

# Report from the WHO Collaborating Centre for International Drug Monitoring • Activities July 2007 - June 2008

## 1. Introduction

The activities of the WHO Collaborating Centre for International Drug Monitoring (also called the Uppsala Monitoring Centre, UMC) are based on an agreement from 1978 between the World Health Organization and the Swedish Government and updated in December 2001.

The Centre is a foundation headed by a board of six members with personal deputies, three appointed by the Swedish government, three appointed by WHO. The board was in January 2007 reassigned for a new three-year period. Chairman of the board is Mr Carl Älfvåg, Director General at Handisam (Swedish Agency for Disability Policy Coordination), Stockholm, Sweden.

## 2. Administration

Director of the Centre is Professor Ralph Edwards. The Centre was in the autumn of 2006 reorganized into one unit, from the earlier two divisions. Marie Lindquist is General Manager, Chief Scientific Officer and Deputy Director. UMC is organized into six departments, each headed by a manager; Finance and Core Services (Birgitta Toreheim), External Affairs (WHO Programme) (Sten Olsson), Production, Development and Quality (Johanna Eriksson), Safety Support and Services (Monica Plöen), Research (Andrew Bate) and Marketing (Annika Wallström).

The organization is managed by a Steering Committee for strategic planning and an Executive Committee for the day-to-day management. The Executive Committee (EC) consists of the Director, the General Manager, the Deputy Director and the department Managers. Dr Ronald Meyboom served as a medical adviser to the Centre working part-time at the UMC. At the end of the period UMC had around 55 employees, whereof five were on parental or study leave.

Funds for operation of the Centre, in the order of 70 million Swedish Kronor, were raised through the provision of products and services to paying clients. Supply of the WHO Drug Dictionary to the pharmaceutical industry accounted for approximately 85% of these receipts. Other income sources are training and other services and consultancies to paying customers.

## 3. Member countries

Only one country, Togo, became a full member of the WHO Programme during the period of this report, taking the total to 84. However, a large number of new associates, awaiting full membership status, set up contact with the UMC: as well as several larger countries in Africa, island states belonging to the Organisation of Eastern Caribbean States made a joint application in May.

## 4. Adverse reaction reporting

Due to development and testing of the new report import process, there was a delay in the insert of the reports to Vigibase. The new report import routine was taken into use in late October 2007 and the backlog of E2B-cases was prioritized for insertion into Vigibase. The total number of processed Individual Case Safety Reports (ICSR) that were correct in format and accepted by the system of the E2B cases during October 2007 to June 2008 was 243 070 (include cases from 30 out of 84 member countries). Countries that submitted their ICSR in the old INTDIS format during the period are still on hold, since the new import process first requires the case reports to be converted into E2B, which facilitates the validation of the cases. INTDIS cases will start to be inserted into Vigibase in October 2008.

By the end of June 2008 the mile stone of 4 million case reports was reached, meaning that 4.11 million cases were active in Vigibase and searchable via Vigisearch.

## 5. Feedback of information to National Centres

### 5.1 Output from Vigibase

Case reports submitted to the UMC are usually screened every three months. For this period (1 July 2007 to 30 June 2008) this process was performed 3 times, due to the implementation of a new report processing routine.

The screening results in the creation of the Combinations Database. This database consist of all drug - ADR combinations reported to the UMC during the past quarter and provide different kinds of quantitative information, for example IC values (a statistical measure of the strength of the relationship in a drug-ADR combination).

The Combinations database was distributed to all National Centres in August 2007, April 2008 and July 2008. Through additional filtering steps, drug-ADR combinations were selected and sent for clinical review to experts within the UMC Review Panel (see 5.5 below).

Member countries are also provided quarterly with updates of the WHO Drug Dictionary and WHO-ART in computer files.

### 5.2 Newsletters

The UMC contributed background information for the WHO Pharmaceuticals Newsletter produced by the QSM team at WHO Headquarters. This publication is distributed to drug information officers in WHO member states and other interested parties around the world, either electronically or printed. It is also available from the WHO web site. Five issues were published during the period.

An agreement with Adis International Inc, publisher of the journal Reactions Weekly, allowed National Centre members of the WHO Programme to subscribe to Reactions Weekly at a reduced rate through the UMC. As part of the deal, the UMC provides Adis with newsletters from National Centres. Through the UMC/Adis partnership National Centres get access to newsletter information and review of drug safety literature from approximately 6000 biomedical journals on a weekly basis. the UMC also contributes to Reactions Weekly with summary information from Vigibase on drug adverse reactions referenced in Reactions Weekly, that are published in literature for the first time.

The Uppsala Reports newsletter is intended for all people concerned with issues of pharmacovigilance. Uppsala Reports gives general information about developments within the WHO International Pharmacovigilance Programme and other activities the UMC is involved in, not related to individual drug safety issues. A message from the Director often stimulates lively debate. This publication is provided free of charge to more than 3,000 recipients worldwide and is also published on the UMC website. Uppsala Reports was published in July and October 2007 and January and April 2008. Major articles focused on feedback from the survey of National Centre needs and post-marketing drug safety activities in the USA, and several articles describing several important changes to data management systems at the UMC. A reader survey was included with Uppsala Reports 40.

### 5.3. Services provided via electronic media

The Centre operates an e-mail address list 'Vigimed'. This list allows e-mail messages to be sent to one address for distribution to all members of the Vigimed list. Vigimed is used for rapid distribution of drug safety alerts and general requests for information related to specific cases. The Vigimed listserver had 353 members from 99 countries by the end of the period. During the year around 310 messages, a decrease of 25% from last year, were shared via the Vigimed mailing list. Topics raised also created many exchanges directly between Vigimed members, not shared with the whole group.

The Centre has continued with regular updating of its home page on the Internet ([www.who-umc.org](http://www.who-umc.org)), with considerable information about the WHO Drug Monitoring Programme, the Uppsala Monitoring Centre and on-going activities. The Products and Services department of UMC maintains a separate website to benefit customers of UMC's commercial products and services ([www.umcproducts.com](http://www.umcproducts.com)).

Vigisearch is a free web-based service for national centres to retrieve information from Vigibase. By the end of the report period 67 countries had requested and received access to this tool.

#### **5.4. Ad hoc retrievals for National Centres**

In addition to on-line searches made by National Centres, requests for ad hoc retrievals in the database continue to reach the UMC. The investigations requested are often of such a complexity that they cannot be managed using the on-line retrieval software. From July 2007 - June 2008 the Centre performed 32 special database investigations for national centres and an additional 15 searches for reviewers and other non-paying customers.

#### **5.5 Detection and analysis of adverse reaction signals**

The UMC has a panel of volunteer consultants to assist in the analysis of potential adverse drug reactions. The Review Panel consists of more than 40 clinical experts from 23 different countries.

Evaluations considered to be signals are presented in the SIGNAL document and circulated to National Centres, Review Panel members and individuals identified by National Centres as legitimate recipients of the document.

During the period, two issues of the SIGNAL document were produced and sent to approximately 230 receivers. To encourage a healthy debate, extracts from the SIGNAL document were made available to international pharmaceutical companies that could be identified as uniquely responsible for the concerned drugs. In total 15 invitations to comment has been sent out and that resulted in 9 responses that have been published in connection to the texts in the Signal document.

### **6. Other collaboration with WHO headquarters, Geneva**

#### **6.1 WHO Public Health Programmes**

The WHO Immunization, Vaccines and Biologicals (IVB) programme has established a Global Advisory Committee on Vaccine Safety (GACVS). This committee has recommended WHO to increase its efforts in improving reporting and analysis of information on vaccine safety globally. Discussions between WHO-IVB and the UMC resulted in the signing of a formal collaboration agreement. As an immediate consequence of the agreement the UMC started the process of recruiting a vaccine safety expert to the UMC, financially supported by WHO. Efforts will focus on safety monitoring of newly pre-qualified vaccines and methodological development for signal identification and analysis of AEFIs from Vigibase. The UMC also provided the GACVS committee with analyses of Vigibase data on specific vaccines on demand. The UMC was also involved in the WHO planning for safety follow up of vaccines to be used in the event of an avian flu pandemic.

The UMC was represented at a meeting in Geneva, organized in March 2008 by the WHO HIV/AIDS department, focusing on definitions to be used in pharmacovigilance activities.

#### **6.2 WHO Advisory Committee on Safety of Medicinal Products**

The Quality and Safety: Medicines team at WHO, Geneva, has established an Advisory Committee on Safety of Medicinal Products (ACSoMP). The committee had its fifth meeting 25 – 27 February, 2008, with R. Edwards, S. Olsson and M. Lindquist representing the UMC. A wide range of items were discussed including interactions between pharmacovigilance and public health programmes, indicators for the performance of pharmacovigilance centres, the scope of the WHO ICSR database, problems related to specific medicines and various definitions.

#### **6.3 Patient Safety**

In partnership with the World Alliance for Patient Safety, the Moroccan Pharmacovigilance Centre and WHO Quality Assurance & Safety: Medicines, the UMC carried out a patient safety pilot project which was completed in early 2008. The UMC analysed data in Vigibase and longitudinal patient data from IMS Health for indicators of medication errors including interactions and contraindicated drug combinations. Several potentially serious patient safety issues were identified. The project also demonstrated the potential for national pharmacovigilance centres to improve the collection of relevant patient safety information.

## **7. Support to development of National Centres and UMC visits**

UMC staff members made site visits working with representatives of national pharmacovigilance systems as follows:

- Argentina (A Celén)
- Italy (R Meyboom)
- Costa Rica (E Sollenbring)
- Viet Nam (S Olsson)
- Tanzania (S Olsson)
- Namibia (R Edwards and S Olsson)
- PR China (S Olsson)

## **8. Training in pharmacovigilance**

The International Pharmaceutical Federation (FIP) held its annual world congress in August 2007 in Beijing, China. For the third time the congress was preceded by a 2-day workshop on pharmacovigilance and patient safety to which a UMC representative again contributed as a faculty member.

The national Chinese pharmacovigilance programme organized a Pharmacovigilance Training Course in Beijing, August 2007, for participants of the 31 regional centres. UMC contributed to this training. The UMC provided core input to the first ever pharmacovigilance training course in Laos which took place from 19-21 November 2007 in Vientiane.

A National Pharmacovigilance Workshop in Abu Dhabi, United Arab Emirates, in December 2007, also including participants from Saudi Arabia and Oman, involved WHO Geneva and the UMC.

A pharmacovigilance training course was organized by the International Society of Pharmacovigilance (ISoP) in Bangkok, Thailand in March 2008 with faculty members from the UMC.

In connection with the inauguration of the Namibian Therapeutic Information and Pharmacovigilance Centre, May 2008, a pharmacovigilance training course was held in Windhoek. UMC was represented in the faculty.

A follow-up training for pharmacovigilance consultants in Africa were carried out in Accra, Ghana in June 2008 with participation from the UMC.

The collaboration between the UMC and the Department of Toxicology, University of Uppsala, in providing a five-week undergraduate course on drug safety and pharmacovigilance to pharmacy students continued. The course was given in November 2007 and again in February 2008.

## **9. Release of adverse reaction information to external inquirers**

Since the WHO 10th International Conference of Drugs Regulatory Authorities (ICDRA) meeting in Hong Kong, 2002 recommended: 'Opening access to the WHO database to all stakeholders with a genuine public health interest and ability to evaluate such case information', case information from all countries participating in the WHO Programme is released to any inquirer fulfilling these criteria.

A considerable demand for database investigations is directed to the Centre from investigators in industry, academia and consumer organizations. Centre staff responded to 105 requests for database retrievals during the period. The inquirers were provided with the results together with the agreed 'Caveat Document'.

## **10. Development of computer support systems**

The scope of the Vigibase development plan is to support fast and reliable reporting of Individual Case Safety Reports (ICSRs) into the database, and to maintain and secure the data for short- and long-term accessibility for analysis and data-mining in compliance with regulations and good information management. Internal efficiency, the infrastructure and work process at the UMC, are

areas where we constantly seek improvements to gain resources for support to develop national centres and for training within pharmacovigilance.

The focus for development of computer support systems for the last year has been concentrated on securing a stable high-quality production environment for all Vigibase operations; from the processing of received ICSRs (Individual Case Safety Reports) into the database, to extraction of data into the WHO Drug Dictionary Enhanced. Attention has also been directed to improving the performance of the search and analysis tools, as well as enhancing search functionality and adoption of the MedDRA terminology in Vigibase.

VigiFlow 4.0, released in June, has been developed into a complete ICSR management tool, with improved functionality as a multilingual user interface, E2B import module, extended E2B export module, a submission manager, address book and a new administrative information module. For the same release a 'limited access' version of VigiFlow was launched, free of charge for WHO Programme members. The 'limited' version is primarily a reporting tool for sending ICSRs to the UMC and should not to be seen as an ICSR management tool.

Other achievements during the year were an improved WHO DD Browser: new features have been added to the search module, plus a function to filter search results. In an additional DD Browser module, it is now possible to browse both the latest version of the Dictionary as well as old versions. The development of VigiFlow and the DD Browser follow the GxP validation routines.

## 11. Terminologies

### 11.1 WHO Drug Dictionaries

The WHO Drug Dictionaries have over the past years become de facto standards for coding medicinal products. The general globalisation and the pharmaceutical companies increased outsourcing of many activities to Asia especially to India and China has put high demands on the dictionaries to provide a global coverage.

The collaboration between the Uppsala Monitoring Centre and IMS Health made it possible for UMC to introduce the WHO Drug Dictionary Enhanced. This dictionary (introduced 2005) contains information from nearly 100 countries among them India and China and covers nearly 100% of the products used in each country.

The total amount of data in the dictionaries is currently

- 194 885 unique names
- 1 472 631 different medicinal products, trade names with for example form and strength information added
- 10 049 different ingredients mentioned in these products

The WHO Drug Dictionaries are developed and maintained according to a strict quality assurance process to secure content and quality. The ATC classifications are regularly revised and updated.

The Uppsala Monitoring Centre and WHO Drug Dictionaries were represented at many conferences such as DIA, ISPOR and ISPE which provides opportunities to meet with subscribers to increase awareness and optimise the use of the dictionaries.

A specific project was initiated together with the Chinese drug authority, SFDA. One of the objectives with this project is to further increase the number of Chinese drugs included in the dictionary both western type medicines and traditional Chinese medicines.

The WHO Drug Dictionary Enhanced has rapidly become the UMC's leading product and more than 80 % of the commercial subscribers are now it. The National Centres are offered both products, the WHO Drug Dictionary Enhanced and the WHO Drug Dictionary, but many have chosen to remain with the WHO Drug Dictionary.

### 11.2 Adverse Reaction Terminology

The WHO Adverse Reaction Terminology (WHO-ART) is maintained by UMC and developed in English. Due to lack of resources, only the Spanish translation has been kept updated, the other languages being: French, German, Portuguese and Italian. WHO-ART is produced four times a year

and sent on CD or as e-mail attachment. The files are from 2008 not sent to ICH countries and countries using VigiFlow for reporting to UMC, other than by request. It has not been possible to produce the printed version during the last year.

Since July 2007, 61 new terms have been included in the WHO-ART hierarchy, 29 of these being preferred terms. 43 changes have been made, mainly through a reorganization of terms some groups of terms.

In co-operation with the MedDRA MSSO, links from WHO-ART Preferred terms to MedDRA have been created. The first release from UMC of this WHO-ART to MedDRA mapping was made in March 2007 to both national centres and commercial customers of WHO-ART, and an update was released in March 2008. The WHO-ART – MedDRA bridge will be updated annually.

Since the MedDRA adverse reaction terminology is used in major reporting countries (and is now required in the E2B), the MedDRA MSSO has requested that MedDRA be introduced into the WHO adverse reactions database alongside WHO-ART. Mapping from all WHO-ART terms to MedDRA and vice versa has been done. A project to validate the correctness of the mapping is on-going, partly with the help of UMC Signal reviewers.

The list of critical terms, a concept that is unique to WHO-ART, was updated in release 1, 2008 of WHO-ART.

A number of companies and other institutions outside the WHO Programme continue to use WHO-ART in their drug safety work. There are 19 companies subscribing to updates to WHO-ART.

## **12. Research and development**

The Research and Development team continues to further improve the UMC's data mining techniques on Vigibase, and, in addition to the detection of novel adverse effects of drugs, its application to vaccine screening, drug-drug interactions and detection of patient safety issues. Method development includes pattern recognition methods, improved stratification techniques and the implementation of state-of-the-art regression techniques.

Tools using the data-mining methods are becoming more of a routine in the UMC's internal processes. The research team has successfully demonstrated proof of the concept of useful screening electronic patient records using the IMS Health Disease Analyzer data set longitudinal patient records.

Presentations at many international meetings in Europe, Asia and North America continue to raise awareness of the UMC's leading work in this area. Further papers describing UMC were published or were under review during the period, as well as several applied issues detected from analysis of Vigibase.

## **13 Co-operation with other organizations**

### **13.1 IMS Health**

The links with IMS Health have been strengthened and broadened considerably over recent years. This is due to an expanded vision in IMS Health which includes more emphasis on value for global public health. The current collaboration focus for WHO Drug Dictionary Enhanced, with data contributed by IMS Health, is toward more in-depth information on products as well as filling some gaps in terms of detail of information in medicines covered.

### **13.2 International Conference on Harmonization (ICH)**

M5 – Data Elements and Standards for Drug Dictionaries/E2B - Data Elements for Transmission of Individual Case Safety Reports

Following a decision in 2006 by the ICH Steering Committee, a new cooperation is in place with the International Standardisation Organisation (ISO) to develop ICH proposed standards into fully international ISO standards. Currently ICH M5 (standards and data elements for drug dictionaries), and E2B (electronic transfer of Individual Case Safety Reports (ICSRs)) have been referred to ISO

for development, including the definition of the technical formats for data exchange, and a maintenance process for the resulting terminologies.

ICH participants are well represented in the ISO task force teams, and the activities relating to M5 and E2B have been limited mainly to monitoring ISO progress.

### **13.3 European Union (EU) / European Medicines Evaluation Agency (EMA)**

As a result of several consultations held in 2007 with representatives from EU/EMA Marie Lindquist from the UMC was invited to a meeting held in January 2008 with representatives from EMA and some European regulators. At this first meeting a discussion took place on how to harmonize activities with the regional pharmacovigilance network organized by the European Union and coordinated by the EMA, in particular how to improve the ICSR reporting efficiency from European countries to the UMC. Currently, the countries in Europe have to send their reports to EMA and the UMC using separate pathways, and it was strongly felt that it should be possible to reach a solution whereby reports are sent only once, to a focal point, from which they can be forwarded to both EMA and the UMC. EMA are currently looking into the possibilities of using their IT gateway for this purpose.

Other topics for possible discussion at future meetings include the issue of openness and transparency of information, and general cooperation in the pharmacovigilance area.

### **13.4 International Organization for Standardization (ISO)**

For a several years, ISO has included several work items in the pharmacovigilance area, as part of the Technical Committee (TC) 215 Working Group 6: Pharmacy and medicines business. WHO has voting rights in Working Group 6 as an ISO liaison partner. Marie Lindquist has attended several ISO meetings in 2007 and 2008, as the WHO representative.

In 2007, two new ISO task forces (sub-groups to the Working Group 6) were formed to develop standards based on ICH business requirements. Apart from a strong attendance by ICH working group members, the new ISO task forces include representatives from the wider health care area. Marie Lindquist represents WHO in the task force groups, with a special focus on the work items relating to medicinal product identification standards. The work has proceeded, albeit slower than anticipated, resulting in draft standard proposals which will be voted on in October 2008. The ICSR task force has had close collaboration in particular with the US health care standards organisation, HL7, which is a partner with ISO in these developments (together with the European standards organisation CEN). A separate group including members of the two task forces has also developed a proposal for a maintenance process for the resulting standard medicinal product terminologies. It is intended to ask candidates for maintenance organisations to respond to a "call for expressed interest" which is expected to be go ahead later in 2008.

The possible role of the UMC as a maintenance organisation for future ISO medicinal product standard terminologies, or parts thereof, must be considered carefully, given that both the scope, and the level of detail required, have increased with the input from non-ICH parties. Also, the proposed maintenance process is very complex and might have a negative impact on the UMC's ability to maintain and develop the WHO Drug Dictionaries for its current customers, including the members of the WHO Programme, according to these users' needs.

## **14. Meeting of representatives of National Centres**

The 30th Annual Meeting of representatives of National Centres participating in the WHO Programme was held in Buenos Aires, Argentina, from 11-13 October 2007 with over 100 delegates from 38 countries. Simultaneous translation was provided (English/Spanish) for some sessions. WHO Headquarters made a report of the meeting available early 2008. Major themes were:

- Making pharmacovigilance better understood among stakeholders and encouraging greater political and financial support
- Broadening the scope of pharmacovigilance
- Crisis preparedness

Two sets of workshops examined: Opening the WHO database, which fields to be open to the public?, Proposal to open access to the Signal Document, How to get information from and to end-users (patients), Identifying risks in special populations – women and children, Communication and Crisis Management in Immunization and Other Health Programmes, Complementing spontaneous reporting with other methodologies, e.g. Cohort Event Monitoring (CEM). An account of the working group sessions and their recommendations may be found in WHO Pharmaceuticals Newsletter No 5, 2007 p7-10.

## 15. Publications

Scientific publications from the Uppsala Monitoring Centre during the period are given in Appendix 1.

## 16. Other presentations and meetings

Representatives of the WHO Collaborating Centre were invited to present research papers, the activities of the WHO Drug Monitoring Programme and related subjects at various meetings and conferences not mentioned above:

- National Chinese Pharmacovigilance Programme, Beijing, China, August 2007 (S Olsson)
- ISPE conference, Quebec, Canada, August 2007. Poster presentation (N Norén, J Strandell)
- ISO P Annual Scientific Meeting, Bournemouth, UK, October 2007 (R Edwards, M Lindquist, K Star, R Meyboom)
- Second International Seminar on ethics in the theory and practice of clinical drug evaluation, Beijing, China, November 2007. (B Hugman)
- The future of pharmacovigilance, Washington DC, USA, January 2008 (R Edwards)
- DIA Europe annual conference, Barcelona, Spain, March 2008 (A Bate)
- DIA Contemporary Pharmacovigilance and Risk Management Strategies, Washington DC, USA January 2008 (A Bate)
- Basic course in Pharmacovigilance (ISO P), Bangkok, Thailand, March 2008 (M Lindquist)
- Spring meeting, Swedish Society for Medical Statistics, Malmö, Sweden, April 2008 (N Norén)
- PHRMA data mining conference, Washington DC, USA, June 2008 (A Bate)
- 3<sup>rd</sup> Annual Pharmacovigilance & Risk Management, London, UK, June 2008 (J Hopstadius)

## 17. Visitors to the UMC

- Pakawadee Sriphiromya and Sareeya Wechwithan, pharmacists from the Thai FDA visited in September 2007.
- In September 2007 Mary Murray and Andrew Gilbert from the University of Adelaide, Australia held discussions with UMC staff, mainly concerning longitudinal patient records.
- Gurumurthy Parthasarathi from JSS College of Pharmacy, Mysore, India spent a week at the UMC in September 2007.
- In relation to the UMC–Utrecht collaboration Patrick Souverein of the Utrecht Institute of Pharmaceutical Sciences, Netherlands visited in September 2007.
- Professor Ulf Bergman, Karolinska Institute Stockholm accompanied by Ahmed M Abdel-Kawab, Amin Awadin and Mohamed A Ibrahim from different universities in Egypt came to learn about the WHO Programme in October 2007.
- Patrick Zuber, recently moved to the Quality Safety and Standards (QSS) team of the WHO Department of Immunization, Vaccines and Biologicals made a fact-finding visit in January 2008.

- February 2008 saw a visit from Takuya Noro, Dr Hideto Yokoi and Dr Tetsuya Kusakabe (Deputy Director, Safety Division) Ministry of Health, Labour and Welfare (MHLW), Japan to discuss problems on compatibility of Japanese language characters with the WHO database.
- Executive director of the RaPID pharmacovigilance initiative Paul Lalvani spent three days discussing the initiative and learning about VigiFlow in February 2008.
- Dr Andy Stergachis, Professor of Epidemiology and Global Health, University of Washington, Seattle visited in February 2008 in relation to the global strategy for pharmacovigilance.
- Dr Martin Kulldorff from Harvard Medical School in the USA made a presentation on statistical methods on 29th February 2008.
- A group of staff from the WHO Collaborating Centre for Drug Statistics Methodology in Oslo spent two days discussing terminologies and classification in February 2008.
- Dr John Knight, senior medical advisor of Benefit Risk Management of Johnson & Johnson Company visited the UMC on 14 March 2008 to discuss possible collaboration.
- Dr Rick Fraunfelder, Director and Associate Professor, Oregon Health and Science University, Portland, USA paid a visit on 3 March 2008.
- Former senior medical officer at the Swedish Medical Products Agency (and current UMC reviewer) Dr Ingrid Trolin, visited on 4 March 2008, talking to staff about vaccines issues.
- At the beginning of April, Nageeb Sulaiman Saeed, Director of the National Health Laboratory and Chairman of the National Poison Control Council from Sudan made a short visit to the UMC to learn about our activities.
- Dr Daniela Stanciu, chief pharmacovigilance officer at the Romanian National Medicines Agency in Bucharest, visited the UMC on 4 April 2008.
- Participants on the Karolinska Institute course 'Pharmacovigilance – Principles and Practice' came from Stockholm to spend a day in Uppsala with visits to both the UMC and the Swedish Medical Products Agency.
- In late April, Dr Kirsti Villikka, Dr Tiina Karonen, Dr Radhakrisnan Rajaratnan, Marja Forsell, Suvi Loikkanen, and Kari Salmela from the Safety and Drug Information department at the Finnish National Agency for Medicines (NAM) spent a day at the UMC.
- Lise Aagaard and Camilla Bilcher from the National Centre in Denmark came for discussions in May 2008.
- Our French collaborator Cedric Bousquet revisited the Uppsala Monitoring Centre on 29-30 May in relation to an on-going project to develop new techniques of using vocabularies for adverse reaction terminologies.
- In June the UMC was visited by Mitsuko Imai from Japan, a pharmacist who had recently started a two-year secondment at WHO HQ.
- Mirthe Pasmans, Research Institute for Psychology and Health, Utrecht University, The Netherlands, had a meeting with Signals staff in June 2008.
- Andrew Herxheimer made a brief visit to the Centre in June 2008.

**Longer-term visitors at the UMC during the year were:**

- Ruth Savage, a UMC Reviewer from the New Zealand Pharmacovigilance Centre, spent a month at the UMC in November 2007 undertaking signal work.
- Maximiliano Bergman from the Argentinean agency ANMAT spent a month at the UMC as part of an exchange, to learn about all aspects of the Centre's work.
- David Coulter, retired head of IMMP in New Zealand spent some months at the UMC in the first half of 2008 undertaking a variety of projects related to WHO-ART.

## Appendix 1

### Publications from the WHO Collaborating Centre 2007/2008

- Alj L, Touzani MDW, Benkirane R, Edwards IR, Soulaymani R. Detecting medication errors in pharmacovigilance database: Capacities and limits. *The International Journal of Risk and Safety in Medicine*, 2007, (19):187-194.
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### Thesis

Jakobsson M. Vaccine pharmacovigilance in the WHO database, in Faculty of Pharmacy, Department of Pharmaceutical Biosciences Division of Toxicology. Uppsala, Uppsala Universitet, 2008, p43.