

# MUR 25

UPPSALA REPORTS April 2004

For everyone concerned with the issues of pharmacovigilance and toxicovigilance

Continuing Medical Education

Profile : Ed Napke

News from Around the World

New Indian pharmacovigilance system

Artemisia - insert



# DIRECTOR'S MESSAGE



Ralph Edwards Director  
the Uppsala Monitoring Centre

Two apparently unrelated matters combined when I was wondering what to write here. One is publication of 'Medicines out of Control? Antidepressants and the Conspiracy of Goodwill'<sup>1</sup>. The book is concerned with the withdrawal syndrome issue and possible dependence with the SSRIs, as well as their widespread use. Our findings on SSRI withdrawal were published back in 1997<sup>2</sup>. But beyond this major example, the book relates the activities of the pharmaceutical industry, regulators and the medical profession, to a complex web, and sometimes even collusion, in which money talks more loudly than wisdom. The authors refer to the machinations described in John le Carré's 'The Constant Gardener'<sup>3</sup>. Some of the fault in the system is not perceived by those involved, and there is much to be considered in the effects of the pressures on industry to maintain its strong economic performance. There is a cascade of scientific and professional activity involving all the above players to make this pharmaceutical bonanza happen. Regulatory activity and professional rigour can appear as a dam in the way of a flow of increasing profitability, rather than as essential safeguards for public health. Strong pressures can be brought to bear on the dam!

The second matter is the possibility that the Intensive Medicines Monitoring Programme might be discontinued. When I was Director of the National Toxicology Group in New Zealand, the IMMP was invaluable in quantifying the extent to which another antidepressant, Mianserin, was related to agranulocytosis, and in following the effects of alerting letters to health professionals. The IMMP results were hotly disputed by industry and some psychiatrists. The former sent two delegations to attempt to falsify the findings, including an independent expert haematologist to review the cases. After several hours work he simply said, "I agree" (with the IMMP evaluation). Being able to link cases to prescribers allowed us to demonstrate that one of the most vocal psychiatrists who said he had never seen agranulocytosis with mianserin was responsible for four cases. They had been admitted to hospital by other physicians without his knowledge. This is but one example of the many successes of the IMMP in providing key information affecting the balances between the effectiveness and risks of medicines, and on managing risk successfully.

The IMMP is a unique and vital spoke in the wheel of global public health. Without it another of the checks and balances in drug safety goes, and the scenario outlined in 'Medicines out of Control?' becomes more tangible. I am neither against the pharmaceutical industry nor capitalism. The industry must be financially able to produce new drugs to improve health, but both must be balanced by independent critique and action. I know that my pharmacovigilant friends in industry and in regulatory affairs strive for this same elusive balance in their daily work, but we must all also value and ponder over intelligent external criticism of what we do.

## References

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- 2 Stahl MM, Lindquist M, Pettersson M, Edwards IR, Sanderson JH, Taylor NF, et al. Withdrawal reactions with selective serotonin re-uptake inhibitors as reported to the WHO system. European Journal of Clinical Pharmacology 1997; 53(3-4):163-9.
- 3 le Carré J. The Constant Gardener. Coronet Books / Hodder & Stoughton, London. 2001.

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News from around the world this month comes from Europe, the horn of Africa and the Far East.



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Following the WHO Programme Annual Meeting in Delhi, we present the new pharmacovigilance system being implemented in India.



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Founder of the Canadian national pharmacovigilance system and public health campaigner Ed Napke is featured in our latest profile.



Insert

A sideways look at Artemisia



## New Zealand Intensive Medicines Monitoring Programme (IMMP)

The IMMP has been in operation for about 30 years, and is the oldest post-marketing surveillance system in the world for monitoring total national population cohorts taking drugs. The IMMP has had major successes in finding new signals (one of the most striking is the totally novel 'pain reactivation' with sumatriptan, where pain is induced in a site of previous operation or trauma); providing confirmation and analysis of very early signals (e.g. captopril and cough); and in establishing effectiveness and risk balanced information (e.g. amiodarone). In spite of its excellent and cost-effective performance, the IMMP is once again under threat of closure. It will be a huge loss for pharmacovigilance if this methodology, and the personnel with the expertise to support it, is lost to the international community.

We would urge you to contact  
Dr Michael Tatley (e-mail: [michael.tatley@stonebow.otago.ac.nz](mailto:michael.tatley@stonebow.otago.ac.nz))  
or Prof David Coulter (e-mail: [dmcoulter@xtra.co.nz](mailto:dmcoulter@xtra.co.nz))  
urgently, to express support for the IMMP and perhaps give helpful suggestions.

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NEWS FROM AROUND THE WORLD

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## Focussed surveillance methods

The Annual Meeting of the WHO Programme for International Drug Monitoring will take place in Dublin, Ireland from 4-6 October 2004. The Local Organiser is Ms Niamh Arthur, Director of the Pharmacovigilance unit of the Irish Medicines Board. The main theme of the meeting will be 'Pharmacovigilance and focussed surveillance methods'. An overlapping session with the ISoP Annual Meeting will be held on the afternoon of the final day.

The structure will be similar to that of the previous meeting in New Delhi. There will be keynote speakers providing perspectives on the main theme. A major part of the meeting will then be spent on discussions in Working Groups. The aim is to arrive at practical recommendations from the Working Groups that may then be adopted or not as recommendations from the general meeting. WHO issue formal invitations to member and associate member countries of the WHO Programme in April.

### Dublin

Dublin is steeped in history and has many artistic connections. Its literary sons include Shaw, Wilde, Joyce and Beckett – indeed there is even a Dublin Writers Museum. There is a wide choice of other museums, galleries and theatres. Dublin also has a rich architectural heritage, and walking around the city will reveal mediaeval, Georgian through to modern buildings. There are also botanical and landscaped gardens to enjoy. Dublin's shops won't disappoint; and if you are looking for a gastronomic experience, Dublin offers a vast choice of restaurants to suit all tastes, as well as traditional (but now smoking-free) Irish pubs.

### International Society of Pharmacovigilance

The topics of the ISoP Conference in Dublin from 6-8 October have been announced as follows:

- Landscapes in Pharmacovigilance
- Medication Errors
- Risk Management Plans
- Future Challenges
- Training and Education

Abstracts for both oral and poster presentations are invited. Closing date for submission is 15th July 2004. Abstracts should be submitted from the conference website at: [www.imb.ie](http://www.imb.ie) under 'Pharmacovigilance Events'.



Trinity College, Dublin

Full up-to-date information on the programme and conference is on-line at [www.imb.ie](http://www.imb.ie) under 'Pharmacovigilance Events'

Or contact:

ISoP 2004 / Irish Medicines Board, Earlsfort Terrace, Dublin 2, Ireland. Tel: +353 (1) 676 4971, Fax: +353 (1) 676 2517  
Email: [isopmeeting@imb.ie](mailto:isopmeeting@imb.ie)

## E-mail discussion

Vigimed is the only world-wide pharmacovigilance e-mail discussion group. Recently Kristina Johansson completed a study of the experiences with this unique IT drug safety tool, of the problems encountered in real-life pharmacovigilance and the mechanisms involved in problem solving. In January she successfully presented the results of her study in a Masters Thesis in Pharmacy at Uppsala University. The study was done together with Björn Hellman of Uppsala University's Faculty of Pharmacy and Ronald Meyboom and Sten Olsson of *the UMC*.

Her report, which took into account the confidentiality and sensitivity of the data, shows that Vigimed is regularly used by many of the National Pharmacovigilance Centres in the WHO International Drug Monitoring Programme in all parts of the world.

Kristina looked at 100 successive questions and 580 answers to them. The drug groups that emerged as a cause of problems or questions were:

- analgesic and anti-inflammatory drugs,
- anti-infectious drugs,
- anti-obesity drugs
- hormones.

Herbal medicines also featured, accounting for 9% of the questions. Interestingly the majority of the Vigimed messages concerned established drugs, i.e. on the market for 7 years or more,



Kristina Johansson, author of a study on experiences with Vigimed

suggesting that National Centres have to devote their time to both new and old drugs! Centres with more than one person having access to Vigimed were found to be more active, both in asking and in answering questions.

The findings of the study by Kristina are welcome information for the further improvement of the Vigimed communication system and will be presented at the forthcoming National Centres meeting in October in Dublin. All of us at *the UMC* were pleased to have for a while a young and bright pharmacy student in our team and it was hard to say goodbye.

## Herbal Medicines in Canada

Ralph Edwards and Mohamed Farah attended the latest consultation meeting for 'WHO Guidelines on Safety Monitoring and Pharmacovigilance of Herbal Medicines' as representatives from the Uppsala Monitoring Centre. This consultation took place in Vancouver, Canada from 31st January to 4th February, hosted by Health Canada, and consisted of intense discussions about the guidelines among a group of experts. The WHO Working Group on Quality Control of Herbal Medicines is co-ordinated by the Traditional Medicines section at WHO, Geneva.

The eventual publication of these guidelines will assist WHO member states to carry out effective safety monitoring for herbal medicines. International sharing of safety information for herbal medicines will also be enhanced. The guidelines will also assist the WHO in fulfilling its leadership role in the monitoring of medicines, including traditional and herbal medicines. This would include technical guidelines, establishment of international standards in manufacture and movement of herbal medicines, and education and training related to herbals.

## Training in Hong Kong

At the request of the Department of Health of The Hong Kong Special Administrative Region of China, John McEwen of TGA, Australia and Sten Olsson, the UMC, carried out a two-day pharmacovigilance training course in Hong Kong on the 20th and 21st March 2004. The training covered the basic methods of drug safety monitoring and how to set up and run a pharmacovigilance centre, focussing on the particular situation of Hong Kong.



*From left: Mr Anthony Chan, Dr Constance Chan, Dr Kelvin Low, Dr Cindy Lai and Dr John McEwen in Hong Kong.*

Special attention was given to the need for safety monitoring of traditional herbal medicines. This discussion was particularly relevant since both mainland China and Hong Kong have experienced a recent event of two herbs being mixed up because of similarities of their Chinese names. Since the herb inadvertently being used contains aristolochic acid, several exposed patients have suffered liver injuries. It was noted that analysis of reports on adverse reactions to herbals requires additional factors to be taken

into account. In Hong Kong practitioners of traditional medicine are registered or listed which allows a direct dialogue with them.

Being completely reliant on identification of drug safety signals by major authorities overseas does not provide the best protection for patients of Hong Kong. Local problems may be missed and problems identified elsewhere may not be prevalent in Hong Kong.

It is expected that Hong Kong will establish its own pharmacovigilance centre in the not too distant future. Whether the Centre may independently join the WHO Programme or be affiliated to the National Centre in Beijing needs to be confirmed with legal expertise. The organizer of the course, Clive Chan, has got his plans ready to start the Centre as soon as he gets a go ahead from his superiors.

## UMC visit Shanghai

As a follow-on to the training course in Hong Kong Sten Olsson paid a visit to the regional Centre in Shanghai, China, from 22-24 April. Adverse reaction reporting in Shanghai dates back to 1984. Close personal contacts with the UMC have been maintained for many years. The Centre has just translated the WHO books 'The Importance of Pharmacovigilance' and 'Dialogue in Pharmacovigilance' into Chinese, and they will be published shortly.

During the visit Dr Du Wenmin, vice director of the Centre, demonstrated the internet-based reporting system established for the Chinese national pharmacovigilance network. The Shanghai



*From left: Miss Wang Xiaoyu, Mr Xu Jianlong; Sten Olsson, Dr Du Wenmin and Miss Wang Hongmin in Shanghai.*

centre received 3,700 ADR case reports in 2003 which is an increase of around 100% from the year before. The catchment area has 17 million inhabitants. The Centre is establishing a patient register of around 300,000 middle-aged and elderly patients with the aim of performing record linkage studies with hospital outcome data.



Left to right Dr Alex Dodoo, WHO Consultant; Dr Kibreab Asrat, Director of Mekane Hiwot Maternity Hospital; Mr Embaye Andom, Head of Pharmaceutical Information Unit



Opening speeches by (left to right) Dr Sergio Rizzo, WHO-Eritrea Programme manager; Mr. Bernardo Kifleyesus, Director General of Department of Regulatory Services; Dr. Michael Gebrehiwet, Special Advisor to the Minister of Health



Participants of Establishment of Pharmacovigilance in Eritrea, 22-25 October 2003, Massawa, Eritrea



The logo appears in the Eritrean Manual of Pharmacovigilance and on the adverse drug reaction reporting form

## Eritrea – big steps in a small country

*Alex Dodoo reports:*

The winding and excitingly tortuous drive from the mountains of Asmara, the capital of Eritrea to the beach at Massawa, could delude one into forgetting that Eritrea is a young country having gained its independence only ten years ago on 28th May 1993. Yet, this small country (population 3 million) has in their national health policies one of the most clearly articulated programmes for pharmacovigilance and drug safety monitoring in Africa.

From 22nd to 25th October 2003, 55 healthcare workers including senior physicians, pharmacists and nurses gathered on the Red Sea Resort of Gurgusom Beach Hotel in Massawa for a National Pharmacovigilance Establishment Workshop. The workshop was facilitated by myself of the Ghana Centre for Pharmacovigilance and Mr Embaye Andom of the Ministry of Health, Eritrea. This partnership highlighted the importance of networks formed during the UMC's biennial training workshop on pharmacovigilance, as both facilitators are alumni of the UMC's 2001 course in Uppsala.

Participants were trained on the size and extent of the ADR problem and on how to identify, manage, treat and report suspected ADRs. They then took active part in designing the Eritrean Spontaneous Reporting Form and also reviewed and adopted an Eritrean Manual on Pharmacovigilance. Key personalities at the workshop included Dr Sergio Rizzo, WHO-Eritrea Programme and Dr Michael Gebrehiwet, Technical Advisor to the Minister of Health, Eritrea. Others were Mr Bernardo Kifleyesus, Director-General, Department of Regulatory Services, MOH and Chairman of the National Drug Committee, several members of the National Committee as well as senior consultants from the major zobas and hospitals in Eritrea. Following the workshop, Eritrea applied for membership of the WHO programme and has been accepted as an Associate Member pending submission of spontaneous reports for full membership.

## Swedish System Review

In 2003 the Swedish Medical Products Agency (MPA) commissioned Folke Sjöqvist, Emeritus Professor of Clinical Pharmacology, to review the Swedish pharmacovigilance system and to provide proposals for development and refinement. He presented the first part of his report in December 2003.

Suggestions include improved facilities for electronic reporting, and for drug safety to be brought to the fore in the quality assurance of the health care system. Better coordination between the MPA, the

National Board of Health and Welfare, the regional county councils, responsible for health care planning and provision, and the National Corporation of Swedish Pharmacies is required. Professor Sjöqvist proposes that hospital drug and therapeutics committees become more active in trying to prevent adverse reactions. He identifies the nurse, being close to the patient, as a good source for adverse reaction information. Also the role of the pharmacist and the patient in reporting adverse reactions is identified.

The second part of Professor Sjöqvist's report will cover the Swedish pharmacovigilance system in an international context.

## Promotion in Bulgaria

*David Coulter reports:*

In October 2003, I made a training visit to Bulgaria. This was in response to an invitation to offer promotion of pharmacovigilance in the medical community and to provide some mentoring in pharmacoepidemiology for the medical staff of the National Pharmacovigilance Centre. My first appointment was with Dr Borislav Borrisov, Executive Director of the Bulgarian Drug Agency and we spent some time discussing pharmacovigilance.

My programme included four lectures on methods and results from the New Zealand Pharmacovigilance Centre, particularly from the IMMP. Each lecture was scheduled for 90 minutes and was ably introduced with background information on the need for pharmacovigilance by Dr Daniela Encheva. The lectures were to the following groups:

- medical students and junior doctors at the National Centre of Hygiene, University of Sofia,
- a large audience of experts from the Bulgarian Drug Agency, the University, the Ministry of Health, National Health Insurance Fund and medical and professional organisations, at the National Centre of Infectious and Parasitic Diseases, Sofia
- pharmaceutical industry representatives and contract research organisations
- academics, senior medical students and interns at the Medical University of Plovdiv. This lecture had to be translated (the others were in English); Dr Lora Nikolova from the National Centre did the translating.

It was a great pleasure to visit the historic cities of Sofia and Plovdiv. To add to this pleasure I was generously hosted by Dr Encheva and Dr Nikolova and the two support staff in the Centre.

It was encouraging to learn that there has been a positive response. For the first time the National Pharmacovigilance Centre was visited by academics

from a university - two pharmacologists from the Medical University of Plovdiv who wished to explore further contact and collaboration. Further, the Head, Dr Daniela Encheva, reports, "We are also very grateful for the support you have provided to us, including your visit to the Agency and the Medical Schools. We experienced an immediate effect of these activities - we were invited to give another presentation for 5th year pharmacy students and to show them pharmacovigilance in practice at our

office. The proposal is to be engaged in such short courses on a regular basis and also to start some projects for course work with several students. I hope this would be of some help to increase the awareness and reporting rates for the near future."

I was most impressed with the quality, enthusiasm and dedication of the staff. They have high objectives and work hard to achieve them in spite of resourcing difficulties.

## Finally, a Pharmacovigilant India!

*Contributed by: Brijesh Regal, WHO National Consultant*

India is a country of immense proportions. Its 3287590 sq. km. area, 1060 million population, 16 official languages and 35 states and union territories (several of which are larger than many European countries) don't lend themselves to conventional logistics. More than half a million qualified doctors cater to the healthcare needs of our vast nation, supported by 624,000 beds in more than 15,000 hospitals. Gigantic number of drugs are produced and consumed in India, which is the fourth largest producer of pharmaceuticals in the world.

Aware of the enormity of task and determined to establish a vibrant, sustainable and credible adverse drug reaction monitoring programme, the central drugs regulatory authority - the Central Drugs Standard Control Organization (CDSCO) - has initiated a well structured and highly participative National Pharmacovigilance Programme.

The National Pharmacovigilance Programme is largely based on the recommendations made in the WHO document 'Safety Monitoring of Medicinal Products - Guidelines for Setting Up and Running a Pharmacovigilance Centre'. The Programme aims to foster the culture of ADE notification in its first year of operation and subsequently aims to:

- generate broad-based ADR data on the Indian population and share it with global health care community through WHO-UMC
- ensure optimum safety of drug products in the Indian market
- provide technical expertise for evaluating statutory AE reports furnished by sponsors conducting clinical trials in India.

Even though India started participating in the WHO pharmacovigilance programme many years ago and has several professionals who have organized many pharmacovigilance workshops, adverse drug reaction monitoring in India is still in its infancy.

Objective analysis of the earlier ADR monitoring attempts in India pointed towards deficiencies in attitude, expertise and management that included lack of reporting culture among physicians, lack of

appropriate monitoring and supervision facility, lack of trained clinical pharmacists and nurses, as major factors. Health care professionals were not clear about what to report, how to, or where to report.

Over three years, CDSCO engaged stakeholders (doctors, pharmacy professionals from hospitals, pharmaceutical industry, clinical research organizations, academics from related fields) to discuss pharmacovigilance in an Indian context and elicit suggestions for conceptualizing a robust nation-wide pharmacovigilance programme for generating, collating, analyzing and evaluating the data.

Two extensively participated discussion meetings culminated in a workshop, in March 2003, where a National Pharmacovigilance Protocol and Standard Operating Procedures were documented, which now form the bed-rock of the National Pharmacovigilance Programme in India.

To effectively deal with the expected scale of operations in the country, our National Pharmacovigilance Programme envisages several Peripheral Pharmacovigilance Centers pooling their data at five Regional Pharmacovigilance Centers which in turn funnel their data to the two Zonal Pharmacovigilance Centers.

Zonal Pharmacovigilance Centers are expected to analyze the data and submit consolidated information to the National Pharmacovigilance Centre where a National Pharmacovigilance Advisory Committee evaluates the data and recommends appropriate regulatory interventions.

The National Pharmacovigilance Center which was at the All India Institute of Medical Sciences is now based at CDSCO. The two Zonal Pharmacovigilance Centers are the major hospitals in New Delhi and Mumbai. All Regional Pharmacovigilance Centers participating in the project are medical college hospitals which have a dedicated area and infrastructure for the pharmacovigilance programme.



*David Coulter with Daniela Encheva (Head of the Centre), Kapka Kaneva and Zdravka Cherneva.*

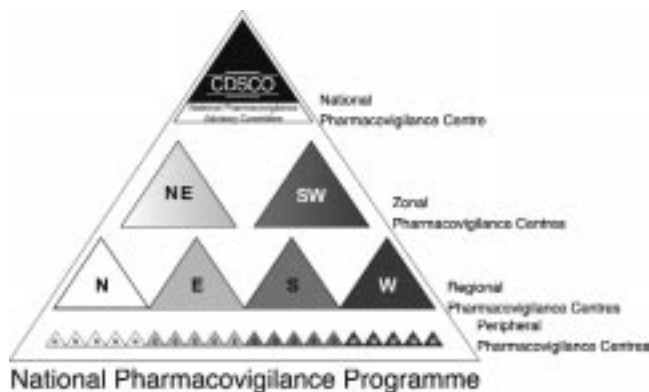


- National Pharmacovigilance Centre
- ▲ Zonal Pharmacovigilance Centres
- Regional Pharmacovigilance Centres
- Peripheral Pharmacovigilance Centres

*Map of India, showing the location of the Pharmacovigilance centres*

## Pharmacovigilant India! – *continued*

Peripheral Centers participating in the programme are clinics, retail pharmacies or hospital pharmacies and their activities are coordinated by the Regional Pharmacovigilance Centers.



In order to overcome the deficiencies observed in the past pharmacovigilance initiatives, clear operational benchmarks and standard operating procedures have been agreed upon by all participating centers. A training programme has been organized for the participating centers where appropriate communication skills to elicit adverse drug reactions information, hands-down training on recording adverse drug reactions information and for collating and submitting the data has been imparted.

### Centers participating in the Indian Programme:

#### Zonal Centre 1

All India Institute of Medical Sciences, New Delhi for North and East India

#### Regional Centers

- i. Lady Hardinge Medical College, New Delhi
- ii. NRS Medical College, Kolkata

#### Zonal Centre 2

SGS Medical College, Mumbai for West and South India

#### Regional Centers

- i. Madras Medical College, Chennai
- ii. KEM Medical College, Mumbai
- iii. Indira Gandhi Medical College, Nagpur

Keeping in view the large number of patients visiting Zonal, Regional and Peripheral centers, the following benchmarks have been established:

1. Each Peripheral Center to record at least 30 suspected AEs each month (30 AEs in about 1500 patients who visit each month would be quite feasible). Completed AE forms shall be forwarded to the concerned Regional Center.
2. Each Regional Center to collate and scrutinize the data received from the corresponding 5 to 6 Peripheral Centers as well as the data generated at the Regional Center itself. Perform the causality analysis of all 120 to 150 forms received every month. The monthly report – prepared in a specific form – to be forwarded to Zonal Pharmacovigilance Centre every month.
3. Zonal Centers to collate the data (approx. 1,000-1,200 forms) received from corresponding Regional Centers. Shall verify / validate the causality analysis. Prepare a professional report for CDSCO in a specified format. Communicate data to WHO Uppsala Monitoring Centre through the National Pharmacovigilance Centre.

All participating professionals are highly buoyant about the success of the programme, particularly since the World Bank has provided US\$ 100,000 for the project. UMC has committed generous technical support for the programme which indeed has the potential to contribute large volumes of data to the UMC's database and enhance the global knowledge in the area of pharmacovigilance.

*Comments may be forwarded to [Brijesh@Apothecaries.net](mailto:Brijesh@Apothecaries.net)*

### Responsibilities of the coordinating officers at the three levels of Pharmacovigilance Centers:

Responsibilities	Peripheral Centers	Regional Centers	Zonal Centers
To collect ADE notifications	✓	✓	✓
To receive blank ADE forms and acknowledge receipt	✓	✓	✓
To fill or get filled the ADE forms [fill all mandatory data]	✓	✓	✓
To forward duly-filled ADE forms to next higher level centre	✓	✓	✓
To maintain a log of all ADE notification forms [blank or filled] received and forwarded	✓	✓	✓
To identify, induce Peripheral / Regional Centers [with concurrence of CDSCO], provide them with general technical support, coordinate and monitor their functioning		✓	✓
To identify and delegate a pharmacologist for management of pharmacovigilance tasks			✓
To identify and delegate a data manager for data management under NPPI		✓	✓
To carry out [or review] causality analysis of all ADEs or Optional review such analysis by the Regional Centres			✓
To forward all duly-filled ADE forms [those generated at the same centre and those received from immediate lower-level centre] as per pre-determined time line	* Weekly [Monday]	* Every 15 days [alternate Monday]	* Only archiving
To forward periodic report to next higher centre as per the MIS format	Every 15 days [1st & 15th of every month]	Monthly [1st of every month]	Monthly [1st of every month]
To liaison with healthcare professionals in order to foster the culture of ADE notification / reporting			
1. Acknowledge the cooperation by the notifier	✓	✓	✓
2. Share with notifier relevant feedback from higher centers	✓	✓	✓
3. To organize and attend training programs / interactive meetings for all lower level centers	✓	✓	✓



## To Heal and Harm

An economic view of drug safety

Jonathan Silcock and Clive Pritchard  
Office of Health Economics

The Office of Health Economics, London, has published a 108-page book on adverse drug reactions. It provides an overview of legislation, incidence, aetiology and prevention of ADRs. The book aims to provide an historical background to modern pharmaceutical regulation, to summarise available data on the harm caused by medicines, to comment on treatment and to provide an economic framework for assessing optimal levels of pharmaceutical safety.

The chapter 'Adverse drug reactions and the development of medicines legislation' charts the development of medicines legislation in economically developed countries. The chapter 'The Incidence of ADRs' discusses the burden of disease ADRs create and the methodological issues surrounding such assessment.



The last 40 pages is the most interesting part. The 'Economics' chapter gives a framework that gives ADRs a central role in determining the nature of pharmaceutical testing and the extent of pharmaceutical use; this chapter is more speculative than preceding chapters due to the relative absence of existing economic analysis in this area. It focuses on the economic aspects of adverse drug reactions

both during clinical trials and in clinical practice. Economic aspects of both over-treatment and under-treatment of diseases are considered. New insights into the cost-effectiveness of preventive measures are not provided by the book.

## Preventing Medication Errors and Improving Drug Therapy Outcomes

A management systems approach

Charles D Hepler and Richard Segal  
CRC Press



This book explores medications use from a social perspective. It identifies and describes the preventable adverse outcomes of drug therapy, and discusses the safety, cost-effectiveness, management systems perspective and proposes systematic solutions. The book is aimed at anyone with an interest in medications use: students preparing for health professions or careers in health service management; graduate students and researchers; practising health care

professionals; pharmacy managers; insurance program managers; health care purchasers. The book mainly focuses on the position in the USA.

Each chapter has a list of references; there is a Glossary and Index.

## Building a safer NHS for patients

Improving Medication Safety

Report by the Chief Pharmaceutical Officer, Department of Health, UK



This official 150-page A4 report explores the causes and frequency of medication errors, highlights drugs and clinical settings that carry particular risks, and identifies models of good practice to reduce risk. Although aimed at managers and professionals in the UK National Health Service, the messages are applicable to many health care systems. The chapters are

1. Introduction: medication safety – a worldwide health priority
2. Medication errors: definitions, incidence and causes
3. The medication process: prescribing, dispensing and administration of medicines
4. Reducing the risks: challenges in specific patient groups
5. Reducing the risks: challenges with specific groups of medicines
6. Reducing the risk: organisational and environmental strategies

Annex 1 contains a summary of good practice recommendations. The text is liberally spread with case examples to illustrate the points made in the text.

It is available from

<http://www.dh.gov.uk/assetRoot/04/07/15/07/04071507.pdf>

## Stephens' Detection of New Adverse Drug Reactions, 5th Edition

John Talbot (Editor), Patrick Waller (Editor)

ISBN: 0-470-84552-X

Hardcover, 762 pages



Detection of new adverse drug reactions is fundamental to the protection of patients from harm that may occur as a result of medication. This book explores the methods used to investigate new adverse drug reactions, discussing all elements from the scientific background and animal toxicology through to worldwide regulatory and ethical issues.

Stephens' Detection of New Adverse Drug Reactions provides comprehensive and up-to-date coverage of material fundamentally important to all those active in the field, whether they work in the pharmaceutical industry, drug regulatory authorities or in academia.

The fifth edition of this classic work includes new chapters on:

- vaccine safety surveillance
- managing drug safety issues with marketed products
- operational aspects of drug safety function
- safety of biotechnology products
- future of pharmacovigilance



the UMC pharmacovigilance training course

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## Spontaneous Reporting and Continuing Medical Education

*Daniela Encheva, from Bulgaria, reports*

### Getting reports in

Under-reporting is a common phenomenon in many countries. It may delay signal detection and cause under-estimation of the magnitude of a problem. That is why promotion of spontaneous reporting is one of the main functions of a national pharmacovigilance centre. Easy access to pre-paid reporting forms, acknowledging the receipt of an adverse drug reaction report, providing feedback to reporters, are some of the well-established means of stimulating spontaneous reporting<sup>1</sup>.

Facing a declining spontaneous reporting rate, Bulgarian Pharmacovigilance Centre tried to explore new alternatives to stimulate submission of reports. The introduction of the concept of continuing medical education (CME) by professional associations in Bulgaria provided a good opportunity. Moreover, effective collaboration with professional associations is a distinctive approach to promoting the pharmacovigilance system.

### CME – the current position

In Europe, continuing medical education is largely a professionally driven activity based on 'recognised' educational activities for a set number of hours a year<sup>2</sup>. The heavy dependence on pharmaceutical industry sponsorship (with its inevitable emphasis on diagnosis and treatment) is a widely acknowledged problem of conventional CME activities. Studies on the outcomes of different CME activities have generally shown that conventional didactic methods have little role to play in performance change, which is the ultimate goal of continuing education<sup>3</sup>.

In this context the Bulgarian Pharmacovigilance Centre considered granting CME credits for reporting-related activities as an effective remedy to above-mentioned deficiencies in the conventional CME activities. This would reflect the modern concept for successful adult learning – to be learner-centred, active rather than passive, and relevant to the learner's needs.

### Reporting = education?

We recognize that submission of ADR reports per se is not an educational activity. Still, it reflects a suspicion of causal relationship and implies the need to receive additional information. This process can be traced to the inquiry-based concept emphasized in continuous professional development<sup>4</sup>.

The feedback information, provided to the reporter by the national centre, faces specific learning needs of the individual and is in fact learning developed in context. Feedback information that discusses the specific case of ADR as risk factors, patient monitoring and other possibilities for risk reduction would fit perfectly with the principles of self-directed learning and problem solving<sup>5</sup>.

The position of the national pharmacovigilance centre and ultimately the Uppsala Monitoring Centre serves as a basis for sharing of individual reporters' experiences. This feature of the feedback information further aligns it with the principles of CME – to be informed by the experience of others.

### The importance of feedback

Additionally reporters can be provided with independent information on the safety profile of the suspected drug, comparison with other drugs from the same pharmacological class or other treatment alternatives. This would combine effectively didactic with interactive methods for CME.

A practical advantage of this type of CME is that it operates at a distance and gives information that is directly linked to the workplace.

The national pharmacovigilance centre in Bulgaria outlined these principles in the discussions with the medical professional association, responsible for the organization of CME system. To further enforce the arguments we wanted to have the experience of other countries as reference in using such a technique to stimulate reporting and improve treatment outcomes.

### Sharing experience

Using the Vigimed distribution list, a discussion was launched on the current status of continuous medical education in different countries and the existing systems for granting CME credit to reporting physicians for submission of ADR reports and assimilation of feedback information. Despite the lack of experience with such systems, most of the national centres showed an increased interest and general support of the idea. Most of the centres that joined the discussion on Vigimed shared the belief that this could be an effective mean for improving reporting rates.

## International examples

Yet only Croatia and Slovenia have an established system of granting CME credit for submission of spontaneous reports. Croatian experience is very reassuring in terms of improving the reporting rates, which nearly tripled since the introduction of the system in 1996. The main arguments for including these activities as CME in Croatia were similar to those already mentioned – every reporter receives an acknowledgement letter with relevant data from the WHO database and the National Centre as well as the latest literature data on ADR, rational prescribing and medication in the report.

In New Zealand the Intensive Medicines Monitoring Programme (IMMP) has an established practice of giving CME credits for replying to IMMP requests for follow-up information. Even before the introduction of the CME points, the IMMP experienced a very good return rate (>75%) so granting CME credit there is considered more an enticement to continue. The number of credit points is 0.5 per activity in both countries and a maximum of 10 points in any calendar year.

Another relevant example, although not directly linked to submission of ADR reports, is the experience at the FDA MedWatch Continuing Education. Credits are granted upon receipt of a completed evaluation form on an article outlining the Vaccine Adverse Event Reporting System, available online. The number of credits is tied to the amount of time needed to read the article and answer the test questions. This principle could also be applied to determine the credits for assimilation of feedback information on an ADR report.

## CME to boost reporting

There are strong arguments that the inclusion of submission of ADR report and assimilation of feedback information as CME activity could contribute both to rational prescribing and improve monitoring the safety profile of marketed drugs. This can stimulate reporting without interfering with the voluntary basis of the spontaneous reporting system and improve the quality of data in reports.

As in all initiatives, the applicability of this approach depends on different country-specific factors – requirements for ADR reporting, the number of reports per year and resources available to the national centre. However we believe that following these positive examples, other countries could benefit through improving reporting rates and developing effective contacts with professional associations.

*Daniela Encheva thanks colleagues of the Bulgarian Pharmacovigilance Centre (Lora Nikolova, Kapka Kaneva and Zdravka Cherneva) as well as all those who responded to the Vigimed discussion.*

## News from Stora Target

### UMC pharmacovigilance training courses

We are very happy to announce that the national pharmacovigilance centre at TGA, Australia, has again invited *the UMC* to carry out the standard UMC pharmacovigilance training course in Canberra 8–19 November 2004. This is an attempt to repeat the successful collaboration between Australian and UMC tutors during the previous course in November 2002. A separate course announcement, including practical information, course fee and registration procedures will be distributed to relevant parties in May.

If you want to be sure to receive such an announcement please contact Anneli Lennartsson at [anneli.lennartsson@who-umc.org](mailto:anneli.lennartsson@who-umc.org)

The next course in Uppsala, the 10th UMC course since 1993, will take place from 23 May – 3 June, 2005. Announcements for this training event will be sent out in October – November this year.

Both training courses, in Canberra and Uppsala, cover theoretical and practical aspects of setting up and running a pharmacovigilance centre and, in a second module, provide an introduction to methods in pharmacoepidemiology.

### Vigibase On-line

Morocco has become the first National Centre to go 'live' on Vigibase On-line, the new ADR reporting software from *the UMC*. Switzerland and Ghana were involved already in the development phase. This exciting development provides software support to pharmacovigilance systems for report management from the initial reporter to regional and national centres and further to the WHO database in Uppsala.

### UMC website changes

There have been several changes made to the section on definitions on *the UMC website*. In particular, the information on causality has been improved and expanded. Ron Meyboom has adapted some of his teaching material from UMC training courses to provide a more attractive and in depth introduction to the subject. To view this, visit the Definitions section of [www.who-umc.org](http://www.who-umc.org).

### Seeing and hearing

Video conferencing is now possible with *the UMC*. We need sufficient prior notice, but can offer lectures to your centre from Uppsala.

Given the many requests we receive to visit different countries, and the difficulty in fulfilling them all, this may be a useful means for you to keep in touch with us.

If you would like to use this facility, please contact Ali Bahceci.

## Safety Monitoring in French

We are delighted to announce that the classic text 'Safety Monitoring of Medicinal Products' is now available in a French translation 'Surveillance de la Sécurité d'Emploi des Médicaments'. *the UMC* is indebted to Rachida Soulaymani-Bencheikh and colleagues at the Moroccan National Centre for assistance.

To obtain copies please contact *the UMC* via [info@who-umc.org](mailto:info@who-umc.org) or see the Communications information on page 3.



Dr Ed Napke is well-known in the world of pharmacovigilance, as one of the founders of national programmes and of international co-operation, as well as a scientist with strong individual views.

From 1965 to 1989 he initiated, developed and expanded the Canadian Drug Adverse Reaction Reporting Program, promoting voluntary reporting from all health professionals and agencies. He integrated this ADR program with a National Poison Control Program and various other adverse reaction reporting programs such as those for vaccines and veterinary medicines.

Ed Napke believes adverse reactions due to medicines, foods, vaccines etc. are public health issues, many of which are due to 'excipients and additives'.

Since 1990 he has been one of the volunteer consultants to the UMC, reviewing the results of the regular computerised screenings of ADR reports, with a particular interest in psychiatric disorders, respiratory system disorders and resistance mechanism disorders.

## A commitment to pharmacovigilance: 40 years on

### Ed Napke reflects on his life in pharmacovigilance

It was fate that got me into this essential service. I happened to be on my way to the USA to do some research when a friend asked me to join the (then) Canada Food and Drug Directorate for a couple of years to bring in the new regulations which were the response to the thalidomide tragedy. This was in the fall of 1963. After several trips to the US FDA, I advised



Ed Napke

my bosses that in order to ensure some degree of safety we had to develop a letter of compliance, which meant that drug manufacturers could not do clinical trials until they met the 'safety' requirements. I also promoted and advised that in the case of an emergency clinical situation the drug could be brought in for that particular case on the condition that the physician keeps records to be given to the regulatory authority for analysis - a single case experiment.

#### Launching Canadian Pharmacovigilance

By 1965, Canada launched its adverse reaction voluntary reporting program and I was given the task to get it going. There were no 'road maps', no staff, and the money was tied up in contracts with ten medical teaching hospitals across Canada. A voluntary program embedded in a regulatory body - a very rough fit. However I decided to expand the surveillance program to include vaccines, devices, veterinary drugs, food, cosmetics, herbal products, consumer reports of allergic reactions and poisonings and to start a Canadian poison control program. This required a great deal of selling and promotion, province by province, organization by organization, initially all by phone. Later, as my staff increased and a budget developed and I was able to obtain further voluntary co-operation for the program from the provincial health care bodies; medical, nursing

pharmacists, veterinaries, health care societies, hospital associates were also involved.

I represented Canada in the 'Feasibility Study' for a WHO Programme - one of the ten nations participating - and convinced the WHO Programme to accept my computer tapes since I didn't have the staff to fill out the WHO forms manually. I developed the colour-coded pigeon-hole system: a manual sorting system to work in conjunction with our computer program. In order to give feed-back to those who co-operated with me I created with our legal experts, the 'caveat' that accompanied the feed-back. This 'caveat' formed the basis for the adverse reaction feed-back by the WHO Drug Monitoring Programme and later by the Uppsala Monitoring Centre.

Over the years, two particular milestones of the Canadian Program were:

- to receive a letter from the Canadian Medical Protective Association stating that physicians who report adverse drug reactions are in a better position to be defended against litigation than those not participating in the program
- to encourage the Canadian Hospital Standards Association to include statements that hospitals have a better accreditation if they have a functioning adverse drug reaction monitoring programme.

I ran the Canadian Program from 1965 to 1989. Fortunately for me the Uppsala Monitoring Centre shortly afterwards accepted my earlier suggestion to form a consultant group, now the Signal Review Panel, to assist in analysing potential signals emanating from the WHO database. I was invited to join this group and it has permitted me to stay involved with the professional issues even after my formal retirement.

#### What causes ADRs?

I have strong views which differ with some current concepts: the role of excipients and additives in causing adverse reactions, the differences between monitoring adverse reactions to drugs (active ingredients) as opposed to drug products. These can explain major differences in adverse reactions country to country, hospital to hospital and can cause misuse of statistics in drug adverse reaction monitoring. The current drug adverse reaction

literature is on quicksand. The adverse reaction investigation almost always stops at the drug product level and the adverse reaction is automatically ascribed to the active ingredient in spite of a growing literature showing that it was the excipient additions in the product that were the causing agents. I believe excipients and additive adverse reactions are major problems, and not a minor problem as currently thought of. In addition to the laundry list of signs and symptoms we need syndromes per product and we need to mine the data that can be found in veterinary usage of the same products, poisonings and adverse reactions.

Perhaps some of my difference with the mainstream is my definition of a drug adverse reaction: an adverse reaction to 'a drug' may be defined as any



*Ralph Edwards, Neda Vócanec (secretary of the Croatian centre in Zagreb), Igor Francetic, (current head of the Croatian centre), Ed Napke and John McEwen (Australia) walking along Placa in Dubrovnik in 1985.*

action or lack of action that is not of therapeutic diagnostic or prophylaxis benefit to the patient. Lack of action, could be a signal for 'interaction', let alone being harmful to the patient because of failure of therapeutic effect. After all it is the patient we must serve, not the drug product.

One must remember that chemical surgery, namely exposing the body to chemical products, is more intrusive than physical surgery.

To me adverse drug reaction monitoring is a commitment, not a job.

## Still campaigning

In addition to his engagement in medicines and the risks associated with the use of them Ed Napke is and has been involved in many other movements advocating a healthy environment. In the 50s and 60s he was concerned about the dangers of cigarette smoke. He became the president of the Non-Smokers Association Ottawa - Hull, and in 1976 they got the

City of Ottawa to prohibit smoking in public places - a first in a major city in the world. He has joined movements combating the use of pesticides, arsenic in wood, fluoridation of drinking water, non-sugar sweeteners etc. As a member of several committees for the Canadian Standards Association he was also deeply involved in bringing out the first Child Resistant Packaging Standard. It is only logical that Ed ends his story by stating that he needs to live at least to 125 to do all that he wants to be done.

## Key Publications

1. Napke, E. and J. Bishop, The Canadian drug adverse reaction reporting program. *Can Med Assoc J*, 1966. 95(25): p. 1307-9.
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3. Napke, E., The Gap To Fill - Human Toxicology. *Canadian Family Physician*, 1969: p. 91-94.
4. Napke, E., Hypnosis in infertility and allergy. *Can Med Assoc J*, 1972. 107(6): p. 496.
5. Napke, E., The Canadian drug adverse reaction reporting program. *Drug Inf J*, 1975. 9(2-3): p. 224-32.
6. Borda, I.T., E. Napke, and C. Stapleton, Drug surveillance data in a Canadian hospital. *Can Med Assoc J*, 1976. 114(6): p. 517-22.
7. Napke, E., Present ADR monitoring methods, in *Drug Monitoring*, Gross & Inman, Editor. 1977, Academic Press: 131(12): p. 1449-52.
8. Napke, E., Adverse Reactions : Some pitfalls and postulates in N.M.G Dukes (Ed) *Side Effects of Drugs Annual 7*, 1983 *Excerpta Medica*
9. Napke, E. and D.G. Stevens, Excipients and additives: hidden hazards in drug products and in product substitution. *Can Med Assoc J*, 1984.
10. Edwards, I.R., et al., Quality criteria for early signals of possible adverse drug reactions. *Lancet*, 1990. 336(8708): p. 156-8.
11. Napke, E., Excipients, adverse drug reactions and patients' rights. *Can Med Assoc J*, 1994. 151(5): p. 529-33

# UMC PRODUCTS & SERVICES

## WHO DD at a glance

The WHO Drug Dictionary (WHO DD) is a unique international classification of drugs providing proprietary drug names used in different countries, together with all active ingredients and the chemical substances with unique reference numbers. The hierarchical record number system allows for easy, flexible information retrieval. Drugs are classified according to the Anatomical-Therapeutic-Chemical (ATC) classification which allows for grouping of drugs in different ways for comparison purposes. WHO DD also contains cross-references to manufacturers, market authorization holders and reference sources.

New drug names are routinely classified and added, but at a small cost it is possible to have drugs entered on request within 3 working days. Drugs are not deleted from the dictionary, although the products may no longer be on the market. Drugs have been entered into this database since 1968, as part of the WHO Programme for International Drug Monitoring. Drugs recorded are those which have occurred in Adverse Reaction reports, but as all drugs taken by patients are included (whether they are suspected of having caused the reaction or not), the database covers most drugs used in countries in the Programme. The data is taken from official data from drug regulators, national drug compendia or other trustworthy sources.

An increasing number of DD entries are entered by companies and regulators when products are launched on the market, which means that the entries get into the dictionary faster. We welcome user comments and suggestions.

## Updates – 1st Quarter 2004

The latest versions of the computerised WHO Drug Dictionary (WHO-DD) and WHO Adverse Reaction Terminology (WHO-ART), are now available. WHO-DD CD contains information for the 1st quarter of 2004. These will be sent to subscribers during May 2004.

### Need help?

If you have any queries about the content of the update package, or any detail of the DD itself, or need further information about your current subscription or how to upgrade it, do call *the UMC*.

### You can e-mail:

drugdictionary@who-umc.org for comments about the DD, corrections, additions, and katarina.hansson@who-umc.org for queries about your subscription.

If you are a subscriber to either WHO DD or WHO-ART and have not yet received the update, please contact Katarina Hansson.

## Meet us there!

UMC staff are planning to attend the following conferences 2004:

- DIA 40th Annual Meeting - Washington DC, USA, 13-17 June
- 20th International Conference on Pharmacoepidemiology & Therapeutic Risk Management - Bordeaux, France, 22-25 August
- Society of Clinical Data Management 2004 Conference - Toronto, Canada, 3-6 October

We look forward to seeing many of you at them; if you wish to arrange a meeting with us, please contact Mats Persson.

## WHO-ART

Information about the WHO Adverse Reaction Terminology has recently been updated. The current version of the computerised WHO-ART is 03:4, containing information up to and including the fourth quarter of 2003. Sample files for download (covering file descriptions and a system organ class file) have also been updated. New terms are classified and added every quarter, but it is possible to enter terms on request for a small charge - a request form is available. The 03:4 printed version is now available.

## UMC in Prague

*the UMC* attended the 16th DIA Eurometing in Prague, Czech Republic, where we held a user group meeting for the WHO Drug Dictionary. The user group meetings are important face-to-face meetings where the users and *the UMC* can discuss important issues and prioritise future development.

*the UMC* also had an exhibition booth where new potential customers of UMC's services could meet UMC personnel. The meeting was an opportunity to

talk to old and new customers, collaboration partners and other contacts. The Eurometing was attended by delegates from the pharmaceutical industry, CROs and regulators not only from Europe but from all over the world. This year many delegates were from the eastern European countries that will join the European Union in 2004.



Daniel on the UMC stand in Prague

## New staff

We welcome two new staff members, who joined the sales and marketing team a few months back.

Hannah Ericson is a real local, having been born in Årsta, Uppsala where she also grew up. Prior to joining *the UMC*, Hannah worked for Swedish Meats as a telephone saleswoman selling meatballs and other delicacies to supermarkets in the area. Previously she lived in London working in the jewellery business.



Hannah Ericson



Katarina Hansson

Katarina Hansson, is also from the Uppsala area, as she grew up in Sala, a small town outside the city. For 12 years she worked in sales in the IT sector, followed by 3 years for an exhibition/event company as a project leader. When not at *the UMC* she enjoys her time with her children, Isabelle (10) and Beatrice (8).

The Centre recently said goodbye to Sally Erikson (Team Support) who moved to pastures new - where we wish all her the best.

# COURSES & CONFERENCES

DATES	TITLE	PLACE	ORGANISER/CONTACT
24 May 2004	The Role of the Qualified Person in Pharmacovigilance	London, UK	Management Forum Ltd Tel: +44 (0)1483 570099 Fax: +44 (0)1483 536424
10-11 June 2004	Back to Basics in Pharmacovigilance	Fareham, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
13-17 June 2004	DIA 40th Annual Meeting	Washington DC, USA	DIA Tel: +1 (215) 442 6100 Fax: +1 (215) 442 6199 www.diahome.org
16-18 June 2004	Essential Training in Global Pharmacovigilance	Munich, Germany	IBC Life Sciences Fax: +44 (0)20 7017 5656 E-mail: marilyn.canale@informa.com
29-30 June 2004	Signal Detection practices within your pharmacovigilance plan	London, UK	IIR Life Sciences Tel: +44 (0)20 7915 5055 E-mail: registration@iir-conferences.com
8-9 July 2004	Compliance in Pharmacovigilance	London, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
29-30 July 2004	Adverse Event Reporting and Pharmacovigilance	London, UK	PTI Courses Tel: +44 (0)20 7915 5123 www.pti-courses.com/adr
1-6 August 2004	8th World Congress on Clinical Pharmacology and Therapeutics	Brisbane, Australia	CPT 2004 Congress Secretariat Tel: + (61 2) 9241 1478 Fax: + (61 2) 9251 3552 E-mail: cpt2004@icmsaust.com.au
22-25 August 2004	20th International Conference on Pharmacoepidemiology & Therapeutic Risk Management	Bordeaux, France	International Society for Pharmacoepidemiology Tel: +1 (301) 718 6500 Fax: +1 (301) 656 0989 E-mail: ispe@paimgmt.com
6-8 October 2004	ISoP Annual Scientific Meeting	Dublin, Ireland	ISoP Administration Tel/Fax: +44 (0)20 8286 1888 www.isoponline.org
12-15 October 2004	II Congreso Internacional de Farmacologia y Terapeutica	Havana, Cuba	Cubatour SA Fax: +53 7-336471 E-mail: opc_eventos@cbtevent.cbt.tur.cu
13-14 October 2004	Risk Benefit Assessment in Pharmacovigilance	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
14-15 October 2004	Medical Approach in Diagnosis and Management of ADRs 2004	Paris, France	DIA Tel: +41 61 225 5151 E-mail: diaeurope@diaeurope.org www.diahome.org
11-12 November 2004	Workshop on Case Narrative Writing for Reporting Adverse Events	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
12-13 November 2004	V Jornadas de Farmacovigilancia	Barcelona, Spain	Institut Catala Farmacologia Tel: +34-93 428 3029 Fax: +34-93 489 4109 E-mail: xp@icf.uab.es
24 November 2004	Data Safety Monitoring Boards & Data Review Committees	London, UK	DSRU Tel: +44 (0)23 8040 8621 Fax: +44 (0)23 8040 8605 E-mail: jan.phillips@dsru.org
29-30 November 2004	Hot Topics in Pharmacovigilance	Paris, France	DIA Tel: +41 61 225 5151 E-mail: diaeurope@diaeurope.org www.diahome.org



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## Communications help at hand

If National Centres are looking for help with communications – written and spoken – we have just the man for you. He is available for support by e-mail, as well by visits when there is a sufficient task to justify the travel. **Bruce Hugman** has worked as a UMC consultant since 1995. He's helped us with our publications (Viewpoint and Expecting the Worst), as well as with marketing, media relations, training and meeting organisation. He's made presentations on communications issues for us at conferences all over the world.



*Bruce Hugman*

Here are some of the things he may be able to help with:

- Written English: writing original text or refining existing text or presentations; training in writing
- Good communications practice: help in developing effective practice and tools for promoting drug safety issues, ADR reporting, general education about medicines
- Media relations: helping you to prepare for and cope with the demands of local journalists or training them in health issues
- Crisis management: as author of 'Expecting the Worst' he can help you with the planning and implementation of a crisis management strategy
- Presentations and courses: an excellent presenter, he can provide your meeting with a lively presentation on a wide range of topics; or help plan and run courses on the above topics.

You can contact Bruce directly (mail@brucehugman.net) or through Sten Olsson (sten.olsson@who-umc.org). Requests made directly to Bruce will usually be referred to the UMC for discussion. We will normally require travel costs and accommodation to be provided and a contribution to the consultancy cost.



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