

UMR40

UPPSALA REPORTS January 2008

For everyone concerned with the issues of pharmacovigilance

New initiatives from the FDA

Reflections from Buenos Aires

Important year ahead for *the* UMC

New ICSR import process

Web news



DIRECTOR'S MESSAGE



Ralph Edwards
Director
the Uppsala Monitoring
Centre

Since 2006 there have been increased warnings about the use of salmeterol in asthma and increased death. Dr David Graham, then a safety reviewer at the US FDA, raised the topic of several drugs he was concerned about, one of which was salmeterol, which in his view had not received attention. He did this amidst great controversy in late 2004.

I have been reading Neil Pearce's book on the fenoterol story¹ and found it interesting to consider some parallels in the current concern between salmeterol and increased mortality. Compare, for example, the references below^{2,3} from the web, with the fenoterol story from New Zealand during that country's epidemic of asthma deaths, which I attempt to summarise below, admittedly with some bias from my own perspective. I was part of the story in a small way being Medical Assessor for adverse reactions in NZ.

A small clinical pharmacology study showed fenoterol-induced cardiac effects like isoprenaline and more than salbutamol, the main competitor. Following this, Boehringer Ingelheim, the fenoterol manufacturer, gained knowledge of Pearce et al's proposed case control study to look at fenoterol and asthma death, as at the time the research group was seeking funding. They raised questions about the study even before it started. Pearce and his colleagues went their way without funding, but then had to fight to get the study results published. The study showed that the relative risk of death in patients with asthma on fenoterol was 1.6 (1-2.3) compared with controls on other drugs. The relative risk rose to 6.5 (2.7-15.3) or even 13.3 (3.5-51.2), for patients with severe asthma, depending on the way severity was measured. One would think that that there would be no dispute about the results, but there were many issues, scientific and political, involved.

The New Zealand Department of Health decided to take no action over the results which they were given, preferring to wait until publication and peer review. In the event, peer review was variable in response and caused difficulties in publication, but some of the more critical comments came from some experts linked with, or said to be influenced by, Boehringer Ingelheim.

Another main player in the dispute was the Asthma Task Force set up to examine the epidemic, and which largely consisted of respiratory medicine specialists. Although little is said about their work in Pearce's book, they had reviewed the deaths and were in the process of concluding that the deaths were due to very poor asthma treatment planning: underuse of inhaled steroids and overuse of bronchodilators. Fenoterol was highly used in NZ and was a high-dose inhaler. This left the possibility that Pearce et al's finding might be explained by inappropriate overuse of a powerful, high-dose drug in the terminal asthma attack and channelling of fenoterol use to the most severe cases. It is not

surprising that Boehringer Ingelheim was more supportive of this view.

The subsequent disputes involving the various parties became public knowledge in the news media. Once the media was involved the situation deteriorated into a battle. Pearce et al vociferously and publicly called for the withdrawal of fenoterol, and chaos reigned with battle lines drawn between the 'researchers' and 'the establishment' on the other side. I tried to intervene to get money for other studies to elucidate the problem, but it was only Boehringer Ingelheim (not the government) which offered to make money available for work to be done, administered through the NZ Medical Research Council. This information was leaked to the press which resulted in my being branded as an industry dupe in the national press!

There is much more to the story, but a major point is the bad feelings, some bad behaviour by the protagonists in defending their 'turf', and irresponsible use of the media led both to indecision by regulators and to great public concern.

In retrospect, I wish I had been more forceful in urging that a clear public warning should be given about the Pearce group's findings very early on. The matter of 'why' could have been dealt with later.

As a postscript, I have since thought it interesting that Pearce et al have claimed that the decrease in asthma deaths, when fenoterol was withdrawn from general use, is support for their argument. It is also a support for the Asthma Task Force, since their work to introduce better asthma treatment plans had impact at the same time.

Pharmacovigilance is not easy, and its errors and problems are repeated. Perhaps intelligent risk management will improve our performance.

This letter is not to be considered as a comparison between salmeterol and fenoterol themselves, but rather as comparing some of the concerns raised and the difficulties of science and policy-making.

A handwritten signature in black ink that reads 'Ralph Edwards'. The signature is written in a cursive style and is positioned above a horizontal line.

1. Neil Pearce, 'Adverse Reactions: The Fenoterol Story' (2007) Auckland University Press, Auckland. ISBN 978 1 86940 3744
2. <http://news.bbc.co.uk/1/hi/health/2793793.stm>
3. <http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01248.html>



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

An independent centre of scientific excellence, *the* UMC offers products and services, derived from the WHO database of Adverse Drug Reactions (ADRs) reported from member countries of the WHO Programme.

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

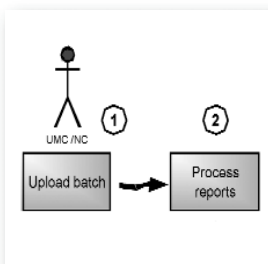
The UMC's important worldwide work is financed solely by the organisation itself, without support from WHO, the Swedish Government, member countries of the WHO Programme or any grant-making body.

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WHO Programme News

Togo joins the Programme

In mid-December, members of *the UMC's* Safety Reporting Support and Service confirmed that 20 ADR reports submitted via VigiFlow by the national centre in Togo had been accepted as being correctly formatted, and that therefore Togo was eligible to join the WHO Programme. Sten Olsson recommended to WHO in Geneva that Togo become the 84th member of the Programme.

Ms Agbenu, who attended a course in Morocco earlier in the year is the contact person, and we hope to have a full description of their activities in the April edition of Uppsala Reports.

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Triple associates

The WHO Programme currently has its largest number of Associate members: national centres desiring to join the Programme but considered 'associate members' while awaiting compatibility between the national and international reporting formats.

Following the two two-week training courses during 2007 – one in Morocco in February and *the UMC's* biennial pharmacovigilance course in May – Kenya, Sudan and Côte d'Ivoire have become Associates.

Kenya

The Ministry of Health, Kenya is at an advanced stage of implementing an appropriate pharmacovigilance system to cover all drugs across all patient populations in Kenya. The Department of Pharmacovigilance, located at the Pharmacy and Poisons Board has been mandated to implement the pharmacovigilance programme in Kenya. The focal person for pharmacovigilance activities is Dr Jayesh M Pandit, clinical pharmacist and currently head of the Department of Pharmacovigilance.

His address is:
Dr Jayesh Pandit
Department of Pharmacovigilance
Pharmacy and Poisons Board
PO Box 27663-00506
Nairobi
Kenya

Sudan

The Director General of the Directorate General of Pharmacy of Sudan has applied via the Eastern Mediterranean WHO Office for membership of the WHO Programme, attaching an implementation plan for a pharmacovigilance centre.

The current contact details are:
Directorate General of Pharmacy
Federal Ministry of Health
PO Box 13711
Khartoum
Sudan
E-mail: pharmacovigilance.sd@gmail.com

Côte d'Ivoire

Through the Ministry of Health and Public Hygiene of the Republic of Côte d'Ivoire in Abidjan, Dr Marcel Koffi-Koumi has notified WHO of his government's intention to create a National Pharmacovigilance Centre and apply for membership of the WHO Programme. Two pharmacovigilance resource persons are named, Professor Jean Claude Yavo, pharmacologist, and Dr Mahama Ouattara, pharmacist, based at the:

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We look forward to welcoming these three and other countries to the full family of WHO Programme members in due course, when they are able to submit ADR reports in the required method.

New Zealand and Australia

At recent conferences there have been a number of enquiries about progress towards the proposed joint New Zealand and Australian Therapeutic Goods Administration. We have now learnt that the establishment of this agency has been postponed due to insufficient parliamentary support in New Zealand. Parliamentary support has not yet been tested in Australia, but was expected. It will be of interest to the pharmacovigilance community to note that whereas Australia currently regulates complementary and alternative medicines, New Zealand has yet to take this step and there has been considerable opposition to such regulation in the New Zealand parliament.

WHO meeting – and more – in Uppsala, 2008

40 years since the founding of the WHO Programme for International Drug Monitoring, the 31st Annual Meeting of National Centres participating in the Programme will take place in Uppsala itself from 20-23 October 2008, preceded by an afternoon seminar for new members and new staff. Formal invitations to national centres will be sent out from Geneva in the first quarter of 2008, and the draft programme will be circulated via Vigimed in due course. The WHO itself will celebrate its diamond jubilee this year, having been set up in 1948.

Following the WHO meeting, on 24 October *the UMC* will be offering a research conference entitled 'Impacting patient safety: Adverse drug reaction signal detection - Quantitative and qualitative approaches in screening healthcare data', also in Uppsala, highlighting some of the areas of research in which *the UMC* is involved and with major international speakers.

To round off this special week, over the weekend of the 25-26 October members of *the UMC's* Signal Review Panel will be convened for two days of discussions related to the processes which form part of the signal detection at *the UMC*.

We very much look forward to welcoming many of you next October, in Uppsala!

October 2008, Uppsala

19 October (afternoon)	Pre-WHO Programme meeting seminar	<i>For new WHO Programme delegates and countries</i>
20-23 October	31 st Annual Meeting of the WHO Programme for International Drug Monitoring	<i>National Centres by invitation</i>
24 October	Research conference	<i>Open meeting (programme and fee schedule available shortly)</i>
25-26 October	Signal Reviewers	<i>Closed meeting by invitation</i>



A view towards the dome of the Gustavianum, the former main building of Uppsala University, built 1622-1625. Under the cupola is the anatomical theatre, added in the 17th century by Olaus Rudbeck, Professor of medicine (and amateur architect). Although still used for lectures, most of Gustavianum functions as a museum including exhibits from university collections of Classical, Egyptian and Nordic antiquities, as well as the history of science and of Uppsala University. The Augsburg art cabinet, the best preserved of the Kunstschränke made by Philipp Hainhofer, is on display, along with Celsius's thermometer.



The river Fyris in Uppsala in autumn

Annual Meetings of the WHO Programme for International Drug Monitoring

- 1978 Uppsala, Sweden
- 1979 Geneva, Switzerland
- 1980 London, UK
- 1981 Uppsala, Sweden
- 1982 Ancona, Italy
- 1983 Brussels, Belgium
- 1984 Washington DC, USA
- 1985 Dubrovnik, Yugoslavia
- 1986 Paris, France
- 1987 Canberra, Australia
- 1988 Uppsala, Sweden
- 1989 Geneva, Switzerland
- 1990 Geneva, Switzerland
- 1991 Barcelona, Spain
- 1992 Ottawa, Canada
- 1993 Geneva, Switzerland
- 1994 Berlin, Germany
- 1995 Bangkok, Thailand
- 1996 Lisbon, Portugal
- 1997 Geneva, Switzerland
- 1998 Tokyo, Japan
- 1999 Ankara, Turkey
- 2000 Tunis, Tunisia
- 2001 Dunedin, New Zealand
- 2002 Amsterdam, Netherlands
- 2003 New Delhi, India
- 2004 Dublin, Ireland
- 2005 Geneva, Switzerland
- 2006 Liège, Belgium
- 2007 Buenos Aires, Argentina
- 2008 Uppsala, Sweden

(Meetings in Geneva were hosted by WHO)

Collaborating Centre marks a quarter of a century

Monica Plöen reports

No, not *the* Uppsala Monitoring Centre, but the WHO Collaborating Centre for Drug Statistics and Methodology; it is 25 years since the collaborating centre was set up due west of Uppsala in Oslo.

The WHO Collaborating Centre for Drug Statistics Methodology was established in 1982 at the Norwegian Institute of Public Health and is funded by the Norwegian government. Its main tasks are development and maintenance of the ATC (Anatomical Therapeutic Chemical)/DDD (Defined Daily Dose) system, including:

- to classify drugs according to the ATC system
 - priority is given to the classification of single substances, while combination products available internationally are dealt with as far as possible;
- to establish DDDs for drugs which have been assigned an ATC code
- to review and revise as necessary the ATC classification system and DDDs
- to stimulate and influence the practical use of the ATC system by co-operating with researchers in the drug utilization field

The current Director of the Centre is Marit Rønning, MSc Pharm.



Participants in the anniversary symposium in Oslo

Anniversary symposium

The 25th anniversary meeting included invited speakers who presented the past, present and future needs for utilization data as a link to rational drug use.

The outside speakers came from different settings:

- ◆ 'Drug use and health policy', Anne Kari Lande Hasle, the Ministry of Health and Care Services
- ◆ 'Drug utilisation from a WHO perspective', Dr Lembit Rågo from WHO Headquarters
- ◆ 'Use of the ATC/DDD methodology in pharmacoepidemiological research today', Dr Morten Anderson, University of Southern Denmark

- ◆ 'The challenges of rational drug use in developing countries', Gugu Nolwandle Mahlangu, the Medicines Control Authority of Zimbabwe
- ◆ 'Drug utilisation studies and rational drug use in Australia', Andrea Mant, University of New South Wales, Australia
- ◆ 'Global systems – local actions; the role of the Norwegian Institute of Public Health in international cooperation' by Anne Bergh, Norwegian Institute of Public Health.

Eighty people were present to celebrate with the Centre. After the symposium there was some delightful music performed by the Oslo Guitar Ensemble, and later a dinner was served and more speeches made.

The two following days the working group had a biannual meeting discussing ATC and DDD classifications in the expert working group.

Laos and Vietnam – neighbours at different stages of pharmacovigilance development

Laos

The first ever pharmacovigilance training course in Laos was carried out in the capital Vientiane on 19–21 November. Influential clinical experts and pharmacists from the major hospitals in the capital area as well as staff of the Lao regulatory authority, the Food and Drug Department (FDD), took part in the training. The main tutor was Sten Olsson from *the* UMC.



Participants of the pharmacovigilance training course in Vientiane

The training was organized and sponsored through a Swedish aid project for implementation of the Laotian Drug Policy. A senior advisor to this programme, Rolf Johansson, contributed to the clinical parts of the training. The focus of the training was on the need for pharmacovigilance, basic principles of spontaneous reporting of drug related problems, practical issues of setting up a pharmacovigilance centre and how to analyse and use the collated data. The roles and responsibilities of different stakeholders and the process towards setting up a Laotian pharmacovigilance centre were discussed in working groups.



Mr Vongtavanh Chiemsisourath from the Food and Drug Department

Vongtavanh Chiemsisourath of the FDD served as a passionate and dedicated interpreter of both language and content of the messages given by the English-speaking tutors.

Vietnam

From Vientiane, Sten Olsson travelled to Hanoi, the capital of Vietnam where he met with the staff at the Vietnamese national pharmacovigilance centre at the Drug Administration of Vietnam (DAV). The Vietnamese centre was established in mid 1990s through Swedish aid to the Vietnamese pharmaceutical sector. Vietnam joined the WHO International Drug Monitoring Programme in 1999.



Dr Nguyen Thu Thuy from the Vietnamese national pharmacovigilance centre

The national pharmacovigilance programme is now being reorganized with the intention of integrating pharmacovigilance with a national network for drug information. Three combined drug information/pharmacovigilance centres will be set up initially in the north, centre and south parts of the country as a joint effort between DAV and pharmaceutical colleges in the three regions. Funds for operations will be provided through the regular budget of Ministry of Health. The UMC was invited to provide advice and support for the new Vietnamese pharmacovigilance network. In the discussions the Vietnamese side was represented by Dr Cao Minh Quang, Vice-Minister of Health, Nguyen Thu Thuy and Hoang Thanh Mai from the present national PV centre and Dinh Hien Van, College of Pharmacy, Hanoi.



From left to right, Duong Xuan An, Vu Thi Hiep, Cao Minh Quang, Hoang Thanh Mai, Vo Thu Thuy, Dinh Hien Van, Nguyen Thu Thuy, in Hanoi.

Leading figures take new directions

Ian Boyd, whose early retirement from the Australian Therapeutic Goods Administration (TGA) we reported in UR39, has established a pharmacovigilance consultancy to cover Australia, New Zealand and South East Asia; this will also involve collaboration with the well-established Elliot Brown Consulting, which covers the European Union and the USA. Ian will offer consulting services in all aspects of pharmacovigilance including signal review and analysis, preparation of risk management plans and PSURs, and safety and labelling review. He can be contacted at ianboydconsulting@incanberra.com.au.

Kees van Grootheest has been appointed Professor of Pharmacovigilance at the University of Groningen (Centre of Pharmacy). He will continue his activities as director of the Netherlands Pharmacovigilance Centre Lareb in combination with the new task.

The University of Groningen is one of the oldest of The Netherlands and was founded in 1614. Kees has been active as executive director of Lareb since November 1996, following his work as physician in Africa and as general practitioner in the Netherlands.

Alex Dodoo commenced a 2-year term as President of the Pharmaceutical Society of Ghana on 1st January 2008. The Society is the umbrella organization for all 1,800 pharmacists in Ghana and is statutorily represented on governing councils of bodies dealing with pharmacy and traditional medicine. It also caters for the welfare of members and sets and monitors professional and ethical standards for pharmacy practice in Ghana.

Dr Alexander Nii Oto Dodoo is a Senior Research Fellow & Acting Director of the Centre for Tropical Clinical Pharmacology & Therapeutics at the University of Ghana Medical School, Accra, Ghana. He started and coordinated Ghana's national pharmacovigilance centre, the first in West Africa. Dr Dodoo holds degrees in pharmacy from Kumasi, Ghana (B Pharm) and King's College, University of London (MSc, PhD). He is also an Executive Committee member of the International Society of Pharmacovigilance.

Buenos Aires hosts 30th annual meeting

Report by Bruce Hugman

More than a hundred people, including representatives of 38 countries, met in Buenos Aires for the 30th annual meeting of the WHO Programme for International Drug Monitoring, from 11-13 October 2007. The meeting was hosted by ANMAT, the Argentinean regulatory authority and its pharmacovigilance team, led by Dr Inés Bignone. For the first time the annual meeting was being held in Latin America and appropriately, simultaneous translation was provided into Spanish, offering much greater freedom for participation by local delegates and other Spanish speakers.



The audience at the meeting in Buenos Aires, with Inés Bignone, front right.

Packed programme

In the crowded 2½ day programme, eight working groups examined issues carried forward from last year and raised by national centres; eighteen problems of current interest were outlined (see box) and nine plenary presentations of activities and issues were made. WHO and UMC reported back on their work since the meeting in Liège, and on future plans.

Resources and impact

Recurrent themes of the meeting were the challenges of making pharmacovigilance better understood among all stakeholders, encouraging greater political and financial support for pharmacovigilance activities, and developing knowledge, skills and methods in the science to have greater impact on patient safety in a very wide range of situations across the world. Broadening the scope of pharmacovigilance to embrace medication error and reports from patients were seen as priorities. The divergence of pharmacovigilance resources and impact around the world, particularly, though not exclusively, as between developed and developing countries, remained a concern for everyone.

Coverage and openness

Crisis preparedness in immunisation programmes and in readiness for pandemic 'flu was discussed, and the need for guidelines and SOPs was identified. Lessons from cohort event monitoring (CEM) in malaria programmes in Africa, and from the visceral leishmaniasis eradication programme in India, Nepal and Bangladesh were presented as examples of methods extending pharmacovigilance well beyond spontaneous reporting. The effective integration of pharmacovigilance into public health programmes was seen as a major challenge and necessity. The desirability of the conditional

opening of ADR databases to greater public scrutiny was generally agreed, as was the principle of making the contents of the UMC Signal document accessible to a wider audience. Updates were presented about the progress of the WHO-ART to MedDRA bridge and the development of the UMC's report-management VigiFlow software, now being prepared to receive CEM and pandemic reports.



At the gala dinner: Ulrich Hagemann (Head of Pharmacovigilance Department, BfArM, Germany), Analía Perez (Director of Medicines Evaluation, ANMAT, Argentina), Shanthi Pal (WHO Quality Assurance and Safety: Medicines) and Sten Olsson (UMC).

A sociable meeting

The meeting was very well organised by the host team, and a relaxed and sociable atmosphere permitted lots of informal discussion between participants, as well as effective and focussed formal sessions and working groups. The gala dinner was held at Madero Tango, one of the city's renowned tango-performance venues. A splendid dinner was followed by a talented display of Argentina's most popular cultural treasure. On the last afternoon, after the meeting, many of the participants took the Tren de la Costa, along the banks of the River Plate, followed by a sunny boat trip round the affluent islands of the Parana River delta.

The official report will be sent the National Centres which are members of the WHO Programme in due course.

Problems of Current Interest topics

- Prophylactic use of sulphadoxine-pyrimethamine (SP) during pregnancy
- Sulfadoxine-pyrimethamine (SP) in intermittent preventive treatment of malaria
- Effect of promethazine use during late pregnancy
- Toxic epidermal necrolysis induced by paracetamol
- Imiquimod and severe skin disorders
- Olanzapine and severe thromboembolism
- Clobutinol and heart rhythm disorders
- Lumiracoxib – Liver disorders
- Rimonabant – Psychiatric adverse reactions
- Aggressive reactions on changing brands of methylphenidate
- ALS-like syndrome and statins
- A Belgian proactive vigilance project
- International homonymous drug names: a cause of medication errors
- Collaboration between the Agency for Medicinal Products and National Institute of Public Health in pharmacovigilance of vaccines (Croatia)
- Tick-borne Encephalitis Virus (TBEV) vaccine
- Thalidomide, new use of an old drug
- Use of levofloxacin and risk of tendon rupture
- Update on nimuselide

New Import Process for ICSRs

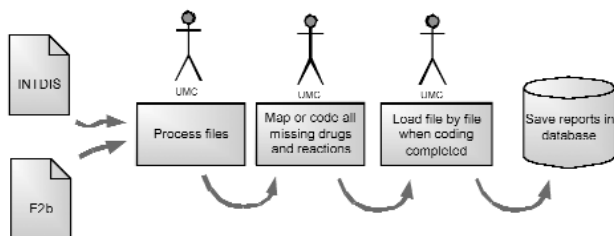
Magnus Wallberg and Helena Sjöström

The need for a new method for *the* UMC entering ICSRs (Individual Case Safety Reports) into Vigibase (the WHO ICSR database) has been recognized. An ever-increasing amount of manual work in preparation of the reports before loading into the database has been required. The time interval from receiving reports to being able to access the information should be as short as possible. The aim of the new import routine is to enter reports into Vigibase with less delay after submission to *the* UMC than before, and with as little manual input/work as possible.

The old import process

Figure 1 illustrates the old process. The essence of the process was the performance of several manual steps in a certain order, before any report in a batch/file submitted to *the* UMC could be processed into Vigibase. When batches with large numbers of reports were received, extensive work was undertaken manually to prepare the file for loading. Incorrect formats of the reports also required manual work before processing. This resulted in an extended time period from receiving the batches until the reports were loaded and accessible in Vigibase for search and analysis.

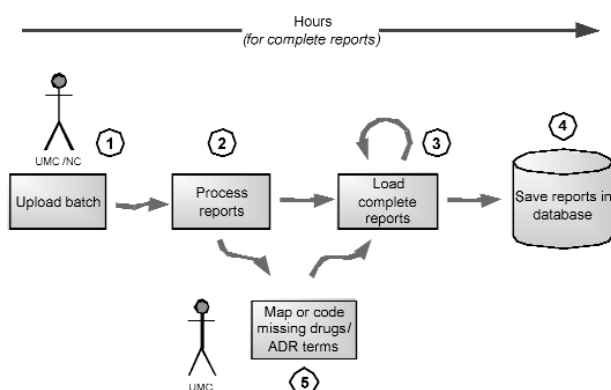
Figure 1



New import process

Figure 2 illustrates the new process.

Figure 2



The main difference is that after uploading a batch of reports in step 1 (see below), all reports in that batch are processed separately and will be loaded into Vigibase separately. This is a major change that affects the entire procedure on how to handle reports. The old method processed the reports as part of a batch until all reports in that batch were prepared and ready for loading into Vigibase.

The new process will have the following steps:

1. Upload batch

The submitted file containing reports is uploaded via a web-based interface.

To begin with the upload will be performed by UMC staff; in the future the upload interface will also be available for National Centres.

2. Process reports

All individual reports in the batch are extracted and stored separately before loading into Vigibase.

3. Load complete reports

All complete reports, reports that do not need any mapping or coding of drug information in the WHO Drug Dictionary (WHO-DD) and/or ADR terms in WHO-ART/ MedDRA, are loaded directly into Vigibase.

4. Save reports in database

The reports are saved in Vigibase.

5. Map or code missing drugs/ADR terms

Drugs that have been identified as missing in the WHO-DD are mapped to existing drugs (if possible), or coded into the WHO-DD. Incoming ADR terms will be handled through a similar process and mapped to MedDRA and WHO-ART. After updating DD/WHO-ART the reports are processed into Vigibase.

With the new import process correct reports can be loaded into Vigibase within hours (theoretically minutes) after they have been uploaded. If the reports are uploaded by a National Centre (as will be possible in the future), the delay at *the* UMC for receiving and uploading the files will be eliminated.

What it all means

So what will these changes mean for member countries and other users of the WHO database? With the new import process up-and-running, complete reports will be loaded directly into Vigibase and the manual element will be minimized, allowing UMC staff to spend more time on the important task of country support and advice. As a spin-off, the workload in handling reports will be smoothed out and correct reports will be activated immediately in Vigibase, meaning that the data will be accessible for search and analysis more rapidly – a significant step forward for patient safety and risk management.

Update on Post-marketing Drug Safety Activities at the US FDA

Gerald J. Dal Pan, MD, MHS

The last several years have witnessed a remarkable growth in interest in drug safety, and especially in post-approval drug safety. Several factors have contributed to this increased focus on the safety of medicines.

First, the breadth and depth of the science of drug safety have expanded. In many regions, population-based data are available for pharmacoepidemiological studies, which allow researchers to examine the safety of medicines in real-world settings. Pharmacogenomics has allowed scientists to have a better understanding of the molecular basis of human response to drugs. Part of the development of the science of drug safety includes better methods for adverse event collection in special populations. For example, the World Health Organization (WHO) has published a monograph on Pharmacovigilance for antiretrovirals in resource-poor countries. Diverse efforts such as these are evidence of improvements in the science and methodology of drug safety.

Second, there has been an increasing societal interest in the safety of medicines. In the US, patients, health care professionals, advocacy groups, the media, and legislators have all engaged in a national discussion on the importance of drug safety throughout the lifecycle of a product. The US Congress, in September 2007, enacted the Food and Drug Administration Amendments Act, which, amongst other things, acknowledges the importance of a robust post-approval drug safety system.

New initiatives at the FDA

At the US Food and Drug Administration, many new initiatives have begun over the past year in the Center for Drug Evaluation and Research. Selected ones dealing with improving the science of drug safety are summarized below.

Analysis of adverse event reports submitted to FDA remains a critical component of the drug safety system. FDA received approximately 472,000 adverse event reports in 2006.

These reports are stored in a database known as the Adverse Event Reporting System, which contains over four million reports. To evaluate these reports more efficiently and to identify and track more effectively safety signals, we plan to begin an upgrade of this system to a web-based accessible system with signal detection and tracking tools.

Because of the importance of spontaneous adverse event reporting in a pharmacovigilance system, FDA plans to publish a request for proposal from outside organizations interested in conducting an analysis of the public health benefits of reporting serious and non-serious adverse events. This research will focus on the number and type of safety concerns discovered by adverse event collection, the age of products at the time the safety concerns are detected, and the types of actions that are subsequently taken to promote patient safety.

To explore more effective ways of examining post-approval drug safety information, FDA is conducting a pilot program using a new systematic method to review the safety profiles of new molecular entities (NMEs) on a regularly scheduled basis after approval to determine whether these reviews should be initiated for all NMEs. Post-marketing evaluations of NMEs will incorporate data from the Adverse Events Reporting System (AERS), data mining analysis, epidemiologic data, post-marketing clinical trial information, and a review of the Periodic Safety Update Reports (PSURs), and US Periodic Reports, to identify potential safety concerns early in the product life cycle. We anticipate that results of this pilot program will be available by the second half of 2008.

Supplementing ADR information

FDA is also actively exploring additional sources of data to supplement the spontaneous adverse event reports in the AERS system. These additional sources of data are important because not all adverse effects can be reliably detected or quantified using a passive, spontaneous reporting system.



Gerald Dal Pan, M.D. Director, Office of Surveillance and Epidemiology (OSE) at the US Center for Drug Evaluation and Research

FDA has entered into a data use agreement with the Agency for Healthcare Research and Quality (AHRQ) to use data from the Centers for Medicare & Medicaid Services (CMS) to conduct a collaborative research project to develop data structures and methodologies for identifying and analyzing adverse drug events. In addition to studying safety issues relating to these specific drugs, the goal of this program is to gain familiarity with CMS data, in anticipation of the availability of expanded data in the near future.

The Veterans Health Administration (VHA) and FDA are working under a recently signed memorandum of understanding to allow sharing of certain information related to the use of drugs, vaccines, other biological products, and medical devices. The purpose of the project is to enhance knowledge and efficiency through the sharing of information and expertise between FDA and VHA regarding medical product safety, effectiveness, and patterns of use.

FDA also plans to obtain access to additional databases and to hire additional epidemiologists and programmers to conduct and oversee observational epidemiological studies using these databases. In

addition, FDA plans to seek input from pharmacoepidemiologists in academia and industry to develop guidance on conducting scientifically rigorous observational pharmacoepidemiological studies using large population-based healthcare databases. The main purpose of such studies is to confirm hypotheses regarding drug-adverse event association, and to quantify the risk of such adverse events.

Active surveillance

In addition to evaluating spontaneous adverse event reports and examining specific drug/adverse event association in large, population-based databases, FDA is also interested in using external databases to identify drug safety signals earlier than current methods do.

To accomplish this, FDA will explore ways to engage in active surveillance of drugs. To begin this effort, FDA sponsored, on March 7 and 8, 2007, a public meeting to explore opportunities for linking private sector and public sector healthcare databases and postmarketing safety monitoring systems to create a virtual integrated, interoperable nationwide medical product safety system. This effort, known as the Sentinel Initiative, could integrate existing and planned private and public sector databases to enable the collection, analysis, and dissemination of safety information about medical products to healthcare professionals and patients at point of care (ie, in the clinic where this information is needed to make informed decisions about safe and effective treatments).

FDA will continue to engage the public and private sectors in a discussion of opportunities for public and private sector collaboration on activities that could develop the data collection and risk identification and analysis components of such a potential system.

Risk evaluation

Risk management of medicines is also an area of active interest at FDA. With input from academia, industry, and the public, FDA plans to evaluate risk management tools and programs for their effectiveness. In addition, FDA plans to conduct assessment of specific risk management plans. As part of this effort, FDA plans to conduct annual systematic reviews and public discussion of the effectiveness of one or two risk management plans and one major risk management tool.

To assist FDA's safety evaluators and epidemiologists in the quantitative evaluation of safety data, CDER created in 2006 a Quantitative Safety and Pharmacoepidemiology Group, which provides biostatistical expertise to a wide range of drug safety questions.

The safety and risks of medicines cannot be evaluated in isolation; rather, they must be weighed against the benefits the medicine. In May 2006, FDA, along with the Institute of Medicine, sponsored a workshop on new approaches to quantitative risk-benefit assessment. FDA plans to continue exploring the possible uses of best practices in this area.

Guiding better drug use

Other areas in which new approaches to drug safety are being explored at FDA include developing techniques for predictive toxicology, identifying cardiovascular risks of drugs, preventing drug-induced liver injury, and using pharmacogenomic information to guide safer and more effective use of drugs.

In addition to these scientific endeavours, FDA has embarked on a variety of measures to improve communication. Examples of these initiatives include a comprehensive review of current public communication tools, establishing an advisory committee on risk communication, and improving communication amongst staff.

FDA also issued guidance on Drug Safety Information - FDA's Communication to the Public in 2007 www.fda.gov/cder/guidance/7477f1.pdf. FDA also inaugurated a new Drug Safety Newsletter in the fall of 2007 (www.fda.gov/cder/dsn). The purpose of this newsletter is to provide postmarketing information to healthcare professionals to enhance communication of new drug safety information, raise awareness of reported adverse events, and stimulate additional adverse event reporting.

The above scientific and communication initiatives are accompanied by a variety of organizational and management changes designed to strengthen the drug safety system.

Impacts of legislation

An exciting new challenge for FDA will be the implementation of the recently enacted Food and Drug Administration Amendments Act (FDAAA), which was signed into law in September 2007. Among other provisions, this law reauthorized and expanded the Prescription Drug User Fee Act (PDUFA), which will ensure that FDA staff have the additional resources needed to conduct the complex and comprehensive reviews necessary to new drugs, including drug safety issues. FDAAA also reauthorized other laws, including the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). Both of these are designed to encourage more research into, and more development of, treatments for children.

FDAAA establishes the Reagan-Udall Foundation for the Food and Drug Administration, a non-profit corporation whose purpose is to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety. An additional feature of FDAAA are sections that include drug safety provisions. These provisions address safety-related labelling changes, risk evaluation and mitigations strategies, post-approval clinical trials and observational studies, and active postmarket risk identification and analysis. These provisions add important tools in our work throughout the total lifecycle of these products. FDA is currently in the process of implementing FDAAA.

For more information on FDA, see www.fda.gov.

For more information on FDA's drug safety initiatives, see www.fda.gov/cder/drugSafety.htm

For more information on the Food and Drug Administration Amendments Act, see www.fda.gov/oc/initiatives/advance/fdaaa.html

Pharmacovigilance symposia at Tropical Medicine Conference

Alex Doodoo reports

The 56th Annual Meeting of the American Society of Tropical Medicine and Hygiene (ASTMH), which took place in November 2007 in Philadelphia, Pennsylvania, witnessed two important symposia on pharmacovigilance – a testimony of the growing recognition of pharmacovigilance as an important scientific and public health discipline.

In the next few years, it is expected that several new and highly efficacious artemisinin-combination therapies (ACTs) will be licensed for the treatment of malaria. The first symposium was therefore on the systems required for 'Safety monitoring of ACTs during scale-up' of ACTs.

Means of monitoring

Feiko ter Kuille of the University of Liverpool and the Malaria in Pregnancy (MiP) consortium urged the establishment of pregnancy registers to record all exposures to ACTs, especially unintended exposures. Citing experience of the successful antiretroviral pregnancy exposure registry (www.APRegistry.com), he called on industry, academia and regulators to collaborate to establish a single pregnancy register for ACTs in pregnancy to permit faster accrual of data on exposure and easier detection of signals.

Speaking on the monitoring of ACTs in malaria endemic countries, Dr Alex Doodoo of the University of Ghana Medical School recommended the deployment of active monitoring systems e.g. cohort event monitoring to complement spontaneous reporting schemes in sub-Saharan Africa. The former, though expensive, will allow a large amount of safety information to be obtained quickly for regulatory purposes and policy-making, whilst the latter will, in time, allow rare and unknown adverse events to be picked up.

Professor Fred Binka of the School of Public Health, University of Ghana highlighted the attractiveness of the existing INDEPTH demography surveillance sites in the collection of safety information and the long term follow-up of patients. There are over 35 such sites in 17 countries with populations who have been followed up over long periods. Any prospective study in these sites will yield highly valuable information since the background characteristics of the population are well known.

Data collection and uses

The second pharmacovigilance symposium (sponsored by Sanofi-Aventis and the Drugs for Neglected Diseases Initiative through an unrestricted educational grant to the ASTMH), continued on a similar theme and focused on the 'Challenges of implementing new ACTs in endemic countries'. It discussed innovative ways of gathering good quality safety and effectiveness data on new ACTs in endemic countries. There is probably more data on the safety of ACTs in pregnancy than previously thought.

Professor Francois Nosten of the Shoklo Malaria Research Unit (SMRU) presented evidence on the accumulating data from the SMRU in Thailand and discussed how malaria on its own accounts for more morbidity in pregnancy than ACTs. He therefore called for careful benefit:risk analyses on the use of ACTs in pregnancy. Dr Ambrose Talisuna of the Ministry of Health asked for well-powered studies to demonstrate safety and effectiveness in the field, whilst Drs Doodoo and Umberto D'Alessandro spoke on the challenges and opportunities for monitoring safety of ACTs in disease endemic African countries.

Linnaeus and Medicinal Products

Mohamed Farah reports

The Swedish Academy of Pharmaceutical Sciences and Uppsala University organised an international conference on drugs of natural origin, in collaboration with the Royal Swedish Academy of Sciences in Uppsala on 5th–8th September. The conference was part of the celebration of the 300th anniversary of the birth of Swedish scientist Carolus Linnaeus – Linné. Mohamed Farah and Elki Sollenbring from *the UMC* attended.

The scientific program of the conference was based on four of Linnaeus many dissertations: *Medicamenta graveolentia*, *Sapor medicamentorum* (the odour and the flavour), *De methodo investigandi vires medicamentorum chemica* (investigational methods), and *Ineberiantia* (poisons and intoxicants). This historical arena was chosen as a platform from which to project recent research in the fields of pharmacognosy and natural product chemistry.

There were welcome guest lectures from American visitors. Distinguished Professor Carl Djerassi from Stanford University spoke on the non-scientific factors which intrude in the use of natural products in medicine – from commercial considerations to political factors in the rise and fall of production of natural medicinal products. Another professor, Koji Nakanishi of Columbia University looked at the way the multi- or non-disciplinary collaborative research can unravel secrets of biological phenomena in natural products with examples from his own research.

In total there were three and a half days of papers and discussion, and an important contribution to the scientific celebrations of Linné in this commemorative year.

Wrestling with ethics and rational drug use in China

Bruce Hugman reports

The Second International Seminar on ethics in the Theory and Practice of Clinical Drug Evaluation was held in Beijing, 18 November 2007. It was repeated in Chengdu, Sichuan Province, three days later. Around eighty people attended each of the meetings, including specialists in bioethics from universities, hospitals, contract research organizations, industry and other research sectors. China is in the process of refining

ethical guidelines and practice across the board, with debate about some of the Helsinki principles and other international standards and their application in China. The work of ethics committees was examined and details of the ethical principles underlying the Shanghai post-marketing research programme were presented. Lively discussion took place on many thorny issues. These meetings were sponsored by AstraZeneca, China.



Participants in the Fourth China International Conference on Rational Drug Use and Pharmacoepidemiology, Guangzhou, November 2007.

In Guangzhou (formerly known as Canton), Guangdong Province, the Fourth China International Conference on Rational Drug Use and Pharmacoepidemiology took place on 22 November. Senior national and provincial officials and academics came from distant places for this meeting, which was organised by Dr Du Wenmin and his team from the Shanghai ADR monitoring centre. Among the many topics of interest presented was a survey of herb-drug interactions; the safety management of traditional Chinese medicines; a research programme to reduce irrational use of antibiotics in six hospitals in Guangdong Province; an introduction to international drug safety information management; rational use and ADR monitoring of OTC drugs; pharmacoepidemiology in hospitals.

As to be expected in China, the meetings were organised with meticulous attention to detail and with sumptuous hospitality.

International guests at the three meetings were Professor Mitchell Levine, from the Centre for the Evaluation of Medicines at McMaster University, Ontario, Canada, and Bruce Hugman, UMC's communications consultant.

Important meeting in the United Arab Emirates

Anna Celén

In December a national pharmacovigilance workshop took place in Abu Dhabi, the capital of the United Arab Emirates (UAE). The conference was jointly organized and coordinated by Fatima Albraiki from the Ministry of Health (MOH) and Abdelkarim Smine from the Health Authority of Abu Dhabi (HAAD). About 70 participants attended from different authorities, hospitals, pharmaceutical companies, universities and other organizations. Most participants came from the UAE but Saudi Arabia and Oman were also represented. Other international guests were Mary Couper from the WHO, Rachida Soulaymani Bencheikh from the National Centre in Morocco and myself representing *the UMC*.

The objectives of the meeting were to raise awareness about drug safety, assess all current national pharmacovigilance activities and review available WHO-UMC resources for support. Most countries in the Middle East (including the UAE) are not yet members of the WHO Drug Monitoring Programme. While many pharmacovigilance activities are conducted within the UAE, the information collected is generally not shared and used. The meeting was the first opportunity for different stakeholders to come together to share experiences, discuss problems of common interest and create a network.

A number of presentations were made about pharmacovigilance activities in MOH, HAAD, local hospitals and global pharmaceutical companies. Adel Alrwisan described the current situation in Saudi Arabia which is on its way to become a member of the WHO Programme and Madiha Juma Almaskari presented the system in Oman, a member country since 1995. Mohammed Al-Haidari who represented the Gulf Cooperation Council (GCC) explained their recommendations from the ADR reporting system symposium in Saudi Arabia in 2003, which have already been agreed upon by Ministries of Health in GCC member states. Mary Couper, Rachida Soulaymani Bencheikh and myself gave presentations on many different topics, such as the need for pharmacovigilance, how to establish a pharmacovigilance centre and communications in pharmacovigilance.

The current situation is that different strategies and methods are being pursued and used independently. The different experiences obtained so far are indeed useful, but a national system must be agreed upon and implemented to achieve more effective pharmacovigilance. There is a great need for a national pharmacovigilance centre to be designated. It should function as a focal point, coordinate all pharmacovigilance activities in the country as well as collaborate internationally.



Participants at the pharmacovigilance workshop in Abu Dhabi.

The outcomes of the meeting were a national action plan and recommendations with roles and responsibilities clearly defined. The location of the National Centre remains to be decided but is the main priority. Other important tasks to be performed are establishment of a national pharmacovigilance committee, design of a single ADR reporting form to be used by all health professionals, provision of enough resources for training, implementation of necessary changes in the current legislation and harmonization of policies in the GCC countries. The aim is that the UAE should become a member of the WHO Programme for International Drug Monitoring within one year.

Poster Winners ISoP 2007

FIRST PRIZE

Dr Claire Guy 'Azathioprine and Pharmacogenetic Testing: Implication in Clinical Practice'. Centre de Pharmacovigilance, Hôpital de Bellevue, Lyon, France

SECOND PRIZE

Dr Francesco Salvo 'Providing Reliable Pharmacovigilance Information via the Web: the Experience of an Italian Website'. Department of Clinical and Experimental Medicine and Pharmacology, University of Messina, Messina, Italy

THIRD PRIZE

Ms Suzanne Reid 'Evaluation of an Adverse Reaction (AR) Reporting Educational Program (curriculum) Developed for Undergraduate/ Graduate Students Studying a Health Profession'. Health Canada, Ottawa, Canada

The judges also highly commended two posters for their importance and originality.

Dr Geraldine Moses and Treasure McGuire for their presentation entitled 'Sleep-Driving, Sleep-Eating and Sleep-Smoking Associated with Zolpidem: Consumers Demonstrating Their Valuable Role in Pharmacovigilance'. Mater Health Services, Brisbane, Australia, and Mr Jantima Youthapitak for his presentation entitled 'ADRs Undergoing Myelogram: A Multidisciplinary Approach' Surat-thani Hospital, Surat-thani, Thailand.

ISoP at anchor in Bournemouth

Kristina Star

It felt very fortunate to be able to attend an excellent ISoP meeting in the October sunshine in Bournemouth this year, and coming home feeling encouraged over how many dedicated and inspiring people work in pharmacovigilance. It was a tremendous scientific programme, encompassing aspects from different actors in our field. The only general regret was that there were so many matters of interest presented simultaneously that one was frustrated in having to miss important subjects.

The programme was dense, covering:

- Future challenges in pharmacovigilance
- Drug hypersensitivity
- Signal detection
- EcoPharmacovigilance
- Vaccine safety
- Pharmacovigilance in Developing countries, and Western Pacific
- Drug safety in clinical trials
- Pharmacovigilance of Herbal Medicines
- Bayesian Statistics
- Publishing a proper ADR report
- Risk management
- Communicating drug safety from a journal perspective
- Prescription Event Monitoring
- A range of clinical drug safety concerns.

The use of patient records for signal detection and in pharmacovigilance was covered during several sessions, e.g. by

- Ralph Edwards in the session 'How do we find useful signals',
- Yoonsook Lee from the National Institute of toxicological research in South Korea, using National Health insurance data,

- Victor Kiri from Pace, Parexel international, Uxbridge, Middlesex, UK presented 'A toolkit for signal detection activities using retrospective real-life data'.

One very inspiring session was about pharmacovigilance in developing countries where, among several, Professor Samira Ibrahim Islam from King Abdulaziz in Saudi Arabia talked about their experience in therapeutic drug monitoring. Very constructive work was presented with an apparent focus on patient needs.

The last to mention 'but not the least' were the poster presentations. It was amazing to go through the poster stands that portray all the research being done within our area. The serious consequences for patients experiencing well-known side-effects was well described in the poster that won the 4th prize named 'Sleep-driving, sleep eating and sleep-smoking associated with zolpidem: consumers demonstrating their value in pharmacovigilance' by Geraldine Moses and Treasure McGuire.



Marie Lindquist presents one of the poster prizes in Bournemouth

SMPV Conference

The Moroccan Society of Pharmacovigilance (SMPV) held its first public meeting in Rabat on 16th November 2007 under the theme of 'Use and mis-use of medicines'.

The day began with an inaugural address from Professor Rachida Soulaymani-Bencheikh, President of the SMPV, where she argued in favour of a global approach involving all players in healthcare with the goal of ensuring proper use of medicines in Morocco.

The Minister of Health, Mme Yasmina Baddou paid tribute to the noted work of the Moroccan Centre for Pharmacovigilance and reminded listeners of the financial cost of mis-use of drugs, for the individual as well as society.

Mme Baddou highlighted two essential points in her address: The necessity of making adverse reaction reporting obligatory, and

working to introduce new legal frameworks to redefine and optimise the role of the national commission of pharmacovigilance.

The many health professionals who attended the day profited from diverse presentations of high quality from national and international experts. Equally, young pharmacists and doctors were able to share their experiences in the area.

With illustrated presentations, the speakers brought out the damage caused by mis-use of medicines in patients. They also underlined the growth of informal channels of distribution of drugs, especially along frontiers outside normal control.

The organisers were thanked for the complete success of this day and the second scientific meeting of the SMPV is awaited eagerly.

Input module of VigiFlow provided for free

We have described VigiFlow, the web-based case management system developed by *the* UMC, in several articles in Uppsala Reports the last few years. In addition to being a complete system for ICSR (individual case safety report) management, VigiFlow offers a convenient way of submitting reports to the WHO database, Vigibase. Currently approximately 25 countries use VigiFlow for their reporting to Vigibase.

Providing national pharmacovigilance centres with software for management of individual case safety reports (ICSR) is outside of the commitment that *the* UMC has towards the WHO Programme for International Drug Monitoring. It is necessary for *the* UMC to recover investments made in developing and maintaining VigiFlow through license fees to users. The UMC has set up a fee structure that is based on the Gross National Income of the country and the level of usage of the system and its support functions. The intention is to make VigiFlow equally affordable for all countries. For commercial customers of VigiFlow prices are adjusted to the market level.

The UMC has now decided to facilitate and stimulate the use of VigiFlow for reporting to WHO by offering the module for recording of ICSR details as a free-of-charge stand-alone service. In its next version, 4.0, VigiFlow will give users the option to record individual case details and submit reports to the WHO database, without any licence fee.

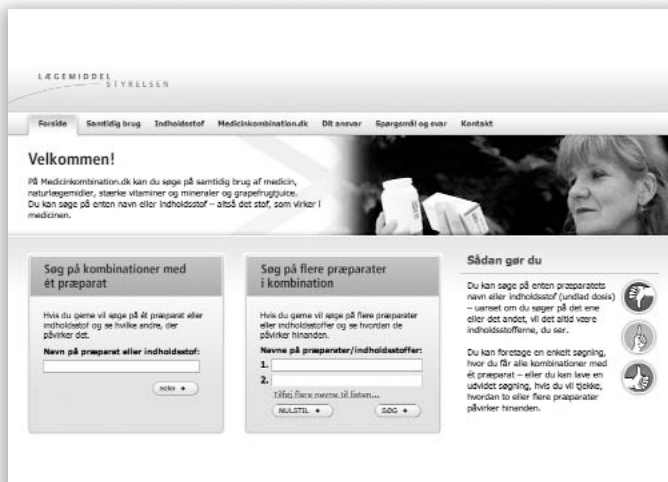
However, if the input module alone is used, VigiFlow is not a complete case management system. Functions for retrievals, listings, statistics and printing of ICSRs in the national database will not be available. Pharmacovigilance centres using only the VigiFlow input module will still be able to retrieve their case information once it is included in Vigibase, by using *the* UMC web-based data retrieval system VigiSearch.

We hope that this new option for submitting case information for *the* UMC free of charge will be appreciated by many, particularly newly-established pharmacovigilance centres with very restrained budgets.

Danish combinations prize

A fascinating Danish website has won a prize at the World Summit Awards, an initiative to promote multimedia communication and to recognise creativity and innovation in the digital field.

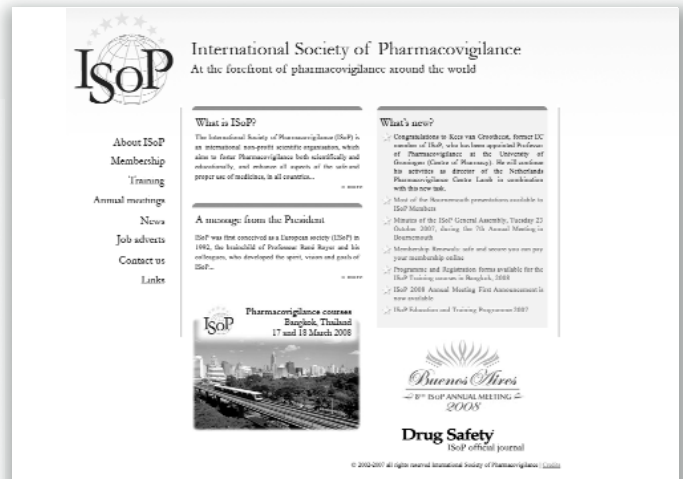
Medicinkombination.dk was selected from 650 e-services from 158 countries in November. The site, launched in June 2007, allows the public to search for information about how medicines interact with each other.



Navigation of the site is in Danish; the descriptions are based on studies that describe the results from clinical trials testing a certain medicine combination in humans. The site contains around 3,000 descriptions of medicinal combinations and includes licensed active substances and selected herbal remedies and strong vitamins and minerals. The aim of Medicinkombination.dk is to simplify complex information about how various medicaments interact, thereby making it comprehensible to all. The search results have symbols that clearly indicate whether a combination is safe to take, whether special precautions should be taken or whether a combination should be avoided.

ISoP more on line

The website of the International Society of Pharmacovigilance (ISoP) has recently been revamped to make it more interesting both to ISoP members and other visitors.



Besides offering the history and background of the Society, all the administrative side of the Society is available, with membership applications and renewals possible over the web.

A growing number of past ISoP Annual Meeting and course presentations are accessible to members (the members section will be increased further in the coming year), and the site is now more attractive with colour pictures. www.isoponline.org

Bangkok and Buenos Aires beckon

A very busy and truly international year lies ahead for ISoP, with two parallel courses in Bangkok in March, and its Annual Meeting in Buenos Aires in October. See the conference listings on p23 for contact and information details - or visit the ISoP website!

UMC receives WHO support for improved AEFI surveillance

In UR35 (October 2006), we reported on a visit to Uppsala by a team representing the WHO vaccines safety unit and the Global Advisory Committee on Vaccine Safety (GACVS). During the discussions it was noted that reports on AEFI (Adverse Events Following Immunization) are submitted to *the UMC* only by a minority of member countries participating in the WHO International Drug Monitoring Programme and often in very small numbers. There is a need for improving the international network for exchange of case-based information on vaccine related problems. Because the WHO Programme so far has been optimized for identifying early signals related to pharmaceutical substances rather than vaccines, tools and services developed by *the UMC* are not necessarily ideal for monitoring vaccine safety. It was also identified that *the UMC* would need additional resources and competence to be able to adapt its current processes to optimally support AEFI surveillance.

As a consequence of the discussions held in Uppsala in 2006 the WHO Department of Immunization, Vaccines and Biologicals recently made a decision to temporarily provide funding for *the UMC* to allow for an improved focus on AEFI surveillance. A new position will be created at

the UMC in 2008. The professional recruited to this post will be responsible for:

- facilitating contacts between *the UMC* and the WHO vaccine safety unit, including GACVS
- helping to identify how current tools used for analysis and assessment of pharmacovigilance data (e.g., VigiSearch, VigiFlow, data mining techniques) may be optimized for application to the vaccine safety area
- assisting in developing strategies for identification of vaccine-related safety signals and liaising with vaccine experts in the review, assessment and communication of vaccine-related safety signals
- supporting national pharmacovigilance centres in addressing vaccine specific queries
- participating in training activities on vaccine safety.

An advertisement for the recruitment of a professional for the new UMC position will be widely published in early 2008 through WHO and UMC channels, e.g. *the UMC* web site.

A global strategy for pharmacovigilance

A partnership has been formed between the University of Washington (Seattle, USA) the WHO (Department of Medicines, Policy and Standards) and Liverpool School of Tropical Medicine (UK). A joint project for Development of a Global Strategy for the Conduct and Use of Pharmacovigilance has received initial funding from the Bill and Melinda Gates foundation. The project includes the following components:

- The performance of a landscape assessment of current and planned pharmacovigilance activities within defined resource-constrained settings and among other stakeholders
- Two meetings in 2008 to identify and prioritize critical challenges in global pharmacovigilance
- On the basis of the assessment and meetings, to identify the most urgent pharmacovigilance priorities for developing countries and create a full grant proposal to develop and implement a global pharmacovigilance strategy.

Principal investigator is Professor Andreas Stergachis at the School of Public Health & Community Medicine, University of Washington.

The landscape assessment of pharmacovigilance activities mentioned above will be carried out in collaboration with *the UMC*. A questionnaire will be distributed to national pharmacovigilance centres and other relevant stakeholders. The time available for performing the investigation is exceptionally short and *the UMC* requests all recipients of the questionnaire to respond as well and as quickly as possible. It will be very important for the further development of the project that analyses are based on accurate and up-to-date information which is highly representative of what is actually happening on the ground.

This project offers a unique opportunity to bring together the evidence and the expertise that is currently sparse and scattered, and make a strong case for the need for more resources for the prevention of drug-related problems and injuries globally. If prioritized many of them could be avoided.

Russia

We have been notified that in October 2007 Vladimir Lepakhin was appointed as the head of the Federal Centre for Drug Safety Monitoring, which was reestablished in Russia last year.

The contact details are:
Federal Centre for Drug Safety Monitoring
Shukinskaya str. 6,
Moscow 123182
Russia

E-mail : lepakhin@regmed.ru
Telephone : +7 499 190 49 53
Fax : +7 499 190 34 61

Professor Lepakhin's career in pharmacovigilance goes back many years; he first attended an WHO Programme meeting in 1985. He then became the vice-minister of health in the Soviet Union, later moving on to WHO. After retirement he was recruited to become an Assistant Director General of WHO.

New UMC Staff

Three new permanent staff have joined *the UMC* over the last quarter, working in different areas of the organization. We asked to them to introduce themselves...

Helena Sköld

Helena grew up on a farm near Almunge, a village east of Uppsala. After earning her MSc in Pharmacy in 2000, she worked for the Swedish Association of the Pharmaceutical Industry, where she was involved in the development of their website www.fass.se. "My last position was with the Swedish Medical Products Agency, assessing quality documentation for approval of new herbal medicines."



Currently Helena is with *the UMC's* Signal Detection team which she finds really interesting. "I can't think of anything at the moment that could top this place for the work tasks or for my colleagues – it's a really nice environment!"

Home life takes all her available spare time. "I live with my husband and our two children and two cats in a small cottage in the countryside. When we moved there a few years ago there was no running water or draining system installed – although we now have those facilities, it is still a long way to go before we can say it's finished – if ever..."

"I do enjoy 'innebandy' (floorball) and often play with others from *the UMC* – actually I used to be a semi-professional goalie and every other Thursday I put on my kit and play with a local league team".

Ola Caster

Ola comes from Eslöv in Skåne (the very south of Sweden). Although his formal job title has yet to be decided he works in the Research department with research of both a methodological type (data mining, statistics) and more clinically applied.



"I have done 9 out of 10 semesters on the Swedish pharmacist education programme (all but the practical semester) and finished a Master's degree in Pharmacy last summer. I have studied mathematics and statistics in parallel with that and finished my Master's degree in mathematical statistics this summer by writing a thesis here at *the UMC*" (see UR38 p19.)

Outside the office he has mainly two interests, "sports and music (or music and sports, I don't know really). On the sports side I play football and innebandy and of course watch lots of sports, mostly on TV (I also went to Germany last summer for the football World Cup). On the music side I listen to lots of music and I also sing in a student male voice choir."

Henrik Sahl

"I was born and raised in Uppsala and began to work at *the UMC* in November as a Sales Support Manager in the Sales and Marketing team. Together with the team I will manage client issues on a day-to-day basis and ensure that our customer's needs are met."

Henrik worked in the pharmaceutical industry for more than ten years in different positions; the last being as a Business Manager at Pfizer, Sweden. "Last year I was selected as a volunteer to Pfizer's Global Health Fellowship and helped the NGO International Trachoma Initiative with their work in Vietnam for six months. This raised my interest for working in an international organization, so when I heard about *the UMC* I felt that this would be a logical next step."



"UMC is like a meeting port and I am impressed by the mixture of people with different backgrounds and competences that are working together to achieve UMC's common goals."

In his spare time Henrik likes to work in his garden and is trying to breed Jardines parrots. "In total I have five African parrots and am a board member of *the Uppsala Tropical Bird association*."

UMC Board of Directors

The operations of the WHO Collaborating Centre for International Drug Monitoring (*the Uppsala Monitoring Centre – UMC*) are governed by an agreement between WHO Headquarters and the Swedish government. The Centre has an international Board where WHO appoints three members and three others are appointed by the Swedish government.



The UMC Board at the recent meeting deciding on plans and budget for the UMC for the coming year (2008). From left in front row: Marianne Dicander, Mary Couper, Mohammed Hassar, Ellen Vinge. Back row: Ulf Bergman, Carl Älfvåg, Lembit Rågo, Anders Rane, Norbert Paeschke.

Board members are appointed for a term of three years and from the term starting 1 January 2007 two new members were appointed; Ms Marianne Dicander Alexandersson, Head of the business unit Private Customer at Apoteket AB (the Swedish Pharmacy corporation) with



June Raine

alternate Ms Ingela Tuvegran, director at Södra Älvsborg Hospital, Borås, and Dr June Raine, Director of Vigilance and Risk Management of Medicines at the UK's MHRA, her alternate being Dr Norbert Paeschke from the German Drug Control Agency, BfArM, who for six years has served as an alternate for Professor Jürgen Beckmann, who stepped down from the board at the end of his term.

The existing members are Chairman of the Board Mr Carl Älfvåg, Director-General, Swedish Agency for Disability Policy Coordination. His deputy is Assistant Professor Ellen Vinge, clinical pharmacologist, University of Lund.

The other members appointed by the Swedish Government are Anders Rane, Professor of Clinical Pharmacology, whose alternate is Professor Ulf Bergman, both from the Karolinska Institute, Stockholm.



New board members Marianne Dicander and Ingela Tuvegran

WHO has appointed Dr Lembit Rågo (alternate Dr Mary Couper) from WHO headquarters, and Professor Mohammed Hassar from the Institut Pasteur in Morocco, with Professor Rachida Soulaymani-Bencheikh from the Moroccan Institute of Hygiene as his alternate.

Busy year ahead at *the UMC*

In wishing colleagues and friends all over the world greetings for a Happy Christmas and a healthy and prosperous New Year in 2008, staff at the Uppsala Monitoring Centre are anticipating an important and exciting year ahead:

- the 30th anniversary of *the UMC*, not to mention the 40th anniversary of the WHO Programme and the 60th of WHO itself!
- a week of major meetings in Uppsala in October – the Annual Meeting of the WHO Programme, a Research Conference and a meeting of the Signal Review Panel,
- Version 4.0 of VigiFlow and updates of our other products and services,
- a move to different offices (still in central Uppsala),
- the retirement of Ralph Edwards after 17 years as Director of *the UMC*, and the appointment of his successor

Utrecht researcher

On September 24th and 25th, Dr Patrick Souverein of the Division of Pharmacoepidemiology and Pharmacotherapy, Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University visited *the* Uppsala Monitoring Centre. After intensified collaboration in the past years, *the* UMC and UIPS signed a contract this summer that gives the latter access to Vigibase for scientific purposes. Dr Souverein is the contact person for UIPS researchers planning to



Patrick Souverein

conduct a study using Vigibase and will be responsible for Vigibase data extraction and programming.

During the two days, several aspects on conducting research with Vigibase, including linkage of the several databases, programming techniques, and potential pitfalls when conducting research were discussed. Furthermore, background information on the processes of ADR reporting and signal detection was provided.

Besides the advantage of meeting people from *the* UMC research, signal and reporting team, the visit has improved understanding of the world behind Vigibase, which is beneficial for the collaboration between *the* UMC and UIPS in general and the quality of future research projects.

Egyptian pharmacologists

At the end of October, *the* UMC was visited by Professor Ulf Bergman from the Karolinska Institutet in Stockholm and three pharmacologists from different universities in Egypt. Ahmed M Abdel-Kawab, Amin Awadin and Mohamed A Ibrahim spent a whole month in Sweden to learn about rational use of drugs and took the opportunity to visit the Swedish Medical Products Agency as well during their day in Uppsala. At *the* UMC, Anna Celén made a general presentation about pharmacovigilance, UMC activities and the



Seated from left: Mohamed Abdellah, Anna Celén, Ulf Bergman, Ahmed Abdel-tawab; standing behind: Sten Olsson, Amin Yehia

WHO Drug Monitoring Programme. Sten Olsson was also involved in the discussions which followed about different strategies of improving ADR reporting in Egypt. *the* UMC has not received any reports from Egypt since June 2003 (Egypt became a full member of the WHO Programme in 2001). The dedicated pharmacologists will hopefully be able to approach the authorities and convince them about the importance of pharmacovigilance. At *the* UMC, we are looking forward to renewed collaboration with Egypt.

Reviewer from New Zealand

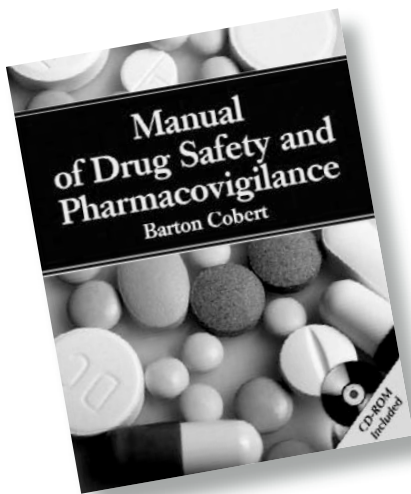
UMC had the pleasure to have one of our signal reviewers visiting the office during November. Dr Ruth Savage, a Medical Assessor and Senior Research Fellow at the New Zealand Pharmacovigilance Centre spent three weeks with us, exchanging New Zealand's spring for one of Sweden's darkest months. We had a really nice time together, doing a lot of work on terminology, for example revising the critical terms in WHO-ART, and producing signal assessments.



Ruth Savage with Kristina Star at *the* UMC

Manual of Drug Safety and Pharmacovigilance

Author: Barton Cobert
 Paperback: 292 pages
 Publisher: Jones & Bartlett Publishers (2007)
 Language: English
 ISBN-10: 0763738891 ISBN-13: 978-0763738891



Co-author of Pharmacovigilance from A to Z (2001), Barton Cobert's latest, Manual of Drug Safety and Pharmacovigilance (2007) is a comprehensive book dealing with various issues in drug safety. The book goes beyond being another drug safety encyclopaedia. It starts with the theory, practice and definitions of pharmacovigilance and takes the reader through clinical trials and its various phases, post-marketing safety, risk management, media and industry as well as regulatory stakeholders in the world of pharmacovigilance,

databases and where they can be accessed etc. It offers useful information and a practical guide to recognising, monitoring and reporting ADRs as well as where to go when faced with a drug safety issue.

Rookies to the world of drug safety as well as experienced pharmacovigilantes have something to take out of this book regardless of the professional setting (academia, industry, regulatory affairs, sales and marketing etc.)

The book comes with a free user friendly CD-ROM which offers an environmentally friendly, easy-to-carry and accessible version of the book.

This is a pharmacovigilance one-on-one worth its price.

Farmacovigilancia

Hacia una mayor seguridad en el uso de medicamentos



Luis Alesso
 ISBN 978-987-05-3343-6
 Published in September 2007, in collaboration with the International Society of Pharmacovigilance, this 300-page textbook is an important contribution to pharmacovigilance literature in Spanish with a particular focus on Latin America. It is well-referenced and contains many diagrams and tables. The aim

of this book, targeted at clinicians, general practitioners and medical and pharmacy students, is to emphasise the importance of pharmacovigilance to enhance and improve patient safety, and physician's reports, as well as stimulate spontaneous reporting, and dismiss the misconception that pharmacovigilance is unfeasible in developing countries.

The authors aim to "a contribution to understanding of pharmacovigilance, through its history, fundamentals, concepts and methods", international approaches, and a detailed look at drug safety in Argentina, including public health and industry.

With a foreword by Nicholas Moore and Giampaolo Velo, this book has been co-ordinated by Luis Alesso from Córdoba National University, Argentina. Authors belong to academy and regulatory authorities from different countries, with a particular emphasis on Argentina.

Small country guides

We have also received two informative handbooks from national centres:



Pharmacovigilance in Nepal – *A guide for health care professionals*, a 30-page booklet giving the background to the pharmaco-vigilance system in Nepal (from Manipal Teaching Hospital), and



Sigurna Primjena Lijekova, a 20-page guide from Croatia adapted from the 2002 WHO guide 'Safety of Medicines – A guide to detecting and reporting adverse drug reactions'.

Latest WHO Drug Dictionaries News

The WHO Drug Dictionaries continue to move forward, increasing their coverage of medicinal product information. In December 2007 the dictionaries contained:

- 193,189 unique names
- 1,154,731 different medicinal products, trade names with for example form and strength information added
- 9,950 different ingredients mentioned in these products

The WHO Drug Dictionaries are used by pharmaceutical companies, contract research organisations and drug regulatory authorities for identifying drug names, their active ingredients and therapeutic use, in the course of their drug safety surveillance.

In 2008 a number of new developments will be available for users of the WHO Drug Dictionaries.

The most important issue in the development of the dictionaries is to find tools to simplify the coding of non-unique names, drug names that for different reasons appear with different active ingredients in the dictionaries. The most important reason is that a trade name is used in different countries and with different active ingredients. *the UMC* is currently reviewing these entries in order to identify entries that may no longer be on the market, and also to identify any unnecessary non-unique entries. The result of this will be a reduced number of non-unique names and tools to identify entries that no longer are on the market. We hope that this will facilitate coding.

The WHO Drug Dictionary Browser

Launched in 2006, the WHO DD Browser enables direct access to all the features in the Dictionary and is available over the internet. It can also supplement a current system which may not have the search capabilities to fully utilize the functionality offered in the browser. You simply enter text verbatim using the browser to search for the entries you need – it's that easy. Straightforward searches and more complicated ones are both simplified using our Drug Dictionary Browser.

The WHO DD Browser will help you to:

- find 'same name' drugs with different ingredients, listed with a code added to the name in the dictionary B-2 format. The Browser then helps you code the correct entry
- search on the active ingredients of concomitant drugs for generic and trade names.

When you find what you're looking for in the Browser, you can use it to:

- code your clinical data or case reports
- understand the active ingredients of the product you've looked up
- understand what the ATC codes mean and differentiate between products that have several codes in the interactive tree in the ATC hierarchy.

Influence Drug Dictionary development

In September 2007 all User Group members were invited to participate in a poll that would assist prioritization of future development of the Dictionaries.

Based on this poll the issues to be developed for 2008 have been selected, being seen as important and urgent in the poll result, and that require little or no investigation.

The remaining issues will be investigated further in various feasibility studies. In order to get more information about these issues a new, slightly modified poll has been produced. We would appreciate if you could take your time to participate in the new poll – influence the future of the WHO Drug Dictionaries!

The documents that describe the different issues are available on our User Group portal. In order to participate in the poll, please follow this link:

www.zoomerang.com/survey.zgi?p=WEB2276N9U9G5

The poll will close on February 29, 2008.

If you have queries or need more information, you can best contact the WHO Drug Dictionary Team at drugdictionary@umc-products.com.

Meet the team!

UMC staff are planning to attend the following conferences in 2008:

- DIA 11th Annual Workshop in Japan for Clinical Data Management, Tokyo, Japan, January 31–February 1, 2008
- 20th Annual DIA Europe Meeting, Barcelona, Spain, 3–5 March 2008 (Booths 215 & 216)
- 23rd Annual DIA Data Management in Transition, Washington DC, USA, 16–18 March, 2008
- IIR CRO Partnership 12th Annual EDC & Beyond, Las Vegas, USA, 14–16 April, 2008
- ACRP 2008 Global Conference & Exhibition, Boston, USA, 25–29 April, 2008 (Booths 500 & 502)
- Annual DIA meeting, Boston, USA, June 2008
- SCDM, Dallas, USA, October 2008.

We look forward to seeing many customers at one of these; if you wish to arrange a meeting, please contact Mats Persson, Sales and Marketing, e-mail mats.persson@umc-products.com, or Annika Wallström, Business Development, e-mail annika.wallstrom@umc-products.com.

COURSES & CONFERENCES

DATES	TITLE	PLACE	ORGANISER/CONTACT
30 January - 1 February 2008	Medical Aspects of Adverse Drug Reactions	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
4-5 Feb 2008	Post-Marketing Studies	London, UK	Center for Business Intelligence www.cbinet.com E-mail: cbireg@cbinet.com
11 Feb 2008	Periodic Safety Update Reports	London, UK	Management Forum Ltd Tel: +44 (0)1483 730071 Fax: +44 (0)1483 730008, www.management-forum.co.uk
27-28 February 2008	Monitoring Safety in Clinical Trials and Drug Development	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
3-5 March 2008	20th Annual DIA EuroMeeting	Barcelona, Spain	DIA Tel: +1 (215) 442 6100 Fax: +1 (215) 442 6199 E-mail: dia@diahome.org
10 - 12 Mar 2008	Advanced Pharmacovigilance	London, UK	Management Forum Ltd Tel: +44 (0)1483 730071 Fax: +44 (0)1483 730008 www.management-forum.co.uk
17 and 18 March 2008	Pharmacogenomics and patient safety	Bangkok, Thailand	International Society of Pharmacovigilance Tel/Fax: +44 (0) 203 256 0027 E-mail: administration@isoponline.org www.isoponline.org
17 and 18 March 2008	Basic concepts in Pharmacovigilance	Bangkok, Thailand	International Society of Pharmacovigilance Tel/Fax: +44 (0) 203 256 0027 E-mail: administration@isoponline.org www.isoponline.org
2-3 April 2008	Back to Basics in Pharmacovigilance	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
9-11 April 2008	P2T Congress, including XXIXèmes Journées de Pharmacovigilance	Clermont Ferrand, France	Société Française de Pharmacologie et de Thérapeutique www.congres-p2t.fr
26-29 April 2008	The International Society for Pharmacoepidemiology (ISPE) 2008 Mid-Year Meeting	Boston, USA	International Society for Pharmacoepidemiology Tel: +1 (301) 718 6500 Fax: +1 (301) 656 0989 E-mail: ispe@paimgmt.com www.pharmacoepi.org
11-12 June 2008	Periodic Safety Update Reports (PSURs)	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
22-26 June 2008	DIA's 44th Annual Meeting	Boston, USA	DIA Tel: +1 (215) 442 6100 Fax: +1 (215) 442 6199 E-mail: dia@diahome.org
2-3 July 2008	Introduction to Pharmacoepidemiology	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
17-20 August 2008	24th International Conference on Pharmacoepidemiology & Therapeutic Risk Management	Copenhagen, Denmark	International Society for Pharmacoepidemiology Tel: +1 (301) 718 6500 Fax: +1 (301) 656 0989 E-mail: ispe@paimgmt.com www.pharmacoepi.org
24-25 September 2008	Critical Appraisal of Medical and Scientific Papers: How to read between the lines	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
6-8 October 2008	8th Annual Meeting of ISoP	Buenos Aires, Argentina	International Society of Pharmacovigilance Tel/fax: +44 (0)20 3256 0027 E-mail: administration@isoponline.org www.isop2008.org



the Uppsala Team

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Helena Sjöström, Pharmacist **Safety Reporting**

Helena Sköld, MSc Pharm **Signal Detection**

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