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Uppsala reports

For everyone concerned with the issues of pharmacovigilance and toxicovigilance

MESSAGE FROM THE DIRECTOR

Never before has the question of safety been higher on the world's agenda. Since the catastrophic events of 11 September in New York and Washington our sense of personal and community security has been subverted. It will be a very long time – if ever – before any of us can look at an aeroplane or a tall building and not be reminded of those apocalyptic events.

We think of our friends and colleagues across the Atlantic and those affected in other countries, shocked, angry, bewildered, maybe bereaved too. To the people of the US, and especially to those many known to us personally over the years, we send our affectionate support and good wishes. We have all been deeply affected by their national tragedy and by its inescapable meaning for us.

In our specialised field of enterprise in drug safety we have for so many years had an international community of friends and collaborators which transcended all the barriers of country and race and religion. It's hard to accept that those differences can, for some others, be the source of murderous hatred.

Our international collaboration in the pursuit of our vision of the improvement of patient welfare and public health is a small but wonderful example of the good that human being can achieve together, against the odds of difference and distance.

In the context of such awful events, that gives us cause for some comfort, for some hope. The seeds of international harmony do exist and there is a part for all of us to play in nurturing them, however small our arena of activity.

Ralph Edwards

Getting the message across

We're often told at *the* UMC that we don't explain well enough what we do. We're about to try and put that right in a big way.

In the next six months a two-part portfolio will be published. It will aim to inform and stimulate a wide audience about the issues, controversies and science in pharmacovigilance.

The first booklet, raises and discusses big, broad issues:

- How safe are medicines?
- What is risk?
- How can harm from medicines be identified and reduced?

and is aimed at anyone, from the most specialised scientist to current and potential patients everywhere.

The companion volume provides detailed, technical information about the activities, services and products of *the* Uppsala Monitoring Centre and about the challenges of world-wide collaboration for improved patient care and public health. This section is intended more for specialists in the field, though there is much of interest to the general reader too.

We are planning to launch the first booklet by the end of this year. Then we'll be distributing it to a wide audience, including specialist and general media.
We hope the publication will not only raise the profile and discussion of drug safety and rational use of drugs world-wide, but also provide detailed, technical information for all those working in the field of pharmacovigilance.

For more information, please contact ***the*** **UMC**.

More countries joining the WHO Drug Monitoring Programme

In the last few months an exceptional number of new National Centres have become part of the WHO pharmacovigilance network. Armenia, Brazil, Egypt, Ghana and Uruguay are now full members of the Programme and Ukraine is regarded as an associate member, awaiting the submission of ADR reports to the WHO data base. Armenia, Egypt and Ghana were associate members earlier but have now started to actively contribute to the international pool of case reports. As of October 2001, there are 65 full members and 5 associated members in the WHO Drug Monitoring Programme.

With Brazil joining the international network, all major pharmaceutical markets in the world are now represented. There has been an active collaboration between the WHO Programme and the Special Centre for Promotion of Pharmacovigilance at CEATOX in São Paolo for several years. The Brazilian drug control authority, ANVISA, is now taking charge of the pharmacovigilance activities in the country maintaining collaboration with CEATOX.

The National Centre contacts in the newcomer countries are:

Brazil
Mr Murilo Freitas Dias
Unidade de Farmacovigilancia (UFARM)
Agência Nacional de Vigilância Sanitárita
SEPN 515 Bl.B Ed. Omega 2 Andar
CEP 70770-502 BRASILIA DF, Brazil
Tel: +55-61-448 1219
Fax: +55-61-448 1275
E-mail: murilo.freitas@anvisa.gov.br

Egypt
Dr Gamila M. Moussa
Director General of Drug Control Department
Ministry of Health
CAIRO, Egypt
Tel: +20-2-3549 802 / 3545 159
Fax: +20-2-3542 627
E-mail: eadrmc@hotmail.com

Ghana
Dr Alex Dodoo
Centre for Tropical Clinical Pharmacology & Therapeutics
University of Ghana Medical School
Korle-Bu Teaching Hospital
ACCRA, Ghana
Tel: +233 21 675 885
Fax: +233 21 666 8219
E-mail: alexooo@yahoo.com

Uruguay

Dra Mabel Burger
Depto de Toxicologia
Hospital de Clínicas
Avda Italia s/n, piso 7
11600 MONTEVIDEO
Uruguay
Tel: +598-2-480 4000
Fax: +598-2-487 0300
E-mail:
hcciat@hc.edu.uy

Dra Carolina Seade Fournie
Depto de Farmacologia
Hospital de Clínicas
Avda Italia s/n, piso 1
11600 MONTEVIDEO
Uruguay
Tel: +598-2-487 27 02
E-mail:
cseade@montevideo.com.uy

Armenia *(see separate article on page 4)*
Dr Samvel Azatyan
Department of Pharmacovigilance and Rational Use of Drugs, Armenian Drug and Medical Technology Agency

Visit from China

On 10 September 2001, Dr Li Shaoli, Dr Wang Lanming and Ms Zhang Sumin from the national centre for ADR monitoring, P.R. China visited *the* UMC. They were accompanied by Ms Li Hui and Ms Cai Weizhen, Eli Lilly, China.

Dr Shaoli, director of the Chinese centre, made a presentation about current activities and future plans for pharmacovigilance in China to *the* UMC staff. Sten Olsson gave a broad overview of the functions and activities of *the* Uppsala Monitoring Centre. Discussions on how to improve reporting from China and how the Chinese Centre might benefit more from the resources of *the* WHO Programme followed. Issues relating to safety monitoring of traditional herbal remedies were given special attention.

The Development of Pharmocovigilance in Armenia

The Republic of Armenia, a former republic of the Soviet Union, is an independent state located on the borders of Turkey and Iran.
There was no acting system for collection and registration of adverse drug reactions in Armenia until 1992 when Armenian Drug

Dr Samvel Azatyan

and Medical Technology Agency (ADMTA) was established. For many reasons ADMTA was the most suitable location for the Pharmacovigilance centre:

- easy access to communications: telephone, fax, Internet and e-mail.
- the swift route from reporters to regulatory authority without any intermediary. This allows us to react upon reports received quickly by making regulatory decisions.
- solution of financial problems (we can use registration fees for funding the activity of Pharmacovigilance centre).
- use of ADMTA publications for easy dissemination of information to interested parties through bulletins, leaflets, booklets, etc.

New Reporting Form

At the beginning, the hard economic and social situation in the country meant extremely low reporting activity by doctors. To solve these problems we began by developing a new reporting form. Using the experience of other countries and the WHO, our new form is very simple and has a number of advantages, which can promote activation of reporting process. The form is bilingual, allowing completion in both in Armenian and in Russian, and it admits the reporting even when the doctor is not sure of the reliability of the information or completeness. Currently the department has got all necessary communications and equipment, and since December 1998, when Armenia joined the WHO Programme as an associate member, it has received free online access to the WHO database.

Drug Safety Bulletin

Low reporting activity remains the major problem in Armenia. Often doctors prefer not report because of difficulties in recognition of adverse effects. To encourage them we established and publish monthly a "Drug Safety" bulletin, also bilingual, which contains up-to-date information on drug safety issues. Increasing the active participation of medical professionals in the ADR Monitoring Programme is the most

Nonna Grygoryan

difficult issue, taking into account the absence of a "reporting culture" among them. Our efforts should be done for the development of such a culture. ADR Monitoring, being an important component of drug policy, will also have an appreciable increasing effect on rational drug use in Armenia.
Our contact is:
Dr Samvel Azatyan, Deputy Director, Armenian Drug and Medical Technology Agency, 15 Moscowian Street, Yerevan, 375001, ARMENIA
Tel: +374-1-584 020, 584 120
Fax: +374-1-151 697
E-mail: azatyan@pharm.am

Creación de la Red de Centros de Farmacovigilancia Iberoamericanos

Mariano Madurga of the Spanish Medicines Agency informs us that following the pharmacovigilance course held in Antigua, Guatemala last May (described in UR14) an informal Latin American Pharmacovigilance network has been established. Costa Rica, Cuba and Venezuela are steering the group forward, which aims to facilitate exchange of information, news about local signals or withdrawals and to encourage the setting up of new National Centres to join the WHO Programme.
Contact:
Jetty Murillo Ocampo
Caja Costarricense de Seguro Social
Centro Nacional de Farmacovigilancia
Avda. Segunda
SAN JOSÉ 1000
Costa Rica
Tel: +506-222 1878
Fax: +506-257 7004
E-mail: jettymurillo@hotmail.com

Quantitative Signal Detection in Pharmacovigilance

Eugene van Puijenbroek, from the Netherlands Pharmacovigilance Foundation Lareb, has published his thesis on the quantitative methods that he has applied to the 30,000 ADR reports in the Lareb database. Quantitative signal detection is not the only analysis undertaken; he also examines drug-drug interactions with oral contraceptives and itraconazole and with diuretics and NSAIDs. Finally, he discusses practical implementation of the quantitative approach in the spontaneous reporting system for ADRs in the Netherlands. The research project was carried out in collaboration with the Utrecht Institute of Pharmaceutical Sciences.
You may contact Lareb via e-mail (info@lareb.nl) or fax 073 642 61 36

Southampton: First International Signal Generation Symposium

Signal generation in pharmacovigilance is an exciting and rapidly emerging field in drug safety. The advancement in computer technology and databases in the past 10 years has enabled the development of complex algorithms to be used to analyse drug safety databases in a search for potential signals. To share experiences in this developing field the Drug Safety Research Unit (DSRU) in Southampton in the south of England on June 25th and 26th 2001 hosted the first international Signal Generation Symposium. 90 delegates attended the upbeat gathering.

Delegates in the sunshine in Southampton

Professor Stephen Evans introduced the symposium with his experiences with Proportional Reporting Ratios (PRRs) at the Medicines Control Agency in the UK. Andrew Bate and Ralph Edwards from *the* UMC then gave an overview on the Bayesian Methodology used at *the* UMC with the World Health Organisation's spontaneous report data. Dr Ana Szarfman from the Food and Drug Administration (FDA) in the USA continued on the Bayesian track and explained how the FDA were looking into syndromes that are associated with drugs. The first afternoon was dominated by speakers from industry reminding us of the importance of good pharmacovigilance as well as the need for clearly defined systems for dealing with the data. Dr Sue McGuirk from GlaxoSmithKline then shared her experiences with PRRs in their database and a comparison with DuMouchel/Multi-item Gamma Poisson Shrinker (MGPS) analysis of the same drugs on the FDA safety database.
Delegates and speakers enjoyed dinner at the Royal Southern Yacht Club on the River Hamble in the evening.

Dr Patrick Purcell from the Australian Therapeutic Goods Administration opened the second day presenting his use of PRRs and profiling of drugs. The theme of PRRs continued when Dr Emma Heeley from the DSRU demonstrated its uses with Prescription-Event Monitoring (PEM) data along with some preliminary incidence rate ratio results. Dr David Coulter from the New Zealand Intensive Medicines Monitoring Programme gave a clinical perspective of signal generation with interesting examples of cases of adverse drug reactions. The Japanese version of PEM (J-PEM) set up by Professor Kiyoshi Kubota, enlightened the audience as to developments in Japan as well as the use of J-MedDRA for signal detection. Dr Elliott Brown highlighted the advantages and pitfalls of using MedDRA, the enormity of it and the potential for sharing information globally. Professor Toine Egberts discussed with examples, the comparison of various measures of disproportionality. The meeting concluded with Dr Ronald Meyboom's views on what to do following the identification of a possible signal and Dr Saad Shakir, on evaluation of signals in pharmacovigilance.
It is intended to publish proceedings in the journal 'Drug Safety'.

Indian Experts Get Together in Agra

The Society of Pharmacovigilance, India, will hold its 1st Annual meeting in Agra (the city of the Taj Mahal) from 8-10 November, 2001.
Organiser Professor K C Singhal writes:

> 'The society with its modest membership of dedicated workers is determined to spread the message of safe drug use in clinical practice. The members include Clinical Pharmacologists, Clinicians and Pharmacists. After the meeting we propose to bring out the proceedings of the Conference. This will include articles on topics of pharmacovigilance, abstracts of papers and other related material.'

the UMC will be represented at the meeting by Bruce Hugman, who will lead workshops on communications topics and skills.

Development of Pharmacovigilance in the former Soviet Union

In the latest issue of the WHO Pharmaceuticals Newsletter, Vladimir Lepakhin reports on the WHO Project on the development of systems of pharmacovigilance in the newly independent states of eastern Europe (NIS).

Eight countries are participants in a project entitled "Implementation and Development of National and Regional Systems of Pharmacovigilance in NIS" (see map above). The preliminary investigation of the status of drug safety monitoring revealed that the situation varied greatly between these countries.
Armenia, Russia and Ukraine had a basic structure in place; others had no ADR monitoring mechanisms.
The targets of the project, drawn up in Moscow in April 2000 are

- Including drug safety control in national legislation
- Establishing and strengthening national/regional ADR monitoring centres
- Education and training of specialists in pharmacovigilance
- Establishing a NIS network on pharmacovigilance
- Involving NIS countries in the WHO International Drug Monitoring Programme

The guidelines for setting up and running a pharmacovigilance centre were adopted for NIS and translated into Russian, then distributed to all countries.
All the targets are being worked towards (*see report on page 4 for progress in Armenia*), but creating a reporting culture among doctors will require the most effort. Six countries have started collection of reports, the most coming in Russia and Ukraine. The informational and educational parts of the Project have been the most successful – over 50 seminars (with a total of over 2,000 participants) have been held, using WHO materials.
Much has been achieved in the NIS in a relatively short period, but there is still a huge amount of work to be done to establish pharmacovigilance in this region.

Latvia looks forward

Inese Studere writes from the State Agency of Medicines of Latvia (SAM).
"When I was a participant on the Uppsala ADR Training course in 1999, we had no ADR monitoring in Latvia – no legislation, no reporting traditions. Our ADR reporting form has been approved in May 2000. An ADR Monitoring Department was established in the State Agency of Medicines of Latvia in 1st January 2001.
I am head of this department, with one officer and a secretary. Since that time, our first success has been in harmonising our pharmaceutical legislation with that of the EU – the Rules of the Cabinet of Ministers on the Surveillance of Adverse Drug Reactions came into force on 1st April 2001. Since 1999 I have participated in the PERF (Pan-European Regulatory Forum) pharmacovigilance program and now represent CADREAC countries (Collaborative Agreement of Drug Regulatory Authorities of European Union Associated Countries) in the EMEA PhVWP as an observer."
In Latvia the pharmacovigilance activities of SAM have found expression in the publications explaining ADR monitoring and pharmacovigilance problems in doctors' and pharmacists' professional magazines. A Scientific Advisory Board for Pharmacovigilance will soon be organised within SAM, but lack of a national plan for the development of pharmacovigilance system remains a great problem.
"When our number of ADR reports is sufficient and other formalities are complete we look forward to joining the WHO Drug Monitoring Programme."

Regrouping in Erice

The publication of the Erice Declaration on Communications in Pharmacovigilance in 1997 started an important process which has gathered momentum ever since. The Declaration called for a new era of openness, transparency and widespread collaboration in pharmacovigilance, and greater attention to effective communication about drug safety issues for all stakeholders.
Since then, the issue of communications has shot up the world agenda and is to be found on the programmes of many conferences and consultations. Increasingly, scientific professionals are recognising that much more attention and resources need to be given to effective promotion of drug safety messages.

Revisiting the mountain-top

Erice is a unique, ancient village perched atop a high mountain at the western end of Sicily. Clear blue skies, pure air and remoteness make it an ideal place for quiet reflection and discussion. At the invitation of Professor Giampaolo Velo – whose second

home is the Ettore Majorana Centre for Scientific Culture in Erice – an international group gathered there in June, 2001 to review the Erice Declaration, to assess what progress had been made and plan further activities. Among the issues covered and the tasks identified were:

- Strenuous efforts should be made to clarify communication on effectiveness and benefit, risk and harm, and to educate professionals, patients and journalists
- Uncertainty and doubt, intrinsic in any scientific pursuit, were still insufficiently admitted, and poorly communicated
- The expression of uncertainty on or in drug packaging was thought to be important but difficult. Improved, empowering information should be made available for patients, though doctors should remain the 'learned intermediary' for interpretation and shared decision-making
- Research is urgently needed into the information needs of healthcare professionals, patients and the general public
- Specialist professional organisations and societies should always prepare non-specialist and lay summaries of their proceedings and circulate them widely
- All learned societies should hold press conferences. They should try to ensure that research findings with important and immediate impact on general medical practice be communicated in the fastest and most effective way possible
- It was very desirable to brand information resources (especially websites) by professional organisations with a seal of approval
- Sudden or imprudent action sometimes replaced wise reflection and learning, especially in drug safety matters, where there was often unreasonable pressure for urgent decisions.
- Safety in pregnancy, and in the treatment of children, were seen as specific areas where more information was needed
- Orphan drugs were seen as needing attention
- Serendipity – through which much good science had developed – should not be stifled by over-regulation or methodological prescription. It was thought very important to foster continued individual, original and imaginative thinking.

Erice Group in ancient courtyard

A paper on the principles of communication of effectiveness, risk, benefit and harm of drugs is in preparation for wide circulation and posting on the internet.

Alongside distinguished Italian doctors and academics (including Giampaolo Velo), others in the group were:
Alan Bennett (UK)
Ralph Edwards (UMC)
Rod Flower (UK)
Per Hedqvist (Sweden)
Jon McGiff (US)
Richard Smith (UK)
Bruce Hugman (UK)
Zeliha Yazici (Turkey).

Pharmacovigilance Training in Mexico

A Pharmacovigilance Training Course in the city of Campeche, with 25 physicians and pharmacists, concluded this June. The course was sponsored by the Health Ministry at Campeche and the Autonomous University of Campeche and was co-ordinated by MS Mirna Uc Encalada.

It consisted of six forty-hour modules:

- Introduction and ADR Mechanisms
- Pharmacovigilance in the Hospital
- Legal Framework
- Clinical Pharmacokinetics
- Mechanisms of Adverse Drug Interactions
- Causality Assessment and Drug Literature Evaluation

Practical activites

On the practical side the participants had to detect and assess the causality of ADRs at the hospitals where they worked; they collected a total of 150 ADRs. An important finding was that some of these ADRs were nystagmus induced by chlorpropamide - possibly a new ADR.

A successful conclusion

By the end of the course, the participants were aware that pharmacovigilantes must become a world team in order to accomplish our main goal, the welfare of every human being. Teachers were Mirna Uc Encalada, Daniel Barreda Puga, Helgi Jung Cook, Miguel Piña Quijano, and Juana Leticia Rodríguez y Betancourt (who was also our correspondent in Campeche).

News *from the* Uppsala Mon

New Look for SIGNAL

A new issue of SIGNAL (September 2001) has been produced and will be sent by post to all National Centres. The appearance of the SIGNAL cover has been freshened up with a new layout which we hope readers will like. Another improvement is that there now is a description of the nature of the signals presented in SIGNAL, on the inner front cover.

New format available

We are now also able to provide SIGNAL as a pdf file. *the* UMC has decided to send it as an e-mail attachment to members of the Vigimed list. We will continue to send the paper printed version of SIGNAL as before.

The SIGNAL document contains summaries of analyses of ADR reports in the WHO database made by *the* UMC review panel. The information in SIGNAL is of a preliminary nature intended for use at drug regulatory authorities in countries participating in the WHO Programme for International Drug Monitoring. The document is produced as required and routinely distributed to all National Centres participating in the Programme.

Your responses to our questionnaire

We have been delighted with the number of responses from all around the world to our short questionnaire in Uppsala Reports 15.

Some respondents have taken the opportunity to correct their address details, or to give the name of colleagues who also wish to receive Uppsala Reports. Although the contents, design, range of content and relevance all got a 'thumbs-up', there were some helpful suggestions, which we will bear in mind for future editions. Thank you all for taking the time to respond.

New contributors

We are particularly pleased that several readers have offered to contribute some sort of article to Uppsala Reports in the future, and we will be contacting all those respondents shortly to discuss what their contribution might be.

Responses still welcome

If for some reason you did not receive the questionnaire, or did not send or fax your form back, please do so, as we need to continue to monitor the acceptability of our magazine.

News from Review Panel

Two new reviewers have joined our panel:

Dr David Clark, Department of Pharmacology, University of Otago, Dunedin, New Zealand; e-mail: david.clark@stonebow.otago.ac.nz

and

Dr Rick Fraunfelder, National Registry of Drug-Induced Ocular Side Effects, Casey Eye Institute, Portland, Oregon, USA e-mail: fraunfer@ohsu.edu

Reviewers at work

Although there was no reviewers' meeting this year, activity in the review group has increased since the meeting in September last year.

However, to allow reviewers to undertake concentrated signal detection work, some have been spending time here in our offices in Uppsala. This increases their feeling of being part of *the* UMC and gives a better understanding of how we work, and what information we have available. It is easier to concentrate when there are no other tasks disturbing you and also at *the* UMC we have many facilities such as direct access to the case reports in the database.

Another benefit is that UMC staff can provide help whenever there are any queries. Accommodation is in a small apartment in the same building as *the* UMC's office (all necessary facilities but no luxury!).

Visitors to Uppsala

Recently visitors have included Dr David Clark, Dr Rick Fraunfelder, Dr Elliot Brown, Prof Chandra Singhal and Dr Emilio Sanz. Dr Ruth Savage will be here in October and Dr Mabel Burger in November.

Staff changes at *the* UMC

the UMC has taken the step of employing a person not living in Uppsala or indeed Sweden. It is Mr Geoffrey Bowring who joined *the* UMC team in July. Geoffrey lives in and will be working from London, although he will visit Uppsala on a monthly basis. He previously worked for EQUUS, the consultancy company we have used for a number of years to assist with communications, text editing and meeting administration. Geoffrey's tasks will include developing materials for distribution, (e.g Uppsala Reports), maintaining contacts with UMC partners, and managing the planning and administration of major events like the Annual Meeting of National Centres. If you attended last year's National Centres' meeting in Tunis you might have met Geoffrey who was part of the secretariat.

itoring Centre

VIGILANCIA DE LA SEGURIDAD *de los* MEDICAMENTOS

Safety Monitoring of Medicinal Products

Guidelines for setting up and running a Pharmacovigilance Centre has been translated into Spanish, and will shortly be published in that language by *the* UMC. To obtain a copy of this concise and informative guide, either in the Spanish version or the original in English, please contact Sten Olsson at *the* UMC.

Is your database a question of chance?

We recently received a letter addressed to:

SVEN JOHNSSON
DRAGGARBRUSSIANFEDERATIONNNSGATAN 25
SE753-20 UPPSAUDI ARABIALA
SWEDEN

....and we'd like to congratulate the Swedish postal service for getting the letter to us! However, we want to keep our database in good condition, so please let us know if you are not receiving post you are expecting from us, or if there is anything wrong with our labels!

Product News

2nd Quarter 2001 Update

The new versions of the computerised WHO Drug Dictionary and WHO Adverse Reaction Dictionary (WHO-ART), containing information for the 2nd quarter of 2001 are now available. These were sent to subscribers during early October 2001.
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 2001 should be available by November/December 2001.

ADRespherics

After the DSRU and ISPE meetings this summer we have received a number of requests regarding our signal detection using the BCPNN methodology. If you are interested in starting using or subscribing to the commercial version of the BCPNN - ADRespherics please do contact Mats Persson (mats.persson@who-umc.org) to set up a telephone conference to discuss more about ADRespherics and what it could do for you and your organisation.

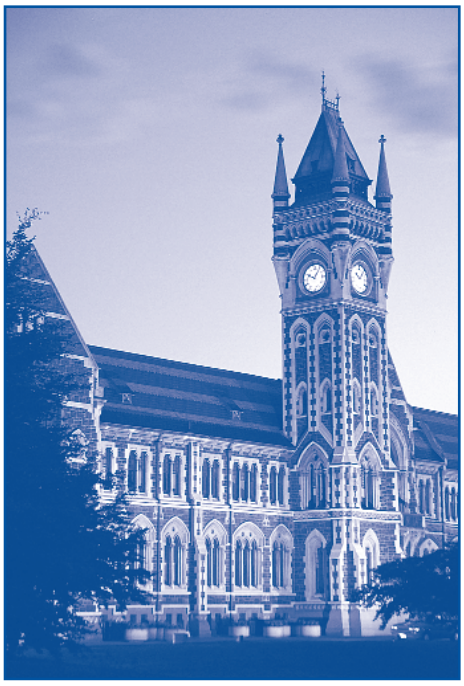
Liza has left

Liza Storm who joined the UMC team in 1987 is no longer working for us. She held several different positions at the Centre before leaving on 1 July this year. Her last function was as head of customer relations.
Contacts with commercial customers are now maintained mainly by Ms Inger Forsell.

24th Annual Meeting of *the* WHO Programme

By the time you receive this Uppsala Reports, National Centres will have had a request for issues to be discussed in the **'Drugs of Current Interest'** sessions in Dunedin, along with an explanatory note and fax-back form. We look forward with much interest to receiving all the ideas.

In addition to 'Drugs of Current Interest', 'Offers and Wants' (see below), and posters from new member countries, there will also be space for National Centres to display any research posters or other information they have produced, which they would like to share with others at the meeting.



"Nearly time"

As it's a long journey from Uppsala to Dunedin, UMC staff will be taking the opportunity to catch up with colleagues in many countries en route.
Ralph Edwards will be running a course in Hong Kong, then presenting a paper in Malaysia.
Other UMC staff will be making working stops in Japan, Australia, Vietnam, Fiji and New Zealand.
The meeting facilitator, Bruce Hugman will be travelling via Jordan, India and Singapore to run teaching events.

Offers and wants

We will have another **'Offers and Wants'** board in Dunedin, to increase the support and sharing among National Centres around the world. Some useful exchanges occurred in Tunis, so please come to Dunedin prepared with any items – the UMC will also participate with our own wants and offers!

Impact of ICH guidelines on non-ICH countries

Dr Mary Couper, QSM, WHO Geneva writes:

Harmonisation of various elements of drug regulatory activities has been undertaken in the last decade as an initiative of intergovernmental organisations at a regional and inter-regional level. The driving force of the harmonisation efforts was the increase of global trade in pharmaceutical products and the growing complexity of technical regulations related to drug safety and quality.

An informal consultation was convened in Geneva in September 2001 by WHO Secretariat to consider recent developments in the activities of global harmonisation of regulatory requirements for pharmaceuticals, in particular the activities of the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use.

Among the topics discussed during this meeting was the new initiative by the ICH to develop guidelines in the area of pharmacovigilance. The meeting was informed of the work already being carried out by *the* Uppsala Monitoring Centre in this area. One of the recommendations from this informal consultation was that "the ICH should be encouraged to benefit from the work already carried out by WHO in the area of pharmacovigilance, and that all ICH countries should be encouraged to participate more actively in the WHO Programme for International Drug Monitoring".

Forthcoming Courses & Meetings in Pharmacovigilance

November 1-2, 2001
1st Annual Workshop in Japan for Global Pharmacovigilance: International Comparison of Pharmacovigilance
Aioi Sonpo Shinjuku Hall, Tokyo, Japan
Contact: Drug Information Association,
Tel +1 215 628 2288
Fax +1 215 641 1229
e-mail dia@diahome.org

November 5-6, 2001
Pharmacovigilance into 2002
London, UK
Contact: DIA Tel +41 61 386 93 93
Fax +41 61 386 93 90
e-mail dia@diaeurope.org

November 7-8, 2001
Workshop on Case Narrative Writing in Pharmacovigilance
Southampton UK
Contact: Jan Philips, Drug Safety Research Unit,
Tel: +44 (0)23 8040 8621
Fax: +44 (0)23 8040 8605
www.dsru.org

November 8-10, 2001
Inaugural conference of the Society of Pharmacovigilance, India
SN Medical College, Agra, India
Contact: Prof KC Singhal,
Fax +91 0571 401331

November 11-24, 2001
Promoting Rational Drug Use in the Community (Course will be in English)
Entebbe, Uganda
Contact: Daphne Fresle, Department of Essential Drugs and Medicines Policy, World Health Organisation, CH-1211 Geneva 27, Switzerland
e-mail: fresled@who.int

November 11-15, 2001
Third International Congress of Medical Toxicology (APAMT),
Penang, Malaysia

November 13-14, 2001
Drug Interactions (Conference No E11-1101)
Contact: Management Forum;
Fax +44 1483 536424 e-mail registrations@management-forum.co.uk

December 4-5 2001
MedDRA - Setting realistic expectations for implementing and using the new terminology to maximise your time and resources.
Marble Arch Marriott, Central London.
Pharmaceutical Division IIR Ltd
Tel: +44 (0)20 7915 5371
Fax: +44 (0)20 7393 0354
email: nkoningen@iir-conferences.com
http://www.iir-pharma.com

December 4, 2001 and **March 4, 2002**
Adverse Event Reporting and Pharmacovigilance
London
Contact: Rostrum
Tel +44 (0)118 933 5343,
Fax +44 (0)118 933 5436 or
rostrum@mdsps.com

December 17-19, 2001
Basic Training Course on Pharmacovigilance (for those working on drug safety in EU/ USA)
Contact: Management Forum;
Fax +44 1483 536424
e-mail registrations@management-forum.co.uk

January 30-31, 2002
Medical Aspects of Adverse Drug Reactions
Southampton UK
Contact: Jan Philips, Drug Safety Research Unit,
Tel: +44 (0)23 8040 8621
Fax: +44 (0)23 8040 8605
www.dsru.org

March 5-8, 2002
DIA Annual Euro Meeting: The Patient is Waiting (Track 4, Effective Pharmacovigilance)
Convention Centre, Basel, Switzerland
Contact:
Tel +41 61 386 9393
Fax +41 61 386 9390 or
diaeurope@diaeurope.org

August 18-21, 2002
18th ISPE Conference
Edinburgh, Scotland

Preparing for Crisis

All organisations are subject to a permanent, small risk of crisis because of accidents, controversial decisions, or unexpected events. Regulatory authorities are no exception – as some know only too well. Those who are prepared for crisis may come through without radical damage; those who are unprepared may suffer considerably.

At last year's Annual Meeting of Member Countries in Tunis, participants were appreciative of an informative and practical review of crisis management theory and planning by Dr John Clements. They asked that *the* UMC should prepare a document on the issues that could be helpful to Member Countries in considering their planning for potential crises.

A draft document ***Anticipating and Managing Crisis*** has been prepared and will be circulated for comment at this year's meeting in New Zealand. Member Countries not represented at the meeting will receive their copy by mail.

Case Studies

One aspect with which *the* UMC would like your help is in the provision of some case studies of crises in pharmacovigilance round the world. If you have experienced a crisis in relation to a drug safety issue – maybe a media scare about potential new risks, or a sudden and unexpected increase in ADRs relating to a particular drug – then it would be great to hear from you.

Having some real-life situations to include in the document, along with details of how the crisis was managed and its outcomes, press cuttings, and any other information would be very useful.

Please send anything which you think could contribute to this publication to Sten Olsson at *the* UMC (sten.olsson@who-umc.org). Identifying details of country, manufacturer, people do not necessarily have to be included – it's the principles and the learning-potential which matter.

the Uppsala Team

Communications information

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Postal Address: *the* Uppsala Monitoring Centre, Stora Torget 3, S-753 20 Uppsala, Sweden

Telephone: +46 18 65 60 60 **Fax:** +46 18 65 60 80

E-mail: (general enquiries) **info@who-umc.org** (sales & marketing enquiries) **sales@who-umc.org**
*Personal e-mail messages may be sent to any member of the team by putting their name (e.g ralph.edwards) in place of **info** or **sales***

Internet: http://www.who-umc.org

Ralph Edwards
Director
Professor of Medicine

Sten Olsson
Head, External Affairs
Senior Pharmacist

Cecilia Biriell
Head, Internal Affairs
Senior Pharmacist

Marie Lindquist
General Manager
Head, Data Management & Research
Senior Pharmacist

Mats Persson
Acting head, Customer Relations
Business Development Manager

Mohamed Farah
Programme leader,
Traditional Medicines

Malin Ståhl
Programme leader,
Signal Detection

Andrew Bate
Programme leader,
Signal Research Methodology

Helena Fucik
Programme leader, Database products

Monica Pettersson
Programme leader, Signal Analysis

Malin Nord
Programme leader, Database Products
(On leave)

Erica Walette
Programme leader, Database Services

Anna-Karin Flygare
Programme leader,
Terminologies & Databases

Jenny Ericsson
Pharmacist

Jessica Nilsson
Pharmacist

Anne Kiuru
Pharmacist

Helena Sjöström
Pharmacist

Daniel von Sydow
Project Co-ordinator

Sven Purbe
Database Manager

Anna Lindquist
Team support, Web Editor
(On study-leave)

Inger Forsell
Programme leader,
Sales and Customer Relations

Maria Bergström
Team Support
Co-ordination & Procurement

Anneli Lennartsson
Team Support, P.A. to the Director

Geoffrey Bowring
Communications and Events Assistant