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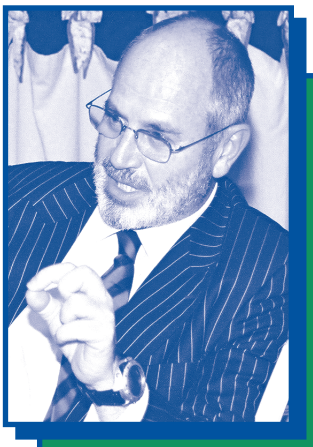
Uppsala reports

For everyone concerned with the issues of pharmacovigilance and toxicovigilance



MESSAGE FROM THE DIRECTOR

Autumn, already here in the northern hemisphere, is the season for celebration of the year's harvest of achievements.

The WHO and *the* UMC have plenty to celebrate in 2002. First, we have a new and greatly enhanced database. A version of this is available for National Centres who might wish to update to ICH E2B standard. The Swiss National Centre (Swissmedic) has been our co-developer in the project.

Second, there are several publications: **The Importance of Pharmacovigilance**; **Viewpoint** Part 1; and the long-term fruits of the Verona initiative and the Erice Declaration, **Dialogue in Pharmacovigilance**. There are guidelines for doctors on reporting, and a number of scientific papers. *the* UMC team has worked hard to achieve these goals and I thank them.

Autumn is also the season for many scientific forums, workshops and other meetings. I ask myself, how many of these contribute enough to make them worthwhile? Scientific meetings become progressively more crowded with parallel sessions, often of competing interest for me. There is usually no time for discussion; there are far too many papers with incomplete work or proposals for future work, and 'so-what?' papers: quantity up - quality down! Please, meeting organisers, make meetings purposeful and productive: none of us has the time just to meet for a chat and fly the flag. Workshops should have a explicit, achievable goal. Often discussions are dominated by one or other individual or group; important minority views are not heard or discussed. Most of these meetings are now called 'consensus meetings' and have a certain status because of that. Many meetings arrive at so-called consensus by either a form of this suppression of opinion, or political correctness. Diffidence and deference often stop people with minority views expressing them strongly. I would really value a return to meetings which publish minority views along with their supporting arguments. A grievous waste of time is drafting documents in committee. Much of this work should be done outside the committee by one person, the committees being involved only in substantive changes, not discussions over grammar!

So, meeting organisers, please make sure our time with you is well spent – purposeful, productive, interactive, valuable!

It is also the season for our Annual Meeting of Member Countries, when we look forward to seeing many of our friends and collaborators pooling their wisdom and experience and planning for the future. I trust that this year in Amsterdam, our participants will not find our activities suffering from the same faults evident in so many other meetings!

My best wishes

Ralph Edwards

End of an era!

On 31st August, Annica Lundström at *the* UMC entered the Japanese drug CONTAC SOGO KAMBOYAKU into the WHO Drug Dictionary on request from AstraZeneca. This was the last drug to be entered in the old format of the WHO Drug Dictionary (INTDIS). The first drug to be entered in the new format of the WHO DD was named Ketanest S and was entered on 21st August 2002. The request came from the National Centre in Germany, Bfarm.

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Drug Safety - hot topic at ICDRA

A report from Mary Couper

The tenth International Conference of Drug Regulatory Authorities (ICDRA) was convened by WHO in June 2002 in Hong Kong. Immediately prior to the conference a satellite workshop was held on 'The Impact of Regulation on the Safe Use of Drugs'. There were fifty-seven participants at this event representing 32 WHO Member States.

The objectives of the workshop were:

1. To discuss country experiences in pharmacovigilance and drug safety work, particularly regarding communicating with stakeholders, impact evaluation and feedback mechanisms.
2. To discuss methods for dealing with pressure from media, industry, governments and other regulatory authorities.
3. To discuss how to deal with controversial decisions and in situations where there is a lack of data, or incomplete data.
4. To identify areas of broader co-operation and data-sharing between Member States and the WHO.
5. To identify issues and gaps in drug safety in developing countries and in the case of traditional medicine and lifestyle drugs.
6. To identify and prioritise issues for discussion in the session on Safety in the main ICDRA meeting.

The workshop consisted of country presentations, technical presentations by some of the participants and staff of the WHO Collaborating Centre for International Drug Monitoring (*the* UMC), as well as plenary discussions.

Crisis Management

It was noted that, while there have been major advances in the area of pharmacovigilance and drug safety, many gaps remain, particularly in the area of communicating safety information to stakeholders. Often this can lead to a crisis. It is important that crisis management plans are prepared and practised even before a crisis takes place. Another need identified was the presence of feedback mechanisms to guide authorities as to whether their interventions have a significant public health impact.

Pressures in drug safety

The workshop also touched on the issue of pressures from stakeholders, most notably from the pharmaceutical industry. While the regulatory authorities, the pharmaceutical industry and other stakeholders share a common interest in providing safe, effective and good quality drugs in the market, friction, controversy and at times conflict still occur. This leads to the other issue of controversy in decision-making, particularly if information is not complete or unavailable. The participants agreed that greater transparency and a judicious sharing of information with the media are necessary. Lastly, the workshop tackled the issues in drug safety and pharmacovigilance,

Clive Chan (organiser), Mary Couper (WHO), Carlo Panelo (rapporteur), in Hong Kong Harbour

particularly in developing countries, where the problems of substandard generics and counterfeit drugs are prominent. The discussions also touched on regulatory gaps and challenges in the area of traditional medicines and natural health products as well as that of lifestyle drugs.

Sharing and transparency

The participants recommended that there should be more transparency and co-operation between regulatory authorities and the WHO in terms of data-sharing. Open access to the WHO adverse reactions database should be granted to all stakeholders with a genuine public health interest and with the ability to evaluate case information. It was also recommended that crisis management capacities among Member States be developed and strengthened through the help of the WHO. In relation to the International Conference on Harmonisation (ICH), it was recommended that WHO should ensure broader participation among countries. These recommendations were taken to the safety monitoring session during the main ICDRA and the full set of recommendations from that session will be published in a forthcoming issue of *WHO Drug Information*.

Largest Gathering Yet!

As we go to press, a record number of representatives from member countries of the WHO Programme for International Drug Monitoring are preparing to go to Amsterdam in the Netherlands for the 25th Annual Meeting of the Programme. Over 110 people from 51 countries in the Programme are registered to attend this important meeting.

The main topics for discussion include:

① Links between toxicovigilance and pharmacovigilance
② The need for continued monitoring of Essential Drugs
③ Drugs of current concern

along with reports on links with other international organisations and updates from *the* UMC.

Sten Olsson says "I'm delighted that so many colleagues from around the world are able join together this year for our Annual Meeting. Active participation like this in the Programme can only strengthen international efforts for drug safety and help all of us to work together."

A report on the outcomes from the Meeting will appear in *Uppsala Reports 21* next January.

Chile: Latin-American Pharmacovigilance Training Course

Cecilia Morgado-Cadiz, Head CENIMEF reports

For the second time the National Drug Information and Pharmacovigilance Centre in Chile (Centro de Información de Medicamentos y Farmacovigilancia - CENIMEF) organized a Latin American Pharmacovigilance ADR training course, from 10th to 14th June 2002 in Santiago, Chile.

There were 52 participants, who were all professionals from academia, hospitals, community pharmacies and regulatory agencies. Most Latin-American countries were represented: Bolivia, Brazil, Cuba, Guatemala, Panama, Paraguay, Peru, Uruguay, and Venezuela, with the remainder from the host country, Chile.
Course activities included lectures, seminars and workshops, with international and national experts leading these activities.

Sten Olsson from *the* UMC presented and discussed:

- Procedures to establish a National Centre,
- The WHO International Drug Monitoring Programme,
- Terminologies for coding ADRs

and

- Signal Identification.

Pharmacovigilance seminar in Cyprus

On the invitation of Dr Louis Panayi, Director of Pharmaceutical Services, Cyprus, Helena Fucik and Ronald Meyboom from *the* UMC assisted the National Pharmacovigilance Centre in Cyprus in performing an internal training session on September 27. This was followed by a seminar for health professionals on September 28. The pharmacovigilance seminar was attended by 350 doctors, pharmacists and nurses wanting to learn more about what pharmacovigilance is about, how it may add to patient safety and what professionals need to do to make the pharmacovigilance system achieve its goals. The seminar was well covered by national media.

Cecilia Morgado-Cadiz (5th from left, front row) and participants at the Santiago course

Colombia: Advanced Pharmacovigilance Course

Mariano Madurga reports

An Advanced Course on Pharmacovigilance was held in Cartagena, Colombia from 29th July-9th August 2002. Like the two previous courses, this two-week (80 hours) course was organised by the Spanish Medicines Agency. Francisco J de Abajo (Director), Dolores Montero, and Mariano Madurga from the Spanish Medicines Agency, with Albert Figueras from Foundatio Institut Catalan de Farmacologia were the training faculty.

Welcome reception during first day of course from Jose R Piqueras, CIF Director, (centre) with Mariano Madurga and Albert Figueras (right).

The course was supported by and held at the "Centro Iberoamericano de Formación (CIF)" of the Spanish Agency of International Co-operation, in Cartagena de Indias, Colombia, with the collaboration of the Pan American Health Organisation. In this marvellous city, 18 health professionals (medical doctors and pharmacists) from eleven Latin-American countries received training in pharmacovigilance skills and pharmacoepidemiological methods. Through a set of practical cases, all steps of the pharmacovigilance process were covered: risk identification, risk quantification, and risk management (decision-making process, measures to be taken and risk communication).

Last day of the course. From left to right: Camilo Jimenez (Colombia), Marco Ojeda, Teresa Montalvo and Eduardo Zea (Ecuador), Janeth Zenteno (Bolivia), Jetty Murillo (Costa Rica), Omar Segura (Colombia), Jose A. Palma (Mexico), Dolores Montero (Spain), Erika Unfried (Costa Rica), Edgard Narvaez (Nicaragua), Francisco J. de Abajo (Spain), Indira I. Credidio (Panama), Ninoska M. Somarriba (Nicaragua), Carmen Orihuela (Peru), Luisa H. Valdivieso (Venezuela), Angel D. Guzman (Guatemala), Herbert L. Diaz (El Salvador), Leticia Vargas (Guatemala) and Pedro N. Capllonch (Republica Dominicana)

During the course participants also described actual pharmacovigilance activities in their countries. Currently, some Latin-American countries such as Costa Rica, Peru, and Venezuela have joined the WHO Programme, whereas others such as Bolivia, Guatemala, and Panama are actively preparing to join the Programme in the near future. The rest of the participating countries, Colombia, Ecuador, El Salvador, Nicaragua, and Republica Dominicana, are making their first steps on the way.

During discussion of practical cases. From left to right: Indira I. Credidio (Panama), Ninoska M. Somarriba and Edgard Narvaez (Nicaragua), Jose A Palma (Mexico), Leticia Vargas and Angel Guzman (Guatemala) with Mariano Madurga (Spain).

All participants expressed their interest in exchanging their experience and information in this field through the network (Red Iberoamericana de Farmacovigilancia) that was created at the course held last year in Antigua, Guatemala (described in UR16).

New Associate Member: Guatemala

Guatemala applied for membership of the WHO Drug Monitoring Programme in July 2002.

Contact person is Dr Helbert Saenz, Ministerio de Salud y Asistencia Social, II Calle A 0 – 42, Altos de Barcenas III, Villa Nueva, Ciudad de Guatemala, e-mail: farmavig_ms@yahoo.com.

The other Associate members, still not actively contributing to the WHO database, are: Moldova, Belarus, Pakistan, Kyrgyzstan, Jordan and Bahrain. There are 68 full WHO Programme members.

Cuba – Story behind the success

Francisco Debesa, Giset Jiménez, Julián Pérez Peña, Jenny Avila, and Teresa Bastanzuri;
Centro para el Desarrollo de la Farmacoepidemiología, Ministerio de Salud, Ciudad Habana, Cuba

Grass roots network

The Cuban National Network of Pharmacoepidemiology (NNP) was set up in 1996 and consists of 175 centres located at the chief pharmacy in every municipality of the country (with more than one centre in large cities). Each centre is run by an experienced family practitioner with additional training in pharmacoepidemiology. This was provided through a specific Diploma in Pharmacoepidemiology, with a 360 hours teaching programme including clinical pharmacology, methods in epidemiology, clinical trials, drug utilization studies, and methods for benefit/risk assessment. The whole NNP is coordinated by the Pharmacoepidemiology Development Center (PDC).

Objectives

The main objectives of the NNP are
(a) disseminating accurate problem-oriented therapeutic information among health professionals,
(b) implementing continuing education activities on drug therapy
(c) carrying out research on drug utilization, and
(d) promoting educational and administrative interventions aimed at improving drug prescription and use.

One of the general objectives of the PDC was to establish an efficient system of pharmacovigilance in the country, and for this we created a new structure, more functional for the collection of the ADR reports using the Internet.

Structure of the system

The structure of the national pharmacovigilance system is:
Pharmacovigilance Coordinating Unit, within the current structure in PDC. This Unit was created in 1999, and its functions include:

- To coordinate the activity of the provincial centres of pharmacovigilance
- To define, design and develop the systems of treatment of the information and create the central national database
- Suspected ADR signal generation
- Analysis of all issues around the signals, particularly confirmation (or refutation) of hypothesis and estimation of risks size
- Evaluation of risk-benefit
- Feedback to all health professionals in a useful way about drug safety
- Feedback to international organisations, and representing Cuba among them.

National Expert Panel Commission of Pharmacovigilance. Its main functions include:

- To receive and evaluate the information on adverse effects of the medications after their registration, authorisation and commercialisation
- To advise the Ministry of Health
- To propose to the Ministry the withdrawal of any medication that has demonstrated an unfavourable benefit-risk relationship.

Provincial Units of Pharmacovigilance, located inside of the provincial groups of pharmacoepidemiology. Among their activities are:

- To receive, to value, to process and to introduce in the database, the reports of suspicion of adverse reactions that arrive at their centre

Adverse Reaction Reporting in Cuba 2001

No. of reports received . . . . . **16,195 (1,447/million inhabitants)**

No. of ADRs **33,601**

Most frequently implicated organs/systems
Body as a whole . . . . . 8,953 (26.6% of reports received)
Gastrointestinal . . . . . 7,884 (23.5% of reports received)
Skin and appendages . . . . . 6,521 (19.4% of reports received)

Most frequent ADRs
Rash . . . . . 3,417 (10.2% of ADRs reported)
Vomiting . . . . . 2,768 (8.2% of ADRs reported)
Nausea . . . . . 1,794 (5.3% of ADRs reported)
Headache . . . . . 1,642 (4.9% of ADRs reported)
Gastric pain . . . . . 1,468 (4.4% of ADRs reported)
Pruritus . . . . . 1,449 (4.3% of ADRs reported)

No. of reported drugs **4,132**

Most frequent suspected groups of drugs (ATC Classification)
Antibiotics for systemic use (J01) 9,221 (27.4%)

Anti-inflammatory and antirheumatic products, non-steroidal anti-inflammatory drugs (M01A) 7,392 (21.9%)
Antihypertensives (C02) 4,622 (13.7%)

Most frequent suspected individual drugs
Captopril 2,998 (8.9%)
Benzylpenicillin 2,970 (8.8%)
Piroxicam 1,334 (4.0%)

No. of serious ADRs . . . . . **1,053 (6.5%)**

No. of fatal ADRs . . . . . **33 (0.2%)**

- To establish causality between adverse reactions and medications
- To review the available scientific information in the field of the adverse reactions
- To propose and to develop clinical research in pharmacovigilance
- To distribute the results obtained by the centre to all the relevant organisations.

Reporting in Cuba

Cuba became a member of the WHO International Drug Monitoring Programme in 1994. In 1998 the Cuban System of Pharmacovigilance gathered around 900 reports (a reporting rate of 75 per million inhabitants/year). In 1999 the responsibility for drug safety monitoring and promotion of ADR reporting became an important part of the continuous education activities of the NNP. The result was a dramatic increase in the number of reports: in 1999, 21,125 reports were received (1,920/10^6 inhabitants), and in 2000 the figure was 28,450 (2,500/10^6 inhabitants), on the other hand in 2001, 16,195 ADR reports were received (1,447/10^6 inhabitants) with an increase in quality assessment. These rates are in order of magnitude, higher than those achieved in other developed countries with the highest reporting rates. The table shows additional information on the reports gathered in 2001.

Training to report

The main limitations of spontaneous reporting are under-reporting, selective reporting, and incomplete drug histories. Different approaches have been tried in order to limit under-reporting. Our approach consisted of integrating ADR reporting with training and continuous education of physicians. We feel that it is of special interest that this experience was developed in a less developed country, during a deep economic crisis, but with a universal and equitable health care system.

Further goals

The efficiency of spontaneous reporting for detecting new, previously undescribed, ADRs depends both on the number and the quality of reports. Now that a high reporting rate has been achieved, the next step will be improving the relevance and quality of reporting, by specifically promoting reporting of suspicions of ADRs related to recently marketed drugs.

ADR reporting in Italy

Marie Lindquist and Ralph Edwards from *the* UMC made an informal visit to the Verona Regional ADR Centre in Italy, this May.

Currently, ADR reports are sent from health professionals in Italy to their local authorities (about 500 local districts). Local authorities send the reports to the National Centre at the National Ministry of Health, via their Regional Centre. Reports from the Veneto, Emilia-Romagna and Lombardy regions are also sent to Verona. There is a National Commission of Drugs in Rome, with a pharmacovigilance sub-committee, which has decided to start a national network for evaluation of reports. An internet program for reporting from local health authorities (e.g. the Verona hospital) to the Ministry has been developed.

With up to 500 people in the local districts using this program, coding consistency is a major challenge. *the* UMC will in the future receive reports both from the Ministry and the Verona centre. At the moment *the* UMC receives reports from Veneto and Lombardia, but not Emilia-Romagna.

Quality evaluation project

A project is proposed to check on how these different elements of pharmacovigilance around Italy interconnect. Ugo Moretti in Verona is to initiate a study to evaluate the difference between local and nationally stored reports; the first phase is to analyse differences, and then consider the impact/influence. The results will be presented at the Annual Meeting of National Centres in Amsterdam this October.

Activities in Verona

The well-established centre in Verona is linked to three bodies; the local university, the local hospital and the regional system. Tasks include:

- Management of case reports
- Being the local pharmacovigilance centre
- Case-control studies (e.g. NSAIDs - bleeding)
- Teaching at the university
- Co-operation with representatives from other regions including training and common projects
- Serving as consultants for hospital physicians on drug and ADR-related issues
- Production of a quarterly bulletin
- Maintaining a website, www.sfm.univr.it

Other News

Chris van Boxtel

Professor Dr C J van Boxtel of the Netherlands, who is a member of the UMC signal review team, has been awarded an Honorary Fellowship by the American College of Clinical Pharmacology.

New Zealand

Dr Michael Tatley has taken over as Head of the Centre for Adverse Reaction Monitoring (CARM) in Dunedin, New Zealand. David Coulter continues as Director of the Intensive Medicines Monitoring Programme (IMMP).

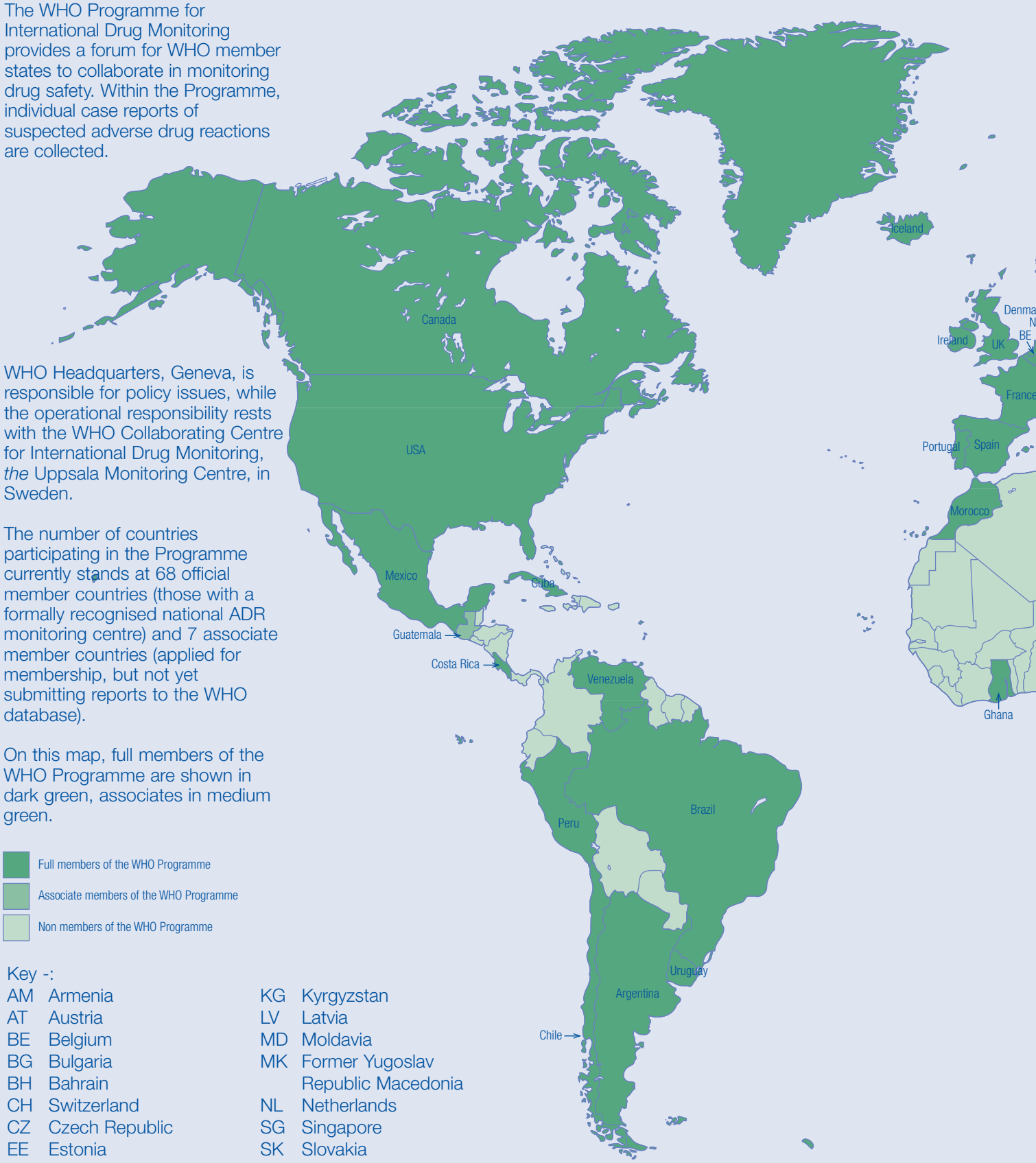
WHO Programme for Interna

The WHO Programme for International Drug Monitoring provides a forum for WHO member states to collaborate in monitoring drug safety. Within the Programme, individual case reports of suspected adverse drug reactions are collected.

WHO Headquarters, Geneva, is responsible for policy issues, while the operational responsibility rests with the WHO Collaborating Centre for International Drug Monitoring, *the* Uppsala Monitoring Centre, in Sweden.

The number of countries participating in the Programme currently stands at 68 official member countries (those with a formally recognised national ADR monitoring centre) and 7 associate member countries (applied for membership, but not yet submitting reports to the WHO database).

On this map, full members of the WHO Programme are shown in dark green, associates in medium green.



Key -:

AM	Armenia
AT	Austria
BE	Belgium
BG	Bulgaria
BH	Bahrain
CH	Switzerland
CZ	Czech Republic
EE	Estonia
HR	Croatia
HU	Hungary
KG	Kyrgyzstan
LV	Latvia
MD	Moldavia
MK	Former Yugoslav Republic Macedonia
NL	Netherlands
SG	Singapore
SK	Slovakia
UK	United Kingdom
YU	Yugoslavia

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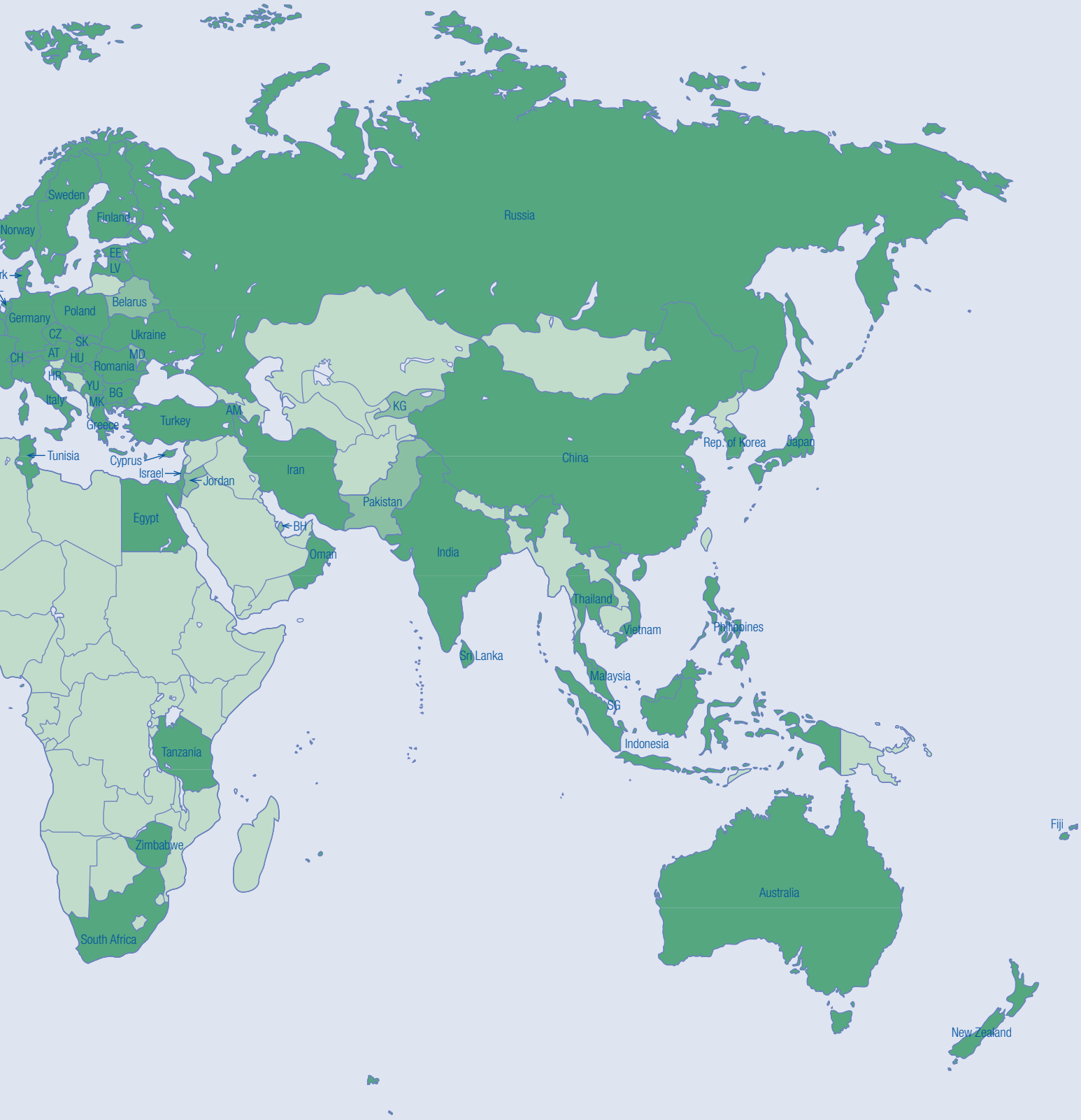


Hospital-based Pharmacovigilance:

Clinical pharmacy, a patient-focused pharmacy activity, is an emerging discipline in India. From being a product-centred profession, pharmacy is slowly changing towards patient-focused activity. The department of clinical pharmacy was established at Jagadguru Sri Shivarathreeshwara Medical College Hospital (JSSH, a 1000-bed teaching hospital) by Jagadguru Sri Shivarathreeshwara College of Pharmacy (JSSCP), Mysore, India during April 1997, and the first of its kind in the country.

Since its establishment, the department has been actively involved in providing clinical pharmacy services including ward round participation, treatment chart review, adverse drug reaction reporting and monitoring, drug information and patient counselling. A hospital-based ADR reporting and monitoring system was started during November 1997 as part of clinical pharmacy services. Through this system, the department has been assisting healthcare professionals across the JSSH regarding the detection, reporting, management and prevention of ADRs occurring at this hospital.

ADR reporting in hospital

The objectives of the initial programme were to implement a hospital-based ADR reporting and monitoring system at JSSH, with a long-term objective to strengthen the national pharmacovigilance programme by assisting in establishing nationwide hospital-based ADR reporting and monitoring. As in many other developing countries, ADR reporting and monitoring are not well established in India. A few ADR reporting and monitoring centres exist; however, their achievements are limited due to lack of funding, lack of trained personnel and lack of communication and promotion of activities. In addition, post-marketing surveillance is not mandatory in India for pharmaceutical companies and lack of awareness amongst prescribers about the importance of ADR compounds the problem.

An easy system

The ADR reporting and monitoring system was implemented at JSSH, Mysore by adopting a suitably developed 'standard operating procedure'. A 'hassle-free', non-cumbersome approach was adopted for easier reporting. This has encouraged healthcare professionals to report suspected ADRs. This system operates in such a way that the initial problems faced were identified and rectified at the earliest by developing suitable strategies to overcome them.

Combining local centres

After the initial successful implementation of the system at JSSH, the ADR reporting and monitoring system was successfully extended to Holdsworth Memorial Hospital (HMH), a 400-bed Christian missionary hospital, and Basappa Memorial Hospital (BMH), a 250-bed multi-speciality private hospital, in Mysore. The department of clinical pharmacy at JSSH now acts as collating centre for reported ADRs for these three hospitals. All the reports received from the three different centres are evaluated for their causality relationship and documented. In all the cases, the department will provide the feedback to the reporter through the well-designed format of a 'thank you note' regarding the reported suspected reaction, not only to provide them with information, but also to encourage them to report further suspected ADRs.

Promotion of the work

The department is also actively involved in the promotion of ADR reporting. As part of our promotional activity, various promotional materials such as banners/posters, thank you note, slogans, circulars at regular intervals were prepared and utilized in an appropriate manner to create awareness among healthcare professionals to encourage further reporting.

In order to prevent a life-threatening ADR occurring in the same patient, the department has prepared the 'Alert card' for the patient and the same is being provided to patients who develop a severe reaction or incurred cost as the result of the treatment of an ADR.

Monitoring and education

Our department will monitor patients who are at especially high risk of developing an ADR, through the ward round participation by staff and by postgraduate students of Pharmacy practice who attend medical ward rounds on a day-to-day basis.

Since the department understands the importance of education in the prevention and management of ADRs it is actively involved in educating the healthcare professionals including prescribers, nurses, working pharmacists and postgraduate students of medicine and pharmacy by means of seminars/workshops, personal interaction and publishing information regarding reported ADRs

The team behind the programme sitting R to L: Dr. B G Nagavi, Dr. G Parthasarathi, Mr. M Ramesh standing R to L: Mr. Sabin Thomas, Mr. B S Sathvik, Mr. Adepu Ramesh

A Clinical Pharmacist's perspective

in the quarterly in-house publication of the department 'Clinical Pharmacy Newsletter'.
All the reported ADRs are documented in well-designed ADR documentation forms and in the computerized format for the easy storage and retrieval of information.

Achievements

In the past 5 years of our experience in the area of the ADR reporting and monitoring system, our department has been successful in achieving the following:

- Establishment of ADR reporting monitoring system in three hospitals
- Creating an awareness among health care professionals about the importance of ADRs
- Educating health care and nursing students and patients
- Promotion of ADR reporting through suitable novel methods
- Research in the area of ADRs including ADR-related hospital admissions
- Research grant of 700,000 rupees from the Government of India as a support to this programme
- Involvement of clinical pharmacists for the first time in India in ADR reporting and monitoring. As a result there is now a unique opportunity for the pharmacy profession to position itself as a leader in the adverse drug reaction-reporting field.

The department has so far assisted and evaluated 1,786 suspected ADRs reported from different centres.

Factors contributing to the success

One of the main reasons for the successful implementation of ADR reporting and monitoring system is that it has been a part of comprehensive patient care activity. The programme is not project-driven or individual-centred. The programme is promoted through the daily activities of clinical pharmacy.
Other factors include:

- Simple ADR notification form
- Simple and well-accepted 'standard operating procedure'
- Constant publicity and campaigning
- Education of healthcare professionals, patients and students
- Commitment and hard work

Future directions for the work

Networking

After completion of their studies, postgraduate students of this department have taken up teacher–practitioner jobs in other institutions where clinical pharmacy education and practice is being developed. In all these institutions ADR reporting and monitoring programmes have been initiated. Networking with these institutions is a priority

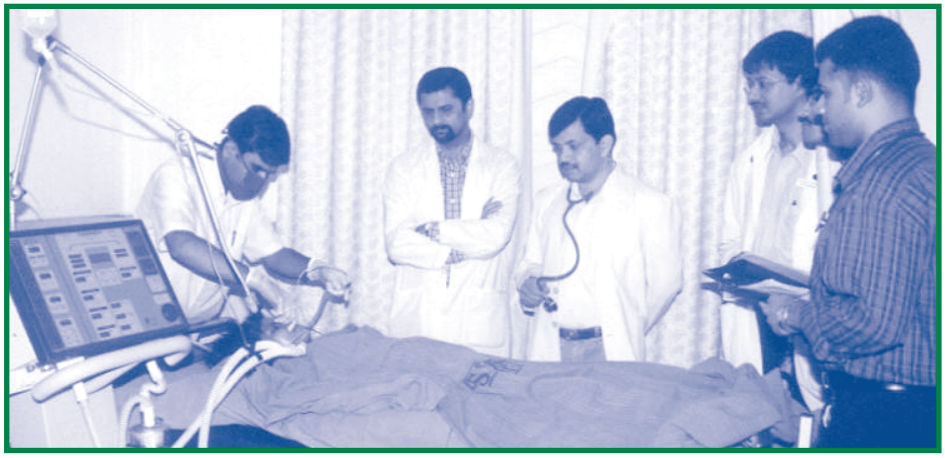
Research in the area of ADR

Post-marketing surveillance of newly marketed drugs to study the ADRs pattern in the local population is taking place. Working in collaboration with Society of Pharmacovigilance (India) and International Society of Pharmacovigilance to strengthen the Pharmacovigilance programme in India is one of the long-term objectives of the department.

Funding

We have been so far working with a very limited financial support. More funding from bodies like the Indian Council for Medical Research, and WHO will make this programme more efficient and widespread. Any collaboration with National Pharmacovigilance Centres from developed countries will be of great help.

The basic philosophy of clinical pharmacy, and our priority, is better patient care through promotion of quality use of medicines and patient safety. We would like to continue to further strengthen this programme and wish to see many more centres coming up with the active involvement of clinical pharmacists. This is very important, as safety in healthcare is a journey, but not a destination.



'Clinical Pharmacist in action' Dr. G Parthasarathi with Dr. Basavana Gowda, Professor of Medicine attending a ward round

Acknowledgement: We thank all the doctors, other health care professionals and administrative staff of the hospitals and JSS Mahavidyapeeta for their constant support and encouragement towards the growth of this department.

Public Health Programmes and Pharmacovigilance

Mary Couper (WHO) reports

The development of new medicines, or medicines for new indications, for broad areas of public health (eg, malaria, tuberculosis) results in the promotion of treatments which expose large numbers of patients to possible additional health risk from adverse drug reactions.

Public Health Programmes (PHPs) and new medicines

A meeting held at the Headquarters of the WHO in Geneva, has recently been looking at the issue. As a result of this and other meetings, it is hoped to establish a method that allows decisions on medicines for new indications to be taken with confidence, based on effectiveness and risk analysis done on a continuous dynamic basis. The meeting proposed a publication and guidelines outlining systems for pharmacovigilance in public health by bringing together the strengths of both disciplines, bearing in mind the limitations of current national and international systems. The ultimate aim of such a document is to promote the safe use and rational use of medicines in public health programmes.

Creating the right model

One model might be to create ADR monitoring systems within each PHP. This would require the creation of a multitude of declaration sheets and a declaration circuit specifically for each programme. Each time a programme is underway, there would be a need for training and encouragement of health professionals to report. However, this scenario would not be really effective and would lead to increased costs. In addition there would be a dilution of competences, especially in developing countries with limited human and financial resources.

Integrating pharmacovigilance and public health

The preferred model, for efficiency and also for rationalisation of health programme expenses, would be to create a global system based on integration of pharmacovigilance and the PHPs. This system would be viable and could be applied to all situations using medicines. Once well established, this reference system would integrate different levels of each newly-proposed programme. It could also reinforce the pharmacovigilance system of the country at each clinical intervention. The objective of this model would be to create a link between different PHPs, which are traditionally well-implemented, and the existing pharmacovigilance systems. Partners in this scenario are:

- At country level: patients, health professionals, pharmacovigilance national centre, PHP managers;
- At international level: WHO and the advisory committee.

Demands on PHPs

There are changing needs and expectations of PHPs that have a bearing on the functions and operations of pharmacovigilance centres. These include greater public expectations than in the past for access to medicines; the needs created by the introduction of new or revised public health programmes and by the introduction of new drugs, such as those for tuberculosis and HIV/AIDS. Furthermore, the requirement for better communication and explanation of public health programmes will necessarily include drug safety issues. These considerations need to take into account the safety and use of drugs not directly controlled by governments and government stores.

Our meeting in Geneva was important because of the introduction of an international advisory committee on safety of medicinal products that will work with other WHO programmes in capacity-building and regional collaboration.

Participants in Consultation Group: Peter Folb, Ken Hartigan-Go, Nilma Kshirsagar, Precious Matsoso, Ramon Palop, Bruce Rowsell, Rachida Soulaymani-Bencheikh, Noboru Takahashi, Ralph Edwards, Sten Olsson, Mary Couper, Shanti Pal. Absent: Peter Arlett, Ben Botwe

Zooming in on PHPs

NEW PUBLICATIONS

Pharmacovigilance

Edited by Ron Mann and Elizabeth Andrews
ISBN: 0-471-49441-0 Hardcover 582 Pages July 2002
£150.00 ¤ 247.50 John Wiley and Sons Ltd

This new book is described by the publishers as 'a one-stop source for pharmacovigilance'. Its six main parts cover all the important aspects of the subject, including legal aspects, drug regulatory requirements, methods of signal generation, reporting schemes and pharmacovigilance in selected system-organ classes. The book then goes on to look at possible future directions. It should be an important addition to all pharmacovigilance departments, regional pharmacovigilance centres and regulatory authorities. It is an unparalleled source of information and reference for all researchers in pharmacovigilance, pharmaceutical practice and medicine.

Expert Opinion on Drug Safety

The first issue of this journal was published in May 2002 by Ashley Publications, www.ashley–pub.com (ISSN 1474-0338). This bi-monthly, peer-reviewed journal is intended to 'focus on the safety and risk-benefit effects of emerging and established drug therapies, review contemporary issues in drug safety and discuss the impact of the field on healthcare delivery'. The first issue contains ten different review articles. The editorial office may be contacted by e-mail: eods@ashley-pub.com

Reprint of 'The Importance of Pharmacovigilance'

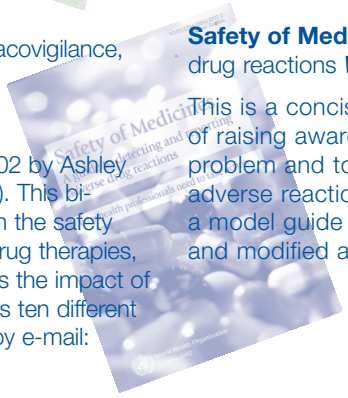
Due to exceptional demand, the 48-page booklet, 'The Importance of Pharmacovigilance' has had an immediate reprint and is available again, from both *the* UMC and the WHO.

Recent publications from the WHO

Aide Memoire on Drug Safety - Pharmacovigilance
An A4 card has been published in French and English by the Quality Assurance & Safety: Medicines section of the WHO.

This handy 2-sided sheet consists of:

- Words of Advice
- Checklist – pharmacovigilance service, national policy
- Key elements



Safety of Medicines – A guide to detecting and reporting adverse drug reactions ***Why health professionals need to take action***

This is a concise 18-page booklet, developed with the objective of raising awareness of the magnitude of the drug safety problem and to convince health professionals that reporting of adverse reactions is their moral and professional obligation. It is a model guide which can be translated into national languages and modified as the local situation may require.

NEW PUBLICATIONS

Viewpoint

In order to promote interest in the safety of medicines to a wider audience, *the* UMC is now preparing slightly abridged versions of Viewpoint in Spanish and French, to be available in the next few months. If you would like more information on non-English versions, please contact us at info@who-umc.org. (Translations in Hungarian and Japanese have also been made; for information on these please use the same e-mail address.)

A summary of the Viewpoint content is also available in Adobe Acrobat format from our website. This summary may be used without any restrictions by media and other interested parties.

Forthcoming Courses and Conferences

Date	Title	Place	Organiser / Contact
25-26 Oct 2002	III Jornadas de Farmacovigilancia 'La Farmacovigilancia en al sociedad de la información'.	Toledo, Spain	Centro de Farmacovigilancia de Castilla La-Mancha, Direccion General de Salud Publica y Participación Fax: + 34 925 26 71 58 e-mail: farmacovigilancia@jccm.es www.jccm.es
30 Oct–1 Nov 2002	Drug Safety Surveillance & Epidemiology Training Course	Hyatt Regency Penn's Landing Philadelphia, PA, USA	Training Administrator Tel: +1 215 628 2288
3-5 Nov 2002	5th European Congress	Rotterdam, The Netherlands	ISPOR Tel: (609) 219-0773 Fax: (609) 219-0774
5-6 Nov 2002	Electronic submission of individual case safety reports in the EU	London, UK	DIA European Office Tel: +41 61 386 9393 Fax: +41 61 386 9390 e-mail: diaeurope@diaeurope.org
6-7 Nov 2002	Workshop on Case Narrative Writing	Southampton, UK	Jan Phillips, Drug Safety Research Unit Tel: +44 (0)23 8040 8621 e-mail: jan.phillips@dsru.org www.dsru.org
2-4 Dec 2002	Best Practice Pharmacoepidemiology and Risk Management	London, UK	IIR, Tel: +44 (0)20 7915 5000 Fax: +44 (0)20 7915 5001 www.iir-conferences.com
5-6 Dec 2002	Prepare to meet MedDRA Challenges	London, UK	International Pharmaceutical Training Tel: +44 (0)20 7915 5055 Fax: +44 (0)20 7915 5056 e-mail: registration@iir-conferences.com
9-10 Dec 2002	Adverse Event Reporting and Pharmacovigilance	London, UK	International Pharmaceutical Training Tel: +44 (0)20 7915 5055 Fax: +44 (0)20 7915 5056 e-mail: registration@iir-conferences.com
11-12 Dec 2002	Drug Adverse Event Monitoring and Management and Pharmacovigilance	Toronto, Canada	IQPC, 415 Yonge Street, Suite 1600 Toronto, ON M5B 2E7 Tel: (416) 596 1141 Fax: (416) 596 9001
16-17 Jan 2003	Spontaneous ADR reports vs. data from pharmacoepidemiological studies in pharmacovigilance - synergism and conflicts	Paris, France	Administration, International Society of Pharmacovigilance PO Box 32974, London SW19 8YG, UK Tel: +44 (0)20 8286 1888 Fax: +44 (0)20 8286 1888 e-mail: administration@isoponline.org www.isoponline.org
30-31 Jan 2003	In Practice, in Progress, in Place? Drug Safety initiatives for 2003	London, UK	IIR, Tel: +44 (0)20 7915 5000 Fax: +44 (0)20 7915 5001 www.iir-conferences.com
19 Feb 2003	Adverse Event Reporting and Pharmacovigilance	London, UK	Rostrum Tel: +44 (0)118 933 5343 e-mail: rostrum@mdsps.com www.rostrumtraining.com
5-7 March 2003	e-ternal medical progress? 15th Annual DIA Euro Meeting (Pharmacovigilance and epidemiology track)	Rome, Italy	DIA Office, Basel Tel: +41 61 386 9393 Fax: +41 61 38693 90 e-mail: diaeurope@diaeurope.org
14-16 April 2003	24th Journées de Pharmacovigilance (Societé Française de Pharmacologie)	Lille, France	Pharmacologie: Tel: +33 (0)3 20 44 54 49 Fax: +33 (0)3 20 62 69 92 e-mail: clibersa@chru-lille.fr
12-23 May 2003	UMC Training Course Pharmacovigilance – the Study of Adverse Drug Reactions	Uppsala, Sweden	Sten Olsson, the Uppsala Monitoring Centre, Stora Torget 3, S-753 20 Uppsala, Sweden e-mail: sten.olsson@who-umc.org
23 June 2003	Adverse Event Reporting and Pharmacovigilance	London, UK	Rostrum Tel: +44 (0)118 933 5343 e-mail: rostrum@mdsps.com www.rostrumtraining.com

Product and Marketing News

WHO Drug Dictionary - always striving for improvements

An expanding dictionary

The rate of additions to the Drug Dictionary – the essential tool for all working in pharmacovigilance – is increasing rapidly. At present over 2,500 new entries are made every year, but this will double over the coming year. *the* UMC has recently completed a major development of the WHO Drug Dictionary. Among the changes, we have introduced extra fields to give a wealth of important new information (including herbal products) to DD users.

Don't get left behind

Many people find the quarterly version of WHO DD essential to keep them up-to-date with all the latest products in use around the world. As a special offer for existing customers wishing to upgrade their subscription from annual to quarterly, until the end of 2002 we are offering a reduction of 25% on the cost of an upgraded subscription.

Interested?

If you'd like to discuss this further, or need more information about your current subscription and upgrading it, call a member of the UMC Sales and Marketing team, who will be delighted to assist you, or e-mail Inger Forsell at inger.forsell@who-umc.org

Updates - 2nd Quarter 2002

The new versions of the computerised WHO Drug Dictionary and WHO Adverse Reaction Terminology (WHO-ART), containing information for the 2nd quarter of 2002 are now available. These were sent to subscribers during September 2002.

If you are a subscriber to either WHO DD or WHO-ART and have not yet received the update, please contact Inger Forsell (inger.forsell@who-umc.org).
Data files for the 3rd quarter of 2002 should be available during November 2002.

Have you moved?

If there is a mistake in our database, or you have changed your address, please let us know. Either return the envelope label, with corrections marked on it, by post or fax, or simply e-mail your correct address to us. We will then be able to amend our address lists.

We'd like to keep our mailing lists in top condition, so do let us know if there are mistakes on our labels or if you haven't received post you are expecting from us. Many Thanks!

UMC staff will be attending DIA conferences in Rome and San Antonio in 2003. We look forward to meeting many of you at these events; if you wish to arrange a meeting with us at one of them, please contact Mats Persson.

Pharmacovigilance Seminars at 2002 World Health Assembly

At the 2002 Word Health Assembly a proposed resolution concerned Quality of Care: Patient Safety. In this connection the Swedish Consumer Institute for Medicines and Health - Kilen - organized two pharmacovigilance seminars at Palais des Nations, Geneva. The theme was 'Consumer Input Improves Quality of Care'. Speakers at the seminars were Dr Mary Couper, WHO-QSM, Geneva, Sten Olsson, *the* UMC, Dr Natalia Cebotarenco, Moldova and Jan Albinsson and Lena Westin from Kilen. Each seminar attracted some 40 participants.

Kilen also made a statement before the WHA committee discussing the Patient Safety-resolution, requesting open access to the WHO adverse reaction database and greater consumer participation in the work for quality of care.

Chinese delegation at *the* UMC

A delegation from the State Drug Administration and the National Institute for the Control of Pharmaceutical and Biological Products of the People's Republic of China visited *the* UMC on 29 August, 2002.

Dr Shao Ming Li, Deputy Director General of the SDA, headed the delegation. Other delegates were Dr Bian Zhenjia, Ms Zhao Lili, Dr Yin Hong Zhong and Dr Wang Junzhi. UMC staff provided an overview of the Centre's activities and Dr Bian Zhenjia presented the current status of ADR monitoring in China. A discussion of future collaboration followed.

the UPPSALA MONITORING CENTRE

Staff Changes at Stora Torget...

This month sees four new faces at *the* UMC, although only one of them is a complete newcomer to the Centre. **Marjatta Leván** (left photo) has recently started work as Administration Manager and deals with financial issues and staff management. She previously worked for a company in the energy sector.

The three other new members of staff have actually been taken over from working freelance to having direct contracts with the Centre. **Magnus Larsson** (centre left photo), **Stefan Lewenfalk** (centre right photo) and **Bo Östling** (right photo) have been working for some time as programmers on the WHO databases, so their joining us marks a strengthening of *the* UMC's capabilities in this area.

In fact, Bo Östling has been working with *the* UMC since the 1st February 1978! His first job after finishing his studies was to assist the fledgling Centre when the WHO database was moved from Geneva to Uppsala in 1978. The database he worked on became the International Drugs Information System (INTDIS). At that time, Bo was based at the Uppsala University Data Centre, and over the years worked for other companies around the town, always keeping the WHO database as part of his responsibilities.

He is currently working with Stefan and Magnus on the development, support and maintenance of the new WHO database Vigibase. We welcome all four to *the* UMC!

In September, we were sad to say goodbye to Maria Bergström, who had been with *the* UMC for seven years; we wish her well in her new job.




the Uppsala Team

Ralph Edwards
Professor in Medicine, Director

Sten Olsson
Head of External Affairs

Cecilia Biriell
Head of Internal Affairs

Marie Lindquist
Head of Data Management & Research, General Manager

Mats Persson
Head of Marketing & Sales, Business Development Manager

Marjatta Leván
Manager, Finance and Personnel

Mohamed Farah
Programme Leader, Traditional Medicines

Malin Ståhl
Programme Leader, Signal Detection

Andrew Bate
Programme Leader, Signal Research Methodology

Helena Fucik
Data Processing Co-ordinator

Monica Pettersson
Programme Leader, Signal Analysis

Malin Nord
Programme leader, Database Products

William Frempong
Data Management

Annica Lundström
Data Management

Erica Walette
Programme Leader, Database Services

Anna-Karin Flygare
Medical Terminologies

Jenny Ericsson
Data Management

Jessica Nilsson
Data Management

Anne Kiuru
Signal Detection & Analysis

Helena Sjöström
Data Management

Daniel von Sydow
Project Co-ordinator

Sven Purbe
Data Management & Quality Assurance Co-ordinator

Anna Lindquist
Team Support, Web Editor

Inger Forsell
Sales & Customer Relations Executive

Anneli Lennartsson
Team Support, Internal Affairs

Sally Eriksson
Team Support

Geoffrey Bowring
External Affairs Co-ordinator

Magnus Larsson
Programme Leader, IT Systems Development

Bo Östling
Senior Systems Developer

Stefan Lewenfalk
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