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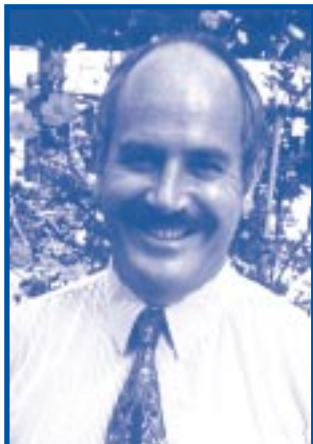
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Uppsala REPORTS

For everyone concerned with the issues of pharmacovigilance and toxicovigilance



- **Internet Learning with *the* UMC**
- **Uppsala Training Course on Adverse Drug Reactions**
- **Review of UMC submitted to the Swedish Government**
- **CIOMS Monograph Moves Ahead**



MESSAGE FROM THE DIRECTOR

The DIA North American Annual Meeting is always an occasion of interest and value. This year's Baltimore event - with around 5,000 delegates - was no exception. However, these huge meetings can be a bit overwhelming: parallel sessions giving information on all topics imaginable; little time for discussion and debate; huge numbers of commercial displays; people to meet and informal discussions to be had; to say nothing of the social programme.

Well, I survived - indeed had a good time! - made my presentation, lived to tell the tale and report on a couple of very interesting issues on page 5.

We've recently had the pleasure of hosting our latest international ADR training course in Uppsala, with twenty-two participants from all over the world. We're very conscious of how few people we can actually meet and train individually, and are developing new internet versions of some of our presentations and training materials. There's a description of what we are doing in this edition of *Uppsala Reports* on page 3 and we're very keen to hear your views on the project. Please contact Sten Olsson and tell him!

There are several important and interesting meetings coming up in the next few months - not least the annual meeting of member countries of the WHO Programme, which is immediately followed by the ESOP annual meeting, both of them in Ankara, Turkey. You'll find full details on page 4.

As always we look forward to meeting you on our travels, and, especially to your keeping in touch with us with your views and suggestions on the work of *the UMC*.

Best wishes to you all.

Ralph Edwards

Meeting of ADR Signal Reviewers

For some fifteen years *the UMC* has been fortunate to have the assistance of volunteer reviewers. These clinical experts review the results of the regular computerized screenings of adverse reaction reports submitted to the WHO programme.

Four times a year each reviewer receives a selection of documents containing extracts from the database displaying potentially new and important reactions in his/her clinical field. The task of the reviewers is to judge the clinical significance of the new association identified by the computer. The results of their work, consisting of a summary of available evidence, are circulated to national pharmacovigilance centres periodically in a document called SIGNAL. The credibility and impact of the procedure and the SIGNAL document were investigated some years ago. One of the conclusions was that most recipients of SIGNAL found its contents useful¹.

More Support and better Results

Up to now *the UMC* signal reviewers, currently around 30, have been operating in isolation, aided only by written instructions and by the remote support of Helena Fucik at *the UMC*.

We are now introducing a completely new package of background information for reviewers: a Combinations Database, derived from a scan by our Bayesian Confidence Propagation Neural Network (BCPNN) of the WHO database. New guidelines have been

produced on how to use the Combinations Database and how to interpret the information contained.

To optimize the signal analysis system, and to include the views of the expert reviewers, we have invited all of them to a two-day meeting in Uppsala 23 -24 August, 1999. We expect that the discussions will lead to a more harmonized approach to signal analysis and that reviewers will learn how to make the best use of information contained in the WHO database and of the support staff at UMC.

We are hoping that the use of the BCPNN methodology combined with an increased efficiency of the panel of reviewers will produce a greater number of new signals and a higher quality of output presented in the SIGNAL document.

Can you help us?

We are always looking for experienced clinicians with an interest in adverse drug reactions to join our panel of reviewers. Unfortunately, we are not able to provide financial support, but we would warmly welcome new volunteers to join our team for this important work. If you are interested in becoming a consultant to UMC and to take part in the process of identifying new ADR signals from the WHO database, please contact Helena Fucik at *the UMC*.

¹H. Fucik, I. Ralph Edwards, Impact and Credibility of the WHO Adverse Reaction Signals. *Drug Information Journal* 30: 461-464, 1996

Internet Learning with *the* UMC

Meet us on your own computer

You can now access active learning materials from *the* UMC on the internet.

As the internet becomes more and more popular in all parts of the world we have decided to supplement our supply of services with internet-based lectures and training programmes. Just like ordinary lectures, the internet-based presentations rely on a combination of sound and visual material and allow for interaction between the presenter and the audience.

Currently materials on *Risk Communication*, *Data-Mining* and *Benefit-Risk Assessment* are available (see below for details).

The more channels for information available, the greater the chance of the message being spread. We felt that some people might prefer to listen to oral presentations on some subjects, rather than reading about them in newsletters or scientific journals. In some respects, and for some people, the spoken word can be a more effective means of communication.

We can't all get to conferences

Important new ideas are often presented at conferences in front of quite small audiences, often recruited from a limited geographical area. Educational overviews of particular subjects are also frequently presented at closed seminars or conferences.

Our idea is to invite professionals from all over the world - and the interested general public - to such presentations by making sound recordings and visual material available on the internet. We're not yet able to make major video recordings available in this way because of band-width limitations.

System requirements

In order to listen to these presentations and watch the visual material you need to have access to a computer with:

- a sound card and a loudspeaker
- an internet connection
- an internet web browser equivalent to Netscape or Explorer version 3 or higher, and your system must also
- be able to receive Java applets.

The lectures are accessible from our general home site <http://www.who-umc.org>

Please tell us what you think!

Since this distribution system requires a rather high level of technical sophistication on the receiver end, we are anxious to have your reactions to this new initiative. Only if you tell us that there is enthusiasm for internet-based learning and that many potential users have or will have access to the technology, will we continue developing this service.

Our future plans include introducing an internet platform that allows for more active interaction, problem solving, testing learning - and more - via the net.

Reaching Wider Audiences

Behind these ideas is a frustration over the limited outreach of the training activities we organize at *the* UMC. Our latest ADR training course (held in Uppsala, 31 May - 11 June, 1999) is an example.

We brought together a considerable number of experts from several countries, with wide experience in pharmacovigilance. The audience exposed to this expertise was only 22 people, because of limitations of space and funding. It would be much more cost-effective if lectures and training material could be made available to a greater number of students in their home offices, rather than having to spend a lot of money travelling to Uppsala. One obvious disadvantage of internet based-learning, however, is that there is really no opportunity for personal networking.

**Intense debates continue even over dinner:
but how many more people world-wide would like
access to this small group's experience?**



Mohammed Farah, Zhang Sumin and Luisa Helena Valdevieso

If you have any views on our internet-based lectures or internet-based learning in general, please do contact Sten Olsson at UMC (sten.olsson@who-umc.org), or by fax (see back page for details).

A Participant's View of the Course - see page 7.

Current UMC Internet Presentations:

At the moment we have set up three presentations on our internet web site.

1. Ralph Edwards, UMC: Principles of Risk Communication

This presentation was made at the International Conference of Drug Regulatory Authorities (ICDRA) in Berlin, Germany, 25 - 29 April, 1999

2. Marie Lindquist, UMC; A data mining approach for signal detection and analysis

This is a recording of a lecture made at The 4th National ADR Monitoring Seminar/Workshop in Manila, the Philippines, 12 - 14 May, 1999

3. Ralph Edwards, UMC: Benefit - Risk Assessments of Medicines. This recording was also made at the National ADR Monitoring Seminar in Manila in May 1999

Other materials are in preparation.



- The Drug Information Association (DIA) in collaboration with the South African national centre for adverse reaction monitoring, is organizing a conference at Eskom Conference Centre, Gauteng, South Africa, on 31 August - 1 September 1999 with the title *Drug Safety: a shared responsibility*.
For more **information** please contact DIA
Tel: +1-215-6282288
Fax: +1-215-6411229
E-mail: dia@diahome.org
- Management Forum organizes a meeting on *Medical Aspects of Drug Safety and Pharmacovigilance* in London, 9 - 10 September, 1999.
For **information** please contact Management Forum
Tel: +44-1483-570099
Fax: +44-1483-536424
E-mail: info@management-forum.co.uk
http://www.management-forum.co.uk
- The *22nd Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Drug Monitoring Programme* is held in Ankara, Turkey, 20 - 22 September, 1999.
For more **information** please contact
Dr Mary Couper, WHO Geneva
Tel: +41-22-7912111
Fax: +41-22-7914730
E-mail: couperm@who.ch
- The European Society of Pharmacovigilance, **ESOP**, will have its *7th Annual Meeting* in Ankara, Turkey, 23 - 24 September 1999, following the meeting of representatives of national centres participating in the WHO Programme.
For more **information** please contact
Ms Sevgi Öksüz
Tel +90-312-2301674
Fax +90-312-2301610
E-mail: tadmer@iegm.gov.tr
- IIR is organizing its *5th Annual International Adverse Reaction Reporting Conference* in San Francisco, USA, 27 - 29 September, 1999.
For more **information** contact IIR at
Tel: +1-888-6708200
Fax: +1-941-3652507
- DIA is organizing a seminar with the title *Medical Approach in Diagnosis and Management of ADRs* in Paris, 27 - 28 September, 1999. Programme chairpersons are Drs Benichou and Danan.
For more **information** please contact your nearest DIA office e.g. in Europe
Tel: + 41-61-3869393
Fax: +41-61-3869390
E-mail: diaeurope@stepnet.de
- A joint meeting of the 3rd Congress of the European Association for Clinical Pharmacology and Therapeutics and the 4th Jerusalem Conference on Pharmaceutical Sciences and Clinical Pharmacology will be held in Jerusalem, Israel 2 - 8 October, 1999. Session XI of the scientific programme deals with *Pharmacoepidemiological Systems for the Study of Drug Safety*.
For more **information** contact the meeting secretariat
Fax: +972-3-5140077 or **+972-3-5175674**
E-mail: eacpt3.jc4@kenes.com
- DIA is organizing a conference in London, UK, 7 - 8 October, 1999, with the title *Improving Pharmacovigilance Working Practices (The CIOMS V initiative)*.
For more **information** contact DIA European Office
Tel: +41-61-3869393
Fax: +41-61-3869390
E-mail: diaeurope@stepnet.de
- The Medicines Control Agency (MCA), UK, will hold *The Sue Wood Symposium - Pharmacovigilance into the new Millennium*, on 11 October 1999 at the Royal College of Physicians, London.
For more **information** please contact Rachael Wharton
Tel: +44-171-7371100
Fax: +44-171-7377071
E-mail: MCA_Events@equus-group.com
- A training course on *Drug Safety Surveillance and Epidemiology* will be organized by DIA in Ypsilanti, Michigan, USA 11 - 13 October, 1999. Another training course on the same theme will be held in Philadelphia, USA, 6 - 8 March, 2000.
For more **information** contact DIA
Tel: +1-215-6282288
Fax: +1-215-6411229
E-mail: dia@diahome.org
- IIR is organizing two training courses with the title *Introduction to Adverse Event Reporting and Pharmacovigilance*. They are both being held in London, UK, the first one 18 - 20 October and the second 6 - 8 December, 1999.
For more **information** contact
Véronique Rapetti, IIR
Tel: +44-171 9155075
E-mail: vrapetti@iir-conferences.com
- DIA organizes a workshop on *Safety Information and Labelling 25 - 26 October, 1999*, in Philadelphia, USA. DIA is also having a meeting on *Research and Regulatory Advances in Drug Safety* in Toronto, Canada 28 - 29 February, 2000.
For more **information** contact DIA
Tel: +1-215-6282288
Fax: +1-215-6411229
E-mail: dia@diahome.org
- The National Drug Institute, Bulgaria, is organizing a seminar on *Drug Safety Monitoring* in Sofia 29 October, 1999.
For more **information** please contact Dr I. Bantutova
Tel: +359-2-445990
Fax: +359-2-9434487
E-mail: pharmacovig@ndi.bg400.bg
- IBC is organizing its 6th International Conference on *Clarifying International Reporting Requirements for Adverse Drug Reactions* in Brussels, Belgium, 29 - 30 November 1999.
For more **information** please contact IBC
Tel: +44-171-4535496
Fax: +44-171-6313214
http://www.ibr-uk.com
- An *International Congress on Frontiers in Pharmacology and Therapeutics in 21st Century (ICPT-21)* is being organized in New Delhi, India, 1 - 4 December, 1999. During the Congress, a one and a half day symposium on Pharmacovigilance is being organised.
For more **information** contact Prof. S.K. Gupta
Tel: +91-11-6593282, 6593633
Fax: +91-11-6862663
E-mail: icpt21@yahoo.com
- Kusuri Canada Corp. presents the *Fifth Annual Training Course in Pharmacovigilance* in Ottawa, Canada, 9 - 10 December 1999.
For **information** contact W. C Appel
Tel: +1-613-5235993
E-mail: wcappel@cyberus.ca
http://www.cyperus.ca/~wcappel/



DIA Baltimore

by Ralph Edwards
Director, *the UMC*

Out of a rich and busy meeting, what was most memorable? I'll restrict myself to two related issues.

THE FDA AND DATA-MINING

The US Food and Drug Administration (FDA) seems to be moving ahead with the idea of using data-mining to analyse their huge database, as we have been doing as a matter of routine at *the UMC* for some time.¹⁻³ This approach was mentioned in the context of an interesting return to a fundamental debate: *what does a large number of reports on a drug and a particular ADR mean?*

This is an issue which will never go away and depends on the interpretive art of pharmacovigilance to resolve. Data-mining is, however, a help in highlighting drug/ADR associations and probabilities, as well as being able to examine complex associations, such as the effects of age, gender and dose.

Naturally the issue of denominator data was also mentioned. The EU BIOMED funded project that *the UMC* and IMS worked on has produced several very different and interesting papers using IMS sales and clinical data.⁴⁻⁸ We are still surprised that while IMS data is widely used in the sales departments of the industry it is used much less in the safety arena. We have been working with IMS to produce a user-friendly package, and in the meantime are able to offer a limited ad hoc service on request.

POISON CENTRES' FASCINATING DATA

The other surprise was that the US has another database of drug safety information! The Poisons Control Centres' network has 20 million case records (I knew about the database but not the extent) and

about half of those relate to drugs. Wouldn't it be interesting to know the epidemiology of drug toxicity in more detail: to know the outcomes, the toxicokinetics and population at risk?

Could we find out more about the effectiveness of safety monitoring or do we know it all? In this session we pursued the idea of closer cooperation between pharmacovigilance and poison control. Apparently herbal remedy problems are well known to the PCCs but not so much to most pharmacovigilance groups. There was general agreement that more interaction between the PCCs and pharmacovigilance centres would be useful.

A thunderstorm delayed flights home, which gave me a chance to chat to a number of industry people trying to get away: they seemed quite resigned to turbulence, certainly in their jobs!

References

1. Bate A, Lindquist M, Edwards IR, Olsson S, Orre R, Lansner A, et al. A Bayesian neural network method for adverse drug reaction signal generation. *European Journal of Clinical Pharmacology* 1998; 54:315-321.
2. Lindquist M, Edwards IR, Bate A, Fucik H, Nunes A.M, Ståhl M. From Association to Alert - a revised approach to International Signal Analysis. *Pharmacoepidemiology and Drug Safety* 1999; 8:S15-S25.
3. Orre R, Lansner A, Bate A, Lindquist M. Bayesian neural networks with confidence estimations applied to data-mining. *Computational Statistics and Data Analysis* 1999; (in press).
4. Lindquist M, Sanderson J, Claesson C, Imbs J.L, Rohan A, Edwards IR. New Pharmacovigilance Information on an Old Drug - an International Study of Spontaneous Reports on Digoxin. *Drug Investigation* 1994; 8:73-80.
5. The ADR Signals Analysis Project (ASAP) Team: (Lindquist M, Pettersson M, Edwards I.R, Sanderson J, Taylor N, Fletcher P, Schou J, Fraunfelder F.T. Omeprazole and Visual Disorders: Seeing alternatives. *Pharmacoepidemiology and Drug Safety* 1996; 5:27-32.
6. The ADR Signals Analysis Project (ASAP) Team: (Lindquist M, Pettersson M, Edwards I.R, Sanderson J, Taylor N, Fletcher P, Schou J, Ståhl M. Withdrawal Reactions with Selective Serotonin Reuptake Inhibitors (SSRIs) as reported to the WHO System. *European Journal of Clinical Pharmacology* 1997; 53:163-169.
7. The ADR Signals Analysis Project (ASAP) Team: (Lindquist M, Pettersson M, Edwards I.R, Sanderson J, Taylor N, Fletcher P, Schou J.) How does cystitis affect a comparative risk profile of tiaprofenic acid with other non-steroidal anti-inflammatory drugs? An international study based on spontaneous reports and drug usage data. *Pharmacology and Toxicology* 1997; 80:211-217.
8. Lindquist M, Edwards I.R. Risks of non-sedating antihistamines. *Lancet* 1997; 349:1322.

A New View of Risk

A new way of measuring risk emerged in July at the annual meeting of the Royal Statistical Society in the UK.

Called *A Simple Scale of Risk*, it has been developed by statistician Frank Duckworth, who was responsible also for the International Nuclear Event Scale.

Like Fujita (tornadoes), Richter (earthquakes), and Beaufort (wind), this is a logarithmic scale, from 0-8, in this case measuring the risk of everyday living.

Zero indicates simply living on the earth for one year; slightly more risky is taking a 160 km train journey, rated at 0.3; at eight is playing a game of Russian Roulette with a full chamber, jumping off the Eiffel Tower, or lying in front of an express train.

The scale has been developed on material abstracted from the BMJ and statistics from the UK Health and Safety Executive. Some of the items are intriguing: dying while washing-up, hoovering the carpet or walking down the street (5.5) is a higher risk than that of murder for a new-born male (4.6) or of one session of rock-climbing (4.2).

An abstract of some of the principal elements appears in the panel below this article. Further information about the scale and its theoretical basis can be obtained from:

The Royal Statistical Society (UK)
Tel: +44-171-638 8998;
E-mail: rss@rss.org.uk

Does this help us think of ways of expressing benefit-risk more simply?

- 8.0 Suicide, Russian Roulette (with six bullets)
Jumping off Eiffel Tower,
Lying in front of an express train
- 7.2 Russian Roulette (one game)
Continuing smoking cigarettes
- 7.1 (male aged 35, 40 a day)
- 6.9 (male aged 35, 20 a day)
- 6.7 (male aged 35, 10 a day)
- 6.4 Deep sea fishing (40 year career)
- 6.3 Rock climbing (over 20 years)
- 5.5 Accidental falls (new born male)
- 5.5 Lifetime car travel (new born male)
Dying while vacuuming, washing up, walking down the street
- 4.6 Murder (new born male)
- 4.2 Rock climbing (one session)
- 1.9 160 km car journey (sober middle aged driver)
- 1.7 1600 km flight
- 1.6 Destructive asteroid impact (in the lifetime of a new born male)
- 0.3 160 km rail journey

CIOMS Monograph Moves Ahead

The CIOMS Communications in Pharmacovigilance monograph is entering its last stages of preparation and is expected to be published around the end of this year.

The international group of experts were in Dublin in April for a last collective editorial meeting. Chapter authors have since been completing their revisions and the editor is now working on the final drafts.

As communications of all kinds move up the international agenda of priorities, not least in medicine and drug safety, this monograph should make a considerable contribution to the debate about the understanding and communication of benefit-risk issues in medicine, and to the greater openness and clarity of drug information at all levels.



Win Castle:
a whimsical glimpse of the leading light of CIOMS in recent years, by herself.

HERBALS LET OFF

A proposal that all herbal remedies and preparations should be licensed has just been dropped by the British Government after substantial protest by Members of Parliament and the public.

News from Around the World

Canada

Dr. Wikke Walop has joined the Division of Immunization as a vaccine safety epidemiologist. She was formerly with the Bureau of Drug Surveillance as a pharmacovigilance epidemiologist. **Dr Robert Pless**, has gone on a leave of absence to work at the CDC in Atlanta, USA, with the Vaccine Safety and Development Branch of their National Immunization Program. Dr Walop is presently the contact person at the Division of Immunization.

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Robert Pless, M.D., M.Sc. Medical Epidemiologist Vaccine Safety and Development Branch, Epidemiology & Surveillance Division, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS E-61 Atlanta, GA 30333 USA.
Tel +1-404-639 8256 Fax:+1-404-639 8834
Email: rkp2@cdc.gov

Australia

The regulatory authority, the TGA, recently created a new Adverse Drug Reactions Unit with responsibility not only for the safety of prescription drugs but also for OTC-drugs and complementary medicines. Head of the new unit is **Dr John McEwen**. He was the head of the ADR section in the early 1980s. During that period he made major and much appreciated contributions to the development of the WHO Drug Monitoring Programme.

The Netherlands

The Netherlands Pharmacovigilance Foundation, LAREB, recently established its internet web site at <http://www.lareb.nl>. The site is available in both Dutch and English versions.

Malaysia

Proceedings from the International Seminar on Pharmacovigilance, organized in Petaling Jaya 12-13 October, 1998 by the Ministry of Health Malaysia and WHO, are now available in print. Contact Ms Abida Haq, fax +60-3-7581312, e-mail ah@bpfk.gov.my, if you want your own copy.

Spain

By order of a Royal Decree of April 1999 the new Spanish Medicines Agency AGEMED (Agencia Española

del Medicamento) was established. AGEMED is responsible also for pharmacovigilance. Some of the key persons at the national pharmacovigilance centre who are now getting new e-mail addresses are Mariano Madurga (mmadurga@msc.es), Dolores Montero (dmontero@msc.es), Francisco de Abajo (fabajo@msc.es) and Gloria Martin-Serrano (gmartin@msc.es).

Uruguay

The Ministry of Public Health recently decided to regulate and centralize the organization of pharmacovigilance in the country and established a pharmacovigilance commission.

USA

An immediate action of the present commissioner of FDA, Dr Jane Henney, when she took office, was to establish a task force to evaluate the system for managing the risks of FDA-approved medical products, focussing particularly on FDA's part in the system. The task force presented its findings in May 1999. Both the Executive Summary and full text report of "*Managing the Risks from Medical Product Use: Creating a Risk Management Framework*" can be found on internet at <http://www.fda.gov/oc/tfrm/executivesummary.pdf> and <http://www.fda.gov/oc/tfrm/riskmanagement.pdf>. The executive summary can also be obtained in paper print from the UMC.

ICDRA

The 9th International Conference of Drug Regulatory Authorities was organized by WHO and the German Drug Regulatory Authority in Berlin 25-29 April, 1999. Recommendations of the ICDRA-9 will be made available by WHO headquarters, Geneva. They include proposals regarding transparency of information in drug safety monitoring, strengthening of the monitoring of safety of herbal medicines and further steps to be taken to combat counterfeiting of medicines.

ISPE

The International Society for Pharmacoepidemiology has moved to a new location. The new contact information is as follows:
2000 L Street, NW
Suite 520
Washington, DC 20036
Tel +1-202-4666120
Fax +1-202-4666490
E-mail: ispe@slackinc.com

France

The French drug control authority, Agence du Médicament, has established an internet web site at <http://agmed.sante.gouv.fr> from which those who know French can follow all drug safety decisions made by the French authority.

Netherlands Antilles

The Association of Pharmacists in Curaçao, in collaboration with the Association of General Practitioners held a training course on Adverse Drug Reactions Monitoring for the physicians and pharmacists of the Netherlands Antilles, 18-23 May 1999. The training course was given by Prof. Lolkje de Jongh and Dr Corinne de Vries of the State University of Groningen, and Dr Arthur Meiners of the Netherlands Medicine Evaluation Board. The course was attended by about 20 physicians and pharmacists.

On the last day of the training course, the participants had to come up with a plan to start a Centre for Adverse Drug Reactions Monitoring in the Netherlands Antilles. The participants then discussed the need and the feasibility of such a project for the Netherlands Antilles. They concluded that such a centre is needed and recommended a prompt start to a pilot study, to assess the feasibility of this project.

It was decided that the Centre for Adverse Drug Reactions Monitoring in the Netherlands Antilles will be a combined project of both the professional Associations. The Bureau of Pharmaceutical Affairs will provide the physical location of the Centre and will designate one of its staff employees, Ms Zjumira Wout, as administrator for the Centre and its database. The Centre will work in close relationship with the LAREB foundation in the Netherlands.

A reporting form has been designed and made available. It has been decided to start accepting reports from now on, while waiting for the pilot study and two pharmacy students from the Netherlands.

As soon as the first ADR reports are received, membership of the WHO Programme for International Drug Monitoring will be applied for.

Contact details for the new Centre
Ms Zjumira G M Wout
Bureau of Pharmaceutical Affairs
Fokkerweg #26, P.O. Box 3824
CURACAO Neth. Antilles
Tel: +599-9-614 877
Fax: +599-9-614 879
E-mail: zgwout@ibm.net



REVIEW OF UMC SUBMITTED TO THE SWEDISH GOVERNMENT

As reported in *Uppsala Reports* no. 9, the Swedish Government early this year decided to make an appraisal of *the UMC*. The review committee, consisting of Ms Åse Lidbäck and Mr Lars Markstedt recently submitted its report to the Government. The report is a 70 page document in Swedish with an English summary.

The main issues and suggestions are as follows:

Scope and extent of activities

In the future there will still be a need for a global adverse reaction database. The activities of the Uppsala centre are sufficiently flexible and the direction is generally appropriate to be continued. To defend its place among other adverse reaction databases it is important, however, that the work with the qualitative analysis of adverse drug reactions is intensified.

Financing

It is both feasible and appropriate to finance the activities through revenues from sales. The special grant from the Swedish Government should be discontinued.

Organization

The set-up of the Centre as a foundation should be kept.

Localization and co-operation

The activities of the Centre should continue to be based in Uppsala but with a closer connection to the University of Uppsala.

Composition of the Board

The board should have a professional and international composition. It should consist of five members to be appointed by the University of Uppsala, three of whom should be nominated by the annual meeting of representatives of countries participating in the WHO programme.

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A Participant's View - UPPSALA TRAINING COURSE ON ADRs AND ADR MONITORING 1999

It was with much trepidation that I arrived in Uppsala on the 30th of May to attend the training course on adverse drug reaction monitoring organised by *the Uppsala Monitoring centre (UMC)*. But, within a hour of arrival, I and the other participants from around the globe had their fears allayed by Sten Olsson and his charming team-mates at an informal cocktail party hosted by them.

The course itself consisted of three units. Unit 1, focussed on clinical manifestations and mechanisms of adverse drug reactions. The highlights of this unit were the two lectures on the impact of genetic and inter-ethnic difference on ADRs, and dermatological manifestations of ADRs presented by Dr Quin-Ying Yue and Dr Gunilla Sjölin-Forsberg.

Unit 2, was centered on spontaneous adverse reaction monitoring. Here we received hands-on training on assessing ADRs. We were also given a chance to share each other's experiences in pharmacovigilance in the respective countries. The most fascinating session to me was on causality assessment and signal generation done by Dr Ronald Meyboom and Prof Ralph Edwards. Unit 3, concentrated on pharmacoepidemiology. The last, but the most hilariously presented lecture was by Dr Nicholas Moore, who made pharmacoepidemiology seem simply child's play.



Lastly, but not the least important aspects of this programme were the social gatherings organised at and around *the UMC*. This enabled us to mix freely with each other and the training team. These activities together with the constant reminder of Prof. Ralph Edwards that we were not just names but essential components of *the UMC*, gave us a feeling of belonging to their global network.

In conclusion I take this opportunity on behalf of all the participants to thank all the staff at *the UMC* for their meticulous planning of the course and for their warm hospitality. I hope all of us will be able to supply the fuel to keep the fire burning at UMC!

Dr Rohini Fernandopulle MBBS, PhD
Sri Lanka

Countries represented were : India, Singapore, China, Malaysia, Brazil, Belgium, Tanzania, Zimbabwe, Poland, Mongolia, Kyrgystan, Sudan, Cyprus, Indonesia, Greece, Mozambique, Latvia, Bangladesh, Venezuela, and the two participants from the drug industry, Eli Lilly and Co. and CSL Ltd.



News from *the* Uppsala Monitoring Centre

BCPNN - Read all about it!

An article describing the theoretical background to the methodology of using Bayesian Confidence Propagation Neural Networks for analysis of new adverse reaction signals in the WHO database was recently accepted for publication in the journal *Computational Statistics and Data Analysis*. The title of the paper is *Bayesian Neural Networks With Confidence Estimations Applied To Data-mining* and the authors are Roland Orre, Anders Lansner, Andrew Bate and Marie Lindquist.

Product news

The current versions of the computerized WHO Drug Dictionary (DD) and Adverse Reaction Terminology (ART) cover information up to and including the first quarter of 1999. The annual revision of ATC-codes, as decided by WHO, has been included in DD for the first quarter of 1999.

The standard version of DDAccess, the Drug Dictionary with search facilities, is updated to contain the first quarter as well (the professional version is updated every quarter).

The paper print of DD (former Drug Reference List), ed. March 31, 1999, will be available during July/August.

Dragon-boat race

In early May *the* UMC team made its first appearance ever in the annual Dragon-boat race in Uppsala. This competition between local Uppsala corporations is fought on the river Fyris, flowing through Uppsala. *The* UMC team had prepared well for the race - but possibly more for the social than the physical aspects of the competition, judged by the result! To symbolize the heroic and socially-useful functions of *the* UMC, the crew chose to appear in costumes inspired by the old English hero Robin Hood (see picture).

'Medieval England provided the inspiration for the UMC's heroic efforts in the Uppsala Dragon boat race: Robin Hood and his merrie band were known for their generosity and commitment to spreading health and wealth.'



Front row (left to right): Mohammed, Anna, Helena, Malin Zaar, Malin Ståhl, Jonathan
Back row (left to right): Cecilia, Ralph, Andy, Marie (Maid Marion), Martin (friend), Ronnie Meyboom (Netherlands), Roland (Neural Networks Consultant)

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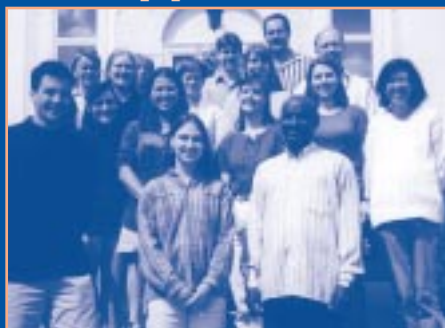
Agreement and by-laws

The 1978 agreement between WHO and the Swedish government should be replaced by an agreement between WHO and the University of Uppsala. The by-laws of the Centre should be up-dated.

the UMC team reaction:

The team is relieved that after the long process the recommendations have been made which seem to promise the continuation and development of the Centre's work without fundamental change.

the Uppsala Team



Director:
Manager (External Affairs):
Manager (Internal Affairs):
Manager (Marketing):
Manager (Research & Development):
Manager (Sales & Promotions):
Scientists:

Pharmacists:

External Affairs Assistant:
Internal Affairs Assistant:
Sales Assistant:

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Sten Olsson
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