• Interview with Lembit Rägo (pages 4-5)

• the UMC with 'best poster' at CPT Conference in Florence (page 8)

• Collaboration with Drug Safety Research Unit in Southampton, UK (page 7)

• WHO database now updated with US reports (page 7)

• Books and other publications (page 11)
TUNISIA FACT FILE

Tunisia is a presidential republic with an emerging economy. Tunis, an ancient city whose past is linked to an even more ancient civilization, has become a major financial centre and an important international destination reflected by its splendid conference and leisure facilities. Visitors will be delighted with the standards of service and the warmth of the welcome! Tunisia is in a unique position to help develop integrated and harmonised international technical services which could get WHO backing. We’re very keen to be asked about and involved in any idea or project which could improve drug safety and patient therapy, and to offer our long experience and considerable expertise wherever they can be useful.

We have made efforts over the years to raise our profile and make contact with everyone to whom we might be useful (Uppsala Reports is part of that effort), but clearly there is still much work to be done.

Our mission is to serve the interests of pharmacovigilance throughout the world: any organisation or individual who feels we might be able to help them should contact us without hesitation.

The UMC is in a unique position to help develop integrated and harmonised international technical services which could get WHO backing. We’re very keen to be asked about and involved in any idea or project which could improve drug safety and patient therapy, and to offer our long experience and considerable expertise wherever they can be useful.

Listening to one’s customers is not always entirely comforting, but it shows we are very much alive and determined to meet the needs of those who have a right to expect the very best from us.

If you have any thoughts about how we can raise our profile, disseminate information about what we do, extend our influence and usefulness please let me know!

Ralph Edwards

The message will be held at the Institut National Sciences Appliquées et Technologie (INSAT), Tunis (see photo below). Three levels of hotel standard are available and to benefit from the lower reservations rate you should already have booked via the Tunisia Convention Bureau. They will confirm the hotel you have been booked in and send a map helping you to get there and to the UMC address.

All representatives from National Centres and other invitees should already have received a mailing in July containing the latest programme, hotel booking forms and information on Tunisia, together with material on the Mediterranean Conference of Clinical Pharmacology which takes place just before the WHO meeting.

In September, a general request for issues to be discussed under the heading ‘Drugs of Current Interest’ and further preparatory material was sent out. Newcomers to the WHO Drug Monitoring Programme are invited to present their systems and activities as posters, allowing for stimulating and intense discussions with colleagues. During plenary sessions simultaneous translation English–French will be provided, and facilities are available for transparency, slide and computer presentations.

An official opening ceremony will take place on 11 November, in the presence of the Minister and the Deputy Minister of Health.

In spite of the fact that we now have access to faxes, e-mails, Internet, satellite conferences etc for exchanging information, no means of communication can replace the personal encounter face-to-face. Also, in the scientific world personal confidence plays a significant role in decision-making. For 23 years now, the annual meeting of National Centres has been the forum at which newcomers and experienced professionals on the drug safety arena have met, exchanged views and information, become friends and brought the science of pharmacovigilance and the WHO Programme forward. The programme for this year’s meeting looks very interesting. Don’t miss the chance of attending this first annual meeting on the African continent, and meeting your colleagues in a most attractive environment.

Tunis Elson, Head of External Affairs, the UMC

The objectives of the annual meeting are:

- to provide a forum for countries participating in the programme to meet and discuss issues of current concern
- for latest developments, best practice and methodology in pharmacovigilance to be explained, promoted and discussed
- to provide a supportive, informative, sociable event in the pursuit of more effective pharmacovigilance worldwide and in developing productive relationships between member countries and other key players.

MESSAGE FROM THE DIRECTOR

What do you think of us?

This is the question we asked National Centres and some of our customers in a survey earlier in the year. The responses were not entirely comforting!

More people than we would wish were unsure about what we do at the UMC. Many said that they contacted us only ‘occasionally’ or ‘rarely’ because of this uncertainty. Many had not visited and did not know about our website (www.who-umc.org). Some have had problems getting through to us, or with their orders for products, or with the speed of our responses. So, it seems we have a lot of work to do to achieve the 100% awareness and quality we seek.

There were many positive and appreciative comments too, so the picture is far from all negative – but our users and customers have presented us with a real challenge which we must address.

If you have any thoughts about how we can raise our profile, disseminate information about what we do, extend our influence and usefulness please let me know!

Ralph Edwards

Uppsala Reports
Lembt Rägo

Dr Lembt Rägo joined the World Health Organization (WHO) in December 1999 as Coordinator of Quality Assurance and Safety: Medicines (QSM). This position includes responsibility for the WHO International Drug Monitoring Programme, and for the UMC. We interviewed Dr Rägo to introduce him to our readers.

1. Uppsala Reports: Dr Rägo, you came to WHO from Estonia. Can you tell us a little about your professional background and what did you do before joining WHO?

I graduated from Tartu University, Estonia, and became a medical doctor in 1979. My postgraduate studies and research resulted in a PhD from Tartu University, and later from Kuopio University, Finland. From 1982 to 1992 I taught pharmacology at Tartu University. Then in 1992 I was elected Professor of Clinical Pharmacology there. From 1989 until 1999 I was adviser on pharmacology, first with the Ministry of Health and then, after the ministries were combined, the Ministry of Social Affairs.

This was an interesting position as it covered everything related to drugs. No other adviser was responsible for policy issues such as planning and implementing pharmaceutical sector reform, creating and implementing national drug legislation, a reimbursement scheme or starting a pharmacovigilance system. As all this had to be achieved quickly after the country regained its independence in 1991, I was also the founder and first head of the Estonian Regulatory Authority 1991-1999. In 1999 the State Medicines Agency moved into brand new premises and nowadays has 45 full-time employees (more information at www.sam.ee). During these years drug utilization monitoring using the ATC/DDD guidelines at a national level was started, and the Drug Information Bulletin and annual data sheet compendium Pharmacea Estica were launched. I have always been working in wonderful people. One could say that the Estonian pharmaceutical sector underwent reform, building from scratch to a fully functioning drug regulatory system, was largely enabled by two people supported by committed younger colleagues joining in step-by-step. This reform has been improved upon by the commitment of my close friend, Dr Raoul Kiivet (now Professor of Health Management and Head of the Institute of Public Health at Tartu University). During 1998-1999, I was also President of the Estonian Society of Pharmacology and an observer member of the European Commission Pharmaceuticals Committee on behalf of the Collaboration Agreement of Drugs with all European Union Countries, CADREC. In 1999 I became a member of the Executive Board of the European Association of Clinical Pharmacology and Therapeutics. Not unnaturally, the university part of my work suffered from other commitments; however, we believed that there was no place for clinical pharmacology if drug regulation did not work. I published quite a substantial number of international articles in the fields of clinical pharmacology and also regulatory affairs. For many years the scientific papers mostly reflected the interest of the students and younger postgraduate students and younger colleagues I had in the University.

2. Uppsala Reports: Being Coordinator of the Quality Assurance and Safety: Medicines team at WHO seems like a very broad area of responsibility. What are the main tasks included in your job description and what is the range of products covered?

In fact, the QSM team includes most of the activities of the former Department of Drug Management and Policies (DMP). This department was merged with another dealing with drugs (Drug Action and Therapeutics) (The Observer 2000-2001, and Medicines Policy Department (EDMI) (Director Dr Jonathan Quick) was created in the cluster of Health Technologies and Pharmaceuticals (HTP), under Executive Director, Dr Yasuhiko Suzuki.

QSM is no longer responsible for quality assurance and safety of biological and blood products. These are now localized in other specialized departments. The team is responsible for cross-cluster coordination of quality assurance and safety issues. Also, QSM no longer deals with the Essential Drug List and treatment guidelines. QSM is therefore able to focus its activities on the Policy Access and Regulatory Support to Member States (PARS) programme. The work is also focused on the WHO Medicines Strategy: Framework and Guidelines for Action 2001-2004 30,000 in the previous budget. We are currently working on how to redistribute the funds within QSM in order to maintain at least some safety-related activities.

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3. Uppsala Reports: In the WHO Drug Monitoring Programme there is a division of responsibilities between WHO headquarters and the UMC. How do you perceive respective roles and do you see any problems in this arrangement today or in the future?

The responsibilities and balances in the WHO Drug Monitoring Programme have been clearer as follows:
The major operational arm of WHO headquarters in the field of drug safety is difficult to overestimate the considerable progress made by the UMC during past decades. Due to its very limited size, WHO headquarters has been restricted in its activities. The programme is going through difficult times when Martin T. Harm, the chief of the former Drug Safety Unit of WHO, retired, and because the team was not fortified, and Martin’s obligations were added to the QSM team coordinator’s job description. However, Dr Mary Couper from QSM helped to continue the ongoing activities. Now she is fully on board and safety issues will become her major activity. Recently, the post of clinical advisor to EIDM/QSM was created and Dr Vladimir Lepakhin has joined our small team on the safety side. So, finally after the reforms, in terms of posts, the safety area has been strengthened in headquarters.

WHO headquarters should probably be more active in overall policy issues as well as in advocacy and promotion of the safety of all medicinal products. More intensive cooperation between headquarters and the UMC is necessary in order to use the very limited resources in an efficient way. A good example of this cooperation is the recent merger of the WHO and UMC newsletters, thus eliminating duplication and giving the clear added value of joint effort. Naturally, there are some problems related to the status of the UMC after the review by the Swedish Government but I would not like to concentrate on possible problems, but rather work for better solutions. My impression is that the UMC is a very good partner in trying to solve the problems.

4. Uppsala Reports: At the forthcoming meeting of ICH (International Conference Coordination Harmoni-zation) in San Diego in November 2000, pharmacovigilance will be on the agenda. Do you think there are potential conflicts of interests between the ICH countries and the WHO in the area of pharmacovigilance?

Again, we should concentrate on common interests rather than on potential conflicts. Naturally WHO should take into consideration the priority of all countries and not only those of the ICH regions. We are not always speaking with one voice trying to find ways in which we could cooperate for the benefit of all countries in the field of pharmacovigilance. It will not be easy but we should try. When we fail to cooperate on the basis of mutual respect for each other’s interests and when we feel that there is a threat to global public health matters, we should make our position very clear in order to get strong support from member states.

5. Uppsala Reports: What role will the WHO Drug Monitoring Programme play in the UMC be playing in the WHO strategy for achieving rational use of drugs worldwide?

It is difficult to overestimate the role of the WHO Drug Monitoring Programme and the UMC in the rational use of drugs. However, unfortunately only a minority of WHO member states have joined the Programme. The WHO Medicines Strategy: Framework for Action 2001-2004 30,000 in the previous budget. We are currently working on how to redistribute the funds within QSM in order to maintain at least some safety-related activities.

“My countries will have joined the WHO Drug Monitoring Programme and the UMC by the numbers to more than 80 from the present 59”.

6. Uppsala Reports: The cost of medicines and medical treatment is getting a lot of attention these days. Do you think that will lead to higher priority for WHO within WHO as a means of limiting the expensive treatment of iatrogenic diseases?

I am very sad to say that for the time being I cannot answer this question (mathematically 100% increase of zero is still zero)! Due to recent ‘efficacy cutting’ for priority areas we lost the budget line “International adverse reaction monitoring system: support to national drug regulatory authorities for adverse drug reaction monitoring” worth $130,000 in the previous budget. We are currently working on how to redistribute the funds within QSM in order to maintain at least some safety-related activities.

“Many countries will have joined the WHO Drug Monitoring Programme and the UMC by the numbers to more than 80 from the present 59”.

7. Uppsala Reports: If you were to get a 100% increase on your budget for drug safety activities, how do you think the increase should be used?

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8. Uppsala Reports: What is your vision for the WHO Drug Monitoring Programme? What role will it have five years from now?

In five years from now: the WHO Drug Monitoring Programme will have overcome the situation of being underfunded. More and more funded activity will be on the agenda. Do you think there are potential conflicts of interests between the ICH countries and the WHO in the area of pharmacovigilance? We are currently working on how to redistribute the funds within QSM in order to maintain at least some safety-related activities.

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BANGLADESH

In August 2000 the Ministry of Health, Peru, submitted its application to WHO for inclusion of a drug in the WHO Drug Monitoring Programme (DMP). A National Centre for Pharmacovigilance and Drug Information (CENAFIM) has been established within the drug control authority, Direction General de Medicamentos, in Lima. It is to be assisted by reference centres and a technical pharmacovigilance committee.

The pharmacovigilance centre will be collecting spontaneous ADR reports and will also be carrying out hospital surveys and epidemiological studies. During 1999 and 2000 some 200 reports have been received from manufacturers, health professionals and patients. These reports have then been submitted to the agreed format, Peru will become the 60th member country of the WHO Programme.

Contact person is Dr Susana Vásques, CENAFIM, Avda Arenerales 302 - Of 319, Maria Lima, Lima, Peru. Tel: +51-14-716 246 Fax: +51-14-716 357 E-mail: cenefam@minsa.gob.pe

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NEW PROJECT - IMPROVED COMMUNICATIONS WITH NATIONAL CENTRES

Although the UMC has frequent contacts with National Centres participating in the WHO Programme, we still feel that communications can be improved and so increase the commitment and involvement of member countries to the Programme.

A special project, headed by Cecilia Biriell, on finding new ways of improving communications was recently started at the UMC.

ADR Reporting

The aim of the project is to make sure that all people at National Centres are aware of the services that the WHO Programme can provide for them, and also improving the centres that have to make the Programme work. The most important of these is to prompt the regular sending of adverse reaction reports to the Uppsala Monitoring Centre.

Communications Data

There can be no communication without correct names, addresses, fax numbers etc. The first task the project group has undertaken is to upgrade the UMC’s address register of National Centres. This may seem like a simple task, but it is in fact quite difficult. Many names of people are not given in correct form, many addresses are still in the old format and some are missing.

We urge all National Centres to respond to our questionnaire and to keep us informed of any changes taking place.

Guidelines

In cooperation with WHO headquarters, a document has been developed stating the obligations for National Centres and explaining services such as database searches, the SIGNAL review and National Centres meetings. This paper will be sent to all National Centres shortly, to make sure that all heads know about this. In the future the paper will be sent out each time we hear about the appointment of a new Centre head.

Newcomers

In the past we have not had the resources to make sure that all people at National Centres are aware of the services provided by the Programme. But now we are putting some of our resources into making an information pack for all newcomers, containing an overview of the Programme, some recent and relevant published articles from the UMC, information about the Drug Dictionary and the WHO-ART etc. There will be different information packs tailored for Centre heads, technical contact persons and other newcomers depending on their needs.

As communications open are planned and we will be back to you later about this project. If you have more ideas in this area, please tell us.

USA

The Center for Drug Evaluation and Research (CDER) of the US Food and Drug Administration recently released a draft guidelines on ‘Content and Format of the Adverse Reaction Section of Drug Labeling’. The guidance document, distributed for comment, is intended to improve the consistency to the content and format. The document can be obtained from the FDA website at: http://www.fda.gov/cder/guidance/1888df.htm or can be obtained from CDER, 80 Shady Grove Lane, Rockville, MD 20857, USA

PHILIPPINES

The Bureau of Food and Drugs recently produced a 10 minute educational video about Adverse Drug Reactions (ADR). This film explains the different types of AEFIs and why they need to be monitored and how reporting should be carried out.

The Bureau has also produced a series of educational audio cassettes on adverse drug reactions. These cassettes cover ADRs in the elderly, IV drug therapy and reactions in the elderly, Volume III cardiology and psychology.

Copies of the video and audio cassettes may be obtained from the UMC. Please contact Annell Lennartsson.

INDIA

Professor N Kishirasagar of the BYL Nair Hospital & TN Medical College, Mumbai, has published a report on ADR monitoring in India and participated in radio broadcasts to advocate rational use of medicines and has also produced posters and stickers in Bengali.

The centre for adverse reaction monitoring has published reports and participated in hospital surveys and education programmes on pharmacovigilance. Following are some topics that were presented:

• pharmacological basis of ADRs
• methods and benefits of ADR monitoring.

The CDER is responsible for monitoring adverse reactions to veterinary drugs, medicines and cosmetics in India. In order to get a better picture of the adverse reactions in the elderly, Volume III cardiology and psychology.

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The third Chinese National ADR Meeting, ‘Clinical Drug Safety’-2000 was held in Hangzhou, April 19-22, 2000. The meeting was organized for the first time jointly by the Pharmacy Administration Committee of the National Institute of Hospital Administration, and the editorial office of the national ‘ADR Journal’. 

CHANCE. China, like many other countries, is going through a major reorganisation of its health services. The national centre is in the process of being moved from the Health Ministry to the State Drug Administration. There is considerable interest in the further development in rational drugs policy and this includes the consideration of the cost impact of ADRs.

NEW ARRANGEMENTS

At the meeting a formal group of the 10 regional centres was formed. This will further the scientific and professional activities in drug safety and act as an advisory group to the National Centre. The National Centre is an administrative and regulatory body which does not involve itself in the collection or use of the ADR report data in any other way than for regulation. With the new bipartite system, the regional centres will be responsible for the collection of reports, preparation of reporting, the analysis of data and the publication of information in the new ADR Journal. The meeting had a full and comprehensive agenda, but did not discuss the economic impact of ADRs. There was considerable interest in the two UMC presentations, one on Clinical Diagnosis of ADRs (Ralph Edwards) and the other on Monitoring of Herbals (Mohamed Farah). The UMC team was accompanied by Dr Cheng Jinghua and Mr Wang Du-you. They visited a tea plantation and helped in the harvest of tea leaves. The correct identification of this plant is: Camellia sinensis var. sinensis (L.) Kuntze = Camellia thea/ Thea bohemia L. = Thea sinensis. Thea viridis L. - all these different names are correct.

Mohamed Farah made a presentation about the monitoring of herbal medicines. He stressed the need for using binomial names instead of common names in the reporting of herbals to avoid confusion.

Main StÅhl represented the UMC with a poster entitled ‘Recent Improvements of International Signal Detection’. This showed results of validations of the UMC’s new signalling system. It was selected as the best poster in the post-marketing drug surveillance session during a guided poster tour conducted by Prof PerÅ–Ney-Royer and Sir Michael Rawlins.

16th ISPE CONFERENCE IN BARCELONA

The International Society for Pharmacoepidemiology (ISPE) holds its yearly meetings alternately in North America and in Europe. This time, Barcelona (21-23 August) was the host city for the conference. 550 delegates attended the meeting - a new record!

New Approach

The conference had a big programme, organised differently from previously - in the mornings longer plenary lectures with ample time for discussion, both about methodology and specific drug safety issues. The keynote address was presented by Dr Patrick Waller from the Medicines Control Agency (MCA), UK who talked about ‘Pharmacoepidemiology - A Tool for Public Health’.

ADRespherics

Many of the normal short presentations were replaced by plenty of posters on all three days. There was also time for discussion with colleagues and friends in the breaks. The UMC participated with an exhibition and demonstration of ADRespherics, the new method for signal detection and analysis using data-mining techniques.

Andrew Bate from the Centre was one of the speakers in a workshop on ‘Signal Identification’ and presented how the UMC data-mining method for signal detection has been validated. The session was well attended and evoked a lot of interest and questions. The whole session was the principal reason why ISPE (International Society for Pharmacoepidemiology) and Drug Safety

in a so-called ‘council meeting’ a discussion was held on how people in countries where pharmacovigilance is not yet well developed, are getting interested in the subject. It was decided that a tentative plan should be developed and presented to ISPE’s executive committee in early 2001. Whether ISPE should try to get people to join the new (International Governmental Organisation) to enable closer cooperation with the WHO, was also discussed.

Toronto 2001

Next year’s conference will be held in Toronto, Canada. In 2002 the conference will take place in Edinburgh, Scotland.

CONSUMER REPORTS ON MEDICINES

The Swedish foundation KILEN - Consumer Institute for Medicines and Health organized a first international conference on Consumer Reports on Medicines in Sigturna, just outside Stockholm, Sweden, 29 September - 1 October 2000 in cooperation with several partners including the UMC. An introductory address was made by Dr Mary Couper of WHO, Geneva. Sten Olsson from the UMC provided an overview of pharmacovigilance activities as they are carried out in different parts of the world. The ambition of the organizers is to create an international network for exchange of drug experience reports originating from patients themselves. Proceedings from this conference may be obtained from Ms Lena Westin, KILEN, Fax: +46-8-6906110, E-mail: kilen@kilen-institutet.se internet: http://www.kilen.org

UPPSALA PHARMACOVIGILANCE TRAINING COURSE 2001

The 6th international training course on Adverse Reactions and Adverse Reaction Monitoring will be held 15-18 May, 2001. The course provides basic theoretical and practical training in pharmacovigilance methodology and an introduction to pharmacovigilance. It is mainly targeted at newcomers at national pharmacovigilance centres and professionals considering establishing such centres. Some participants from last year’s course attended. Invitations will be distributed by end of November 2000. If you want to be sure to get an invitation, please contact Anneli Lennartsson at the UMC.

US VACCINES DATA NOW IN WHO DATABASE

The Centre for Disease Control (CDC) in USA recently submitted all the US vaccine reports to their VAERS database to the WHO programme in the required format. The reports, amounting to some 108,000, are attributed to 129 different vaccine products. They will be incorporated into the WHO database by the end of October, 2000.

STAFF CHANGES

In July 2000 Jonathan Edwards, who has been responsible for IT (Information Technology) strategy and internal IT support at the UMC since 1997, decided to leave our Centre. He took up a new position at a company in Uppsala developing Internet-based software.

We have employed a new pharmacist, Ms Helena Sjöström, who joined the UMC in September. To start with she will mainly be working with processing of incoming adverse reaction reports and recording of drug names, occurring on such reports. Look out for her picture in Uppsala Reports 14.

The Communications Presentation Team: from (right to left) Dr Tony Wong, Dr Andrew Henheimer, Bruce Hugman, Dr Kenneth Hartigan-Go, Prof Ralph Edwards accompanied by Dr Ellen Vinge
IIR is arranging a conference on Blood Product Safety, 16-17 October 2000, London, UK. For information contact IIR at Tel: +1-886-670 8200 Fax: +1-941 365 2507

Instituto Nacional de Higiene “Rafael Rangel” in Caracas, Venezuela, is organizing its VIII International Course on Normative and Regulatory Aspects of Registration and Control of Drugs 25 September - 20 October, 2000. As part of this course a workshop on pharmacovigilance will be held 18-20 October. Course manager is Ms Gerda Ackerman Fax: +58-2-6624 797 E-mail: lottyack@cantv.net

The Drug Information Association (DIA) is organizing the following events of interest to drug safety and pharmacovigilance:

- A training programme on Medical Approach in Diagnosis and Management of Adverse Drug Reactions in Paris, France, 12-13 October, 2000
- A workshop with the title MedDRA - A Practical Approach to Implementation 30-31 October, 2000, Washington DC, USA
- A training course in Applied Epidemiology, 2-3 November, Philadelphia, USA
- Adverse Experience Workshop in Washington DC, USA on 8-10 January, 2001
- A workshop on Safety Information and Labelling in New Orleans, USA, 12-13 February, 2001

For more information on the DIA events contact:
Tel: +1-215 628 2288 Fax: +1-215 641 1229 E-mail: dia@diahome.org

Tel: +41-61-386 9393 Fax: +41-61-386 9390 E-mail: diaeurope@stepnet.de

The III Brazilian Congress of Hospital Pharmacy will be held in Salvador, Bahia, Brazil, 5-8 November 2000. Pharmacovigilance will be one of the main topics of this congress. For more information, please contact Professor Lucia Noblat E-mail: lacb@ufrb.br

The Drug Safety Research Unit (DSRU) in Southampton, UK, will organize three different postgraduate events, a Workshop on Narrative Writing in December 2000, a Workshop on Medical Aspects of ADRs in spring 2001 and the 1st Annual DSRU Conference on Pharmacovigilance in June 2001. For information please contact Georgina Spragg: Tel: +44-7308-408 600 Fax: +44-7308-408 609 E-mail: georgina.spragg@dsru.org

Rostrum will organize a training programme on Pharmacovigilance and Adverse Event Reporting on 11 April, 2001. For information please contact Rostrum: Tel: +44-708-734876/725413 E-mail: rostrum@pils.com Internet: www.rostrumtraining.co.uk

The 1st Umeå International Summer Conference on Adverse Drug Reactions will be held in Umeå, Sweden, 14-15 June, 2001. The subtitle is: Predicting, detecting, understanding and avoiding ADRs. The conference is organized by the Division of Clinical Pharmacology, Umeå University, S-901 85 Umeå, Sweden. For more information contact Ms Aina Mattsson Fax: +46-90-120 430 Email: aina.mattss@pharm.umu.se

New German Handbook on Adverse Drug Reactions

Handbuch der unerwünschten Arzneimittelwirkungen, edited by R. Müller-Derlingenhausen, R. Lasek, H. Duppenbecker and K-H Munter is published by Urban & Fischer, München, 1999 (ISBN 3-437-21240-0). The first part of this (750 page) book is divided into 21 chapters, each covering one therapeutic group of medicines. To each generic substance an overview of known adverse reactions is provided, with frequent references given. The second part has eight general chapters on such topics as mechanisms, methods of detection and study, and special concerns regarding herbal preparations and biologicals.

Drug Risks in Medical Practice

This book in the Slovak language (Riziko Liekov v Medicinskej Praxe), edited by Professor Milan Kirška, was published earlier this year by the Slovak Academic Press, Bratislava (ISBN 80-88908-58-2). The initial hundred pages cover general subjects of pharmacovigilance and drug risks. The remaining 375 pages provide summary information on adverse reactions by therapeutic group, specified on substance level.

Monitoring Drug Safety - A Shared Responsibility

This is a 15 minute VHS-video produced by the Drug Information Association (DIA) explaining why adverse reactions occur and how drug risks are detected, through the phases of development of a new medicine and after marketing. It emphasizes the need for close collaboration between patients, health professionals, producers and authorities to ensure that drugs are used safely and risks are detected early. Professional advice for the production of this video has been provided by Bruce Rowse, Health Canada and Win Castle, SmithKline Beecham. The video can be acquired from DIA at a postal price of USD 25. Contact Sue Creco, Fax no +1-215-6411229 E-mail: grecos@diahome.org

Don’t Tell the Patient - Behind the Drug Safety Net by Bill Inman

This is an autobiography and a description of the early developments in post-marketing drug safety monitoring by one of the pioneers who was instrumental in the establishment of the "Yellow card" system and later created the Prescription Event Monitoring scheme in the UK. Highland Park Productions, Bishops Waltham, UK, ISBN 0-9675812-0-6

Drug Benefits and Risks

A new multi-author, international textbook edited by Prof. Chris van Boxtel, Budiono Santosa and Ralph Edwards. Published by Wiley, UK

This is a book about practical therapeutics and the surrounding general and pharmacological knowledge. The aim of the book is to give expert guidance on how to treat patients. Whilst the book is concerned with the best possible evidence-based therapy and information, it also aims to be a practical and useful guide wherever in the world patients are treated. To achieve this, authors of the various sections have been brought together from around the world, and have peer-reviewed each other’s contributions.

The publishers have tried to keep the price low, so allowing as many as possible to have access to the book. The style and kinds of questions which could be asked to reinforce learning will vary all over the world, and the addition of highlights could also draw emphasis to text inappropriately. For all these reasons also the book is standard in its format. Teachers will need to formulate their own strategy for using this book in their teaching.

The editors would claim that part of problem-based learning is to have a starting point where practical information is given and also some of the surrounding philosophy. Where problem-based learning has been developed, the discussion and interaction with a local expert is usually an initial part of the exercise. Sadly, there are many places in the world where this practical expert advice is not easily available for a variety of reasons, neither are many textbooks available. The aim of this book is allow experts to say, in their own way, what they think is important in their discipline.

Through sponsorship by the Dutch Rad-Ar council 800 free copies will be made available for emerging countries via the member National Centers of the WHO Programme for International Drug Monitoring. It is hoped they will find it useful, as even promote its use in their countries.

Safety Monitoring of Medicinal Products

Guidelines for setting up and running a Pharmacovigilance Centre, published by the UMC in 2000. There is a limited number of copies available of the first printing. The guide will be reprinted and translated into other languages to ensure wide availability. Please contact Sten Olsson if you would like a copy.

Poisoning, Poison Control and Environmental Toxicology

This book (95 pages) is edited by Professor S.K. Gupta, Professor of Pharmacology at the All India Institute of Medical Sciences and head of the Indian national pharmacovigilance centre. The book is based on presentations made at a symposium under the aegis of the International Congress on Frontiers in Pharmacology and Therapeutics in the 21st Century in New Delhi 1-4 December, 1999. It is divided into three sections:

I. Problem of poisoning and its management
II. Environmental toxicology
III. Rules and regulations

The book is published by Utkarsh Prints, New Delhi, and may be obtained from Professor S.K. Gupta, Fax: +91-11-686 2662 E-mail: skgupta@medinsternet.in
WEB-BASED TRAINING COURSES

WHO Drug Dictionary and WHO-ART

As previously advised, the UMC has developed web-based training courses for users of the WHO Drug Dictionary and the WHO Adverse Reaction Terminology. The courses, providing video and audio presentations, include descriptions of the features of the thesauri and how they may be used. Self tests are included. They can be found on the UMC website at http://www.who-umc.org The website has now also got the added facility of answers to Frequently Asked Questions (FAQs). Contact Liza Storm at the UMC to get your passwords to the courses.

2ND QUARTER 2000 UPDATE

The new versions of the computerized WHO Drug Dictionary and WHO Adverse Reaction Dictionary (WHO-ART), containing information for the 2nd quarter of 2000 are now available.

DO WE HAVE YOUR DETAILS CORRECT?

We hope that your received this issue of Uppsala Reports correctly addressed to you. If we have incorrectly spelt/omitted your name, parts of your address or your title, please do let us know. It is vital that we have your correct communications details and we need your help in ensuring this. It would also be very useful to us if you could reconfirm your telephone, fax, email and website details – you can do this by sending us your most up-to-date communications details by post, fax, or email c/o Anneli Lennartsson at the UMC.