Mahmmud was formerly head of the Pharmacy Department/MOH-Iraq and also head of the Need Estimation Department.

Serbia Conference

Branka Terzić

A very successful pharmacovigilance course was organized in December 2011 by the Clinical Pharmacology section of the Serbian Medical Society and the Medicines and Medical Devices Agency of Serbia (ALIMS).

About 120 physicians and pharmacists from all regions of Serbia attended. Cardiac toxicity, side effects of anti-seizure drugs, anti-hypertensives, antidepressants, oral anticoagulants, dual anti-platelet therapy and a new Rulebook on the method of reporting, collecting and monitoring adverse

reactions to medicines (Official Gazette of R, No. 64/2011) were included in the lectures, which also covered topics related to the WHO Programme for International Drug Monitoring. The number of reports on adverse drug reactions in Serbia has been increasing and it is hoped that with this course even more activity by Serbian health professionals will be encouraged.



Side effect of drugs in surgery - Dragana Maca Kastratovic

Can we use national centre meetings better?

Sten Olsson

I was very pleased to learn from Mira Harrison-Woolrych in New Zealand and Kees van Groothest from the Netherlands, that they recently had a joint scientific article published.¹ The publication was the result of a collaboration that started with a presentation by Mira in the 'Problems of Current Interest' session of the meeting of national centres in Accra, 2010. When I commended them on their initiative to join forces between national pharmacovigilance centres Kees replied that this has happened before, and referred me to another joint article that he had been involved in.² Learning about this collaboration between centres, two issues immediately came to mind:

- Are there other examples of collaborations between countries, initiated by contacts or information shared at national centres meetings that have resulted in new information being made available to the healthcare community?
- Can we do more to stimulate this kind of inter-country collaboration between meetings?

If you have ideas on how we may organize the WHO Programme meetings to better capitalize on the fact that we have our huge concentration of pharmacovigilance expertise present in one part of the world for a few days, please let us know.

For WHO and UMC organizers, tangible results – as exemplified above – are very important to demonstrate the relevance of the annual national centres events.

Staff at medicines agencies can help us by sending us more examples of practically useful information these meetings have generated. Such a list of results will clearly reinforce the importance of both organizing and attending the annual national centres meeting.

1. Harrison-Woolrych M, Härmark L, Tan M, Maggo S, van Groothest K. Epistaxis and other haemorrhagic events associated with the smoking cessation medicine varenicline: a case series from two national pharmacovigilance centres. *Eur J Clin Pharmacol*. 2012, Feb 8.
2. van Groothest K, Sachs B, Harrison-Woolrych M, Caduff-Janosa P, van Puijenbroek E. Uterine Perforation with Levonorgestrel Releasing Intrauterine Device. Analysis of Reports from Four National Pharmacovigilance Centres. *Drug Safety* 2011; 34: 83 - 88

Turning the UMC course into action

Geoffrey Bowring

The UMC always asks the students from its pharmacovigilance course in Uppsala for feedback six months after they have returned home, to learn about their experiences since the course. We find out if they have worked in pharmacovigilance since they attended the UMC course, their main achievements and progress, ways in which reality back home affected their action plans prepared during the course, real obstacles to their goals, and whether the knowledge gained was sufficient and appropriate. Most students send us their answers.

Some are able to list an impressive range of achievements from having their institution recognised as the national pharmacovigilance centre, all the way through to short training sessions for agency colleagues and health professionals. In one country new regulations and procedures were listed along with communications initiatives with other directorates, and newsletters and leaflets.

Typical obstacles to achieving goals include financial limitations, scarce human resources and poor engagement of the authorities; one person noted that reality differs from the action plan as "things go more slowly than that planned".

One participant from southern Africa described it as "an amazing experience for me and my institution" with an increased number of reports and quality of reports also improved. He also had the opportunity to train colleagues in VigiFlow, CemFlow and terminologies, and the unit was involved in training the national immunization programme on AEFIs. The opportunity of meeting UMC staff the staff face-to-face "really helped in communicating with staff at UMC when we have challenges".

In one country the person trained soon moved to another division although thankfully all the course materials were passed on and some progress was reported; few ADR reports were received, however. Most of those who attended wanted further training. We will report on the 2012 UMC course in Uppsala Reports in July.

PV toolkit hits

Sharon Ako-Adounvo

The web-based Pharmacovigilance toolkit, officially launched on 18th January 2012 (UR56, p11), has been heavily used by countries since then with over a thousand visits per month. National Centres in both developed and developing countries have shown keen interest in its development and offered multiple suggestions. The top ten countries for visitors are India, United Kingdom, Spain, Mexico, Colombia, Germany, Ghana, Ukraine, France and Sweden.

The PV toolkit (www.pvtoolkit.org/) is currently being translated into Spanish and Burmese. Translations into French and others languages will hopefully be following and we will be announcing further news on this later in the year.

Drug safety online

Geoffrey Bowring

Following on from previous studies into the use of the internet for dissemination of drug safety information, a recent paper from the Oxford University Clinical Academic Graduate School, Oxford, UK looked in detail at ten countries' websites which provided some or all of the information in English.

The drug safety information from these websites was variable from site to site, although a wider study is called for to investigate this further. The vast majority of the sites did not mention the UMC or give the WHO definition of pharmacovigilance, although all of them included details of national pharmacovigilance guidelines and details of whom to contact with queries about ADRs.

Barker CI, Talbot JC, Aronson JK. Selected national pharmacovigilance websites: an analysis of contents. *Drug Saf*. 2012 Feb 1;35(2):141-8.

New staff

Sarah Fridén

Sarah was born in Uppsala, but moved away when she was little. She later returned to pursue a Master of Science degree in Pharmacology at Uppsala University. After her degree she worked in Stockholm at one of the first retail pharmacies to open after deregulation of the state-owned Swedish pharmacy monopoly. "I wrote my master's thesis at the UMC research department about 'Gender differences in International Adverse drug Reaction surveillance'. I also worked during the summer with signal detection and the Drug Dictionary which made me interested to get back to UMC at some point." Since February this year Sarah has become an Analysis Specialist.



Nadja, Sarah and Eva

"In my spare time you can find me doing some sort of handicraft or visiting thrift stores and flea markets, at home and abroad. I love to travel and some of my fondest memories of moments abroad are a New Year's Eve in Tokyo, a coast to coast trip through the USA, and fruit picking while travelling around New Zealand. My interest in other cultures was one of the things that made me join the UMC. I really enjoy the different backgrounds of people here."

Nadja Jastrebova

Nadja is a new member of the Education, Training and PV Consulting section within Pharmacovigilance Services. She joined the UMC as a consultant in 2010 to work in the WHO DD Information Management Section, and later worked half-time providing support to Russia and other member countries where knowledge of Russian is an advantage. Now a permanent staff member, she retains a focus on Russian-speaking countries, but is also contact person for most countries in Europe. Nadja is also involved in translation projects from English to Russian.

"I come originally from Russia, born in Vyshniy Volochek, a small town between Moscow and Saint Petersburg. We moved to Sweden when I was a teenager in 1990, and I've lived in Uppsala since 1994. I have an MSc in Pharmacy and defended my doctoral thesis in Medical Biochemistry, where the subject was structure of heparan sulfate, a polysaccharide, during its interactions with growth factors." Outside work Nadja is interested in psychology and mental well-being, and has obtained a diploma in life coaching. During holidays she loves to travel with her family to new places and cultures.

Eva Svärd

Eva is originally from a small village in the province of Dalarna; the name of the region is Svärdsjö (Svärd lake) but the surname does not come from that! "I moved to Uppsala for studies in Pharmacy at Uppsala University and graduated in 1990. My working career started that year at a pharmacy in Stockholm. After 5 years I made a drastic change in my life and moved to San Diego with my husband who was doing his post-doc in Microbiology at UCSD and I had the luxury of being a California housewife for two years." On returning to Uppsala Eva worked for 12 years at a dispensing pharmacy. "But it is never too late to make a change of career, so in spring 2010 I became a consultant at the WHO DD Information Management Section, a position which is now permanent. My key responsibility is as Herbal Coding Specialist, which means I coordinate WHO Herbal Dictionary substance maintenance. I have an interest in herbs and during 2011 studied pharmacognosy at Uppsala University. The opportunity to maintain and develop the Herbal Dictionary is a challenge that I am really looking forward to."

"I like to spend time with family, my husband and our two boys. We have a summerhouse in my home village where we go as much as we can – one major interest is running."

Sofia Örnberg

Sofia is from Enköping, less than one hour from Uppsala. After education at Linnéskolan in Uppsala, further studies in Tourism and Service, and one year working in London, she moved permanently to Uppsala in 1999. "After over 10 years in customer service and sales support at Dibs Payment Services / DebiTech, I registered with an agency which contacted me regarding a vacancy at the UMC Sales & Marketing team." Sofia is 'In-House Sales Representative', assisting UMC's

commercial customers (particularly of the WHO Drug Dictionary Enhanced) with price information and matters relating to contracts, also building long-term relationships with new and returning customers.

"As a mother of two playful boys, 3 and 5 years old it feels like I don't have time for many hobbies. But I like to enjoy a nice dinner with friends and family. My husband works as a chef and when he is tired of cooking, we go out for a dinner at any of the nice restaurants in Uppsala and try their menu instead."

Mikael Nilsson

Born in Falun, Mikael moved to Uppsala in 1999 and obtained his MSc in Engineering Physics at Uppsala University of Technology in 2003. He worked as Process Developer at SSAB in Borlänge, then as a programmer at TSONIC in Uppsala. His most recent job was as Statistical Programmer at Quintiles, Uppsala, on a variety of services to pharmaceutical and life sciences companies, using SAS to program databases and make lists and tables used in the study reports. At UMC Mikael works as a Sales Engineer, a technical role that supports the sales team in customer interactions, as well as helping the support team in responding to technical questions regarding the use of our dictionaries. He also has responsibility for the Software Certification Program.



Mikael and Sofia

"Outside work I enjoy fishing and hunting. During the fishing season (spring, summer) I like to spend time at my cottage near Sundsvall, fly fishing for salmon and sea trout in the river Ljungan. During autumn I mostly go hunting for moose with my Norwegian elk hound called Toulpa."

Marie Wallin

Marie is originally from Bollnäs in central Sweden. She worked in the hotel business in Uppsala for a long time, as well as a year at the Swedish Medical Products Agency, before getting the chance to work at the UMC. Here Marie is closely involved in welcoming external visitors, as well as being a course and conference administrator. She also takes care of many of the essential 'behind the scenes' activities such as office supplies, without which any office will come to a halt.

As well as being a keen photographer (whose pictures turn up regularly in *Uppsala Reports*), she enjoys walking with her flat-coated retriever named 'Soya'.

Christina Larsen

Christina was born in Stockholm, and grew up in the coastal town of Gävle, undertaking studies in economy at the Linné University in Växjö. She moved to Uppsala in 1988 and has worked since then in several positions in accounts and finance departments, most recently as a controller in the finance department at medical equipment company ScandiDos in Uppsala. She recently joined the UMC as a Finance Accountant. Her spare time is mostly spent with her family and friends.



Christina and Marie

Visitors from France

Kristina Star

In February, the UMC had the pleasure to welcome Dr Maryse Lapeyre-Mestre and Dr Joelle Micallef from the CEIP (Centres d'Évaluation et d'Information sur la Pharmacodépendance) – Addictovigilance in Toulouse and Marseille, France.

The visitors presented their extensive current work within signal detection of drug dependence and abuse in France, and we discussed potential future collaborative projects.



Maryse Lapeyre-Mestre, Joelle Micallef and Kristina Star

ISoP training in Berlin

This year's ISoP advanced training courses, taking place at the H10 Berlin Kurfürstendamm just off the Kurfürstendamm boulevard in the German capital, offer two contrasting options. There will be two-day training courses, one entitled New EU Post-Licensing Legislation and Benefit-Risk Management and, in parallel, Future Perspectives for EU Pharmacovigilance.

The first will cover in detail the amendments to the EU post-marketing legislation (effective July 2012) which represent a major change in EU medicines legislation. A full day will also be devoted to new developments in benefit-risk management practice. The second course examines the new mandatory elements to EU pharmacovigilance practice, offering opportunity for

open discussions and thoughts on good pharmacovigilance practice, medication errors, drug interactions and biologicals and biosimilars.

Programme and Registration forms are available from the ISoP Administration office: administration@isoponline.org or at www.isoponline.org/index.php?page=training

Best Paper award to UMC researchers

Sten Olsson

The UMC was awarded the Best Paper prize at the recently concluded ACM SIGHIT International Health Informatics Symposium 2012, in Miami, USA, for a paper entitled 'Robust Discovery of Local Patterns: Subsets and Stratification in Adverse Drug Reaction Surveillance' by Johan Hopstadius and Niklas Norén.

Nearly 300 papers were submitted to the conference out of which the top 17% were selected for oral presentation. Johan Hopstadius presented the paper in a session on 28 January and received the Best Paper Award from keynote speaker Jonathan R. Wolpaw, in a ceremony on 30 January. The conference gathered 200 participants from 38 countries.

(ACM: Association of Computing Machinery; SIGHIT: Special Interest Group on Health Informatics)



Jonathan R. Wolpaw (right) presents the prize to Johan Hopstadius in Miami

Lareb Prize for Ron Meyboom

Eugène van Puijenbroek



Fred Dijkers and Ronald Meyboom, with the prize, a vase by local ceramic artist Gert de Mulder

Ronald Meyboom has been awarded the 'Lareb Prize' for outstanding achievements in the field of pharmacovigilance. The Prize was presented on 21 March at the annual meeting of the Netherlands Pharmacovigilance Centre Lareb by Dr Fred Dijkers, President of the Board, in the presence of the Board, Scientific Advisory Committee and staff.

Ron has a long track record dedicated to pharmacovigilance with major contributions to national and international development the field. When studying medicine at the University of Leiden he developed a keen interest in pharmacology and in particular the pathogenesis of adverse drug reactions. In his PhD degree (1998) his thesis 'Detecting Adverse Drug Reactions' laid a scientific basis of spontaneous reporting, signal detection and causality assessment. In the early 1990s he played an essential role in the development of Lareb and has been a mentor and teacher of many of its employees. He has enjoyed long-term associations with the Department of Clinical Pharmacology and Pharmacoepidemiology at Utrecht University and at the WHO Collaborating Centre for International Drug Monitoring in Uppsala.

DATES	TITLE	PLACE	ORGANISER/CONTACT
8-9 May 2012	How to prepare for pharmacovigilance audits and inspections	Berlin, Germany	DIA Europe Tel.: +41 61 225 51 51 Fax: +41 61 225 51 52 Email: diaeurope@diaeurope.org
22 May 2012	Preparing the development safety update report	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
23-24 May 2012	Staying Current and in Control in the Constantly Changing Global Regulatory Pharmacovigilance Environment	West London, UK	Drug Safety Research Unit Tel: +44 (0)23 8040 8621 www.dsru.org/ E-mail: jan.phillips@dsru.org
23-25 May 2012	National Patient Safety Foundation: 14th Annual Patient Safety Congress	Washington DC, USA	National Patient Safety Foundation http://npsfcongress.org/
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 www.who-umc.org
26-29 May 2012	The Asia Pacific Conference on National Medicines Policies (APCNMP)	Sydney, Australia	APCNMP http://www.apcnmp2012.com.au/
11-12 June 2012	ISoP training courses: New EU PV legislation; Medication Errors, Off-label Use and Risk Management	Berlin, Germany	ISoP Tel/Fax: +44 (0)203 256 0027 E-mail: administration@isoponline.org www.isoponline.org/ > Training
13-14 June 2012	Periodic Safety Update Reports (PSURs)	Fareham, UK	Drug Safety Research Unit (details as above)
19-21 June 2012	Pharmacovigilance – Basic training course for those working in the EU, USA and Japan	London, UK	Management Forum Ltd (details as above)
29 June 2012	New Pharmacovigilance Legislation	London, UK	Management Forum Ltd (details as above)
4-5 July 2012	Introduction to Pharmacoepidemiology	Southampton, UK	Drug Safety Research Unit (details as above)
11-13 July 2012	All Africa International Conference on Basic and Clinical Pharmacology (includes sessions on drug safety)	Accra, Ghana	IUPHAR www.iuphar-africa2012.org/
18-20 July 2012	Medical Aspects of Adverse Drug Reactions	Southampton, UK	Drug Safety Research Unit (details as above)
23-26 August 2012	28 th International Conference on Pharmacoepidemiology & Therapeutic Risk Management	Barcelona, Spain	ISPE www.pharmacoepi.org/meetings/ E-mail: ISPE@paimgmt.com
5-6 September 2012	Back to Basics in Pharmacovigilance	Fareham, UK	Drug Safety Research Unit (details as above)
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
1-3 October 2012	International Conference and Exhibition on Pharmacovigilance and Clinical Trials	Chicago, USA	OMICS Group Conferences Tel: +1-650-268-9744; Fax: +1-650-618-1414 E-mail: pharmacovigilance2012@omicsonline.org or pharmacovigilance2012@omicsgroup.com www.omicsonline.org
3-8 October 2012	FIP Centennial Congress (includes 'Creating a future of better pharmacovigilance' / information sessions)	Amsterdam, Netherlands	FIP www.fip.org/amsterdam2012/
30 October – 2 November 2012	12 th ISoP 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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About UMC > UMC staff – on our website.

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