Uppsala reports

For everyone concerned with the issues of pharmacovigilance and toxicovigilance

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**MESSAGE FROM THE DIRECTOR**

If it's true that one of the only constants in modern life is change, it's equally evident to us all that change is taking place at an ever-accelerating pace.

An important issue for us is the commercial pressure influencing the speed at which pharmaceutical companies need to bring new drugs to market. Their search for "blockbuster" drugs which can be marketed globally and deliver significant profits also raises concerns for pharmacovigilance.

The high challenges for the global pharmacovigilance community are to develop ever more effective methods of finding early signals of drug problems and to determine true benefits and risks. If the scientific challenges are great, then so are those of communication: more knowledge being developed at an accelerating pace needs more and more refined and transparent methods and channels of communication. Our goal of universal rational drug use will not be achieved easily! These - and many other issues - are the constant theme of the work of the UMC and they will be among the many topics which we shall be examining at the Annual Meeting of Member Countries in Tunisia in November. I hope we shall see many of you there to join in the global effort to stay abreast - and ahead - of so much demanding change.

**23rd Annual Meeting of WHO Drug Monitoring Programme**

The Tunisian Ministry of Health has kindly extended an invitation to WHO to organize the 23rd Annual Meeting of Representatives of National Centres participating in the WHO International Drug Monitoring Programme. This will be held in Tunis on 12-14 of November, 2000, with a pre-meeting tutorial on 11 November.

The meeting will be held immediately following the 7th Mediterranean Congress of Clinical Pharmacology, Carthage, Tunisia, 8-10 November 2000.

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
- for the UMC to exercise its accountability to member countries and seek their advice as to future directions, service levels and search priorities
- to provide a supportive, informative, sociable event in the pursuit of more effective pharmacovigilance worldwide and in developing productive relationships between member countries

Please send your message to Professor Peter Folb, Department of Pharmacology, University of Connecticut, School of Medicine, 163 Farmington Ave, Farmington, CT 06030, USA. If you have any questions or suggestions please contact Sten Olsson at the UMC.

National Centres have been invited to suggest topics for the meeting agenda. Newcomer countries to the WHO programme will be invited to present their pharmacovigilance systems as posters. These will be published in Uppsala Reports Following the meeting, the UMC will work closely with the Tunisian hosts to arrange all practical matters relating to the National Centres Meeting. If you have any questions or suggestions please contact Sten Olsson at the UMC.

Questions regarding the Clinical Pharmacology Congress may be submitted to Professor Belkahia, Centre National de Pharmacovigilance, Sis Hôpital Charles Nicolle, TUNIS 1006, Tunisia Tel: +216-1-562 098 Fax: +216-1-571 390 E-mail: chahbi.belkahia@msn.tn

**Changes to The WHO Adverse Reaction Newsletter**

Since 1981, the UMC has produced and distributed (to participating National Centres on a three-monthly basis) the WHO Adverse Reactions Newsletter. The focus of the newsletter has been information on specific drug related safety issues. The content has been based on communications, including national ADR bulletins, provided by the participating countries, supplemented with information from the WHO database.

WHO Headquarters, Geneva, later started an information sharing activity, including distribution of the WHO Pharmaceuticals Newsletter, which is sent to specially designated drug information officers in all member countries of WHO and a great number of other experts and partners around the world. A substantial part of the WHO Pharmaceuticals Newsletter deals with information on adverse reactions and safety aspects of individual medicinal products. Although there is a substantial overlap in content between these two publications, the distribution is somewhat different.

At a meeting in Geneva in February 2000, it was agreed that, to avoid duplication of work, the UMC would stop producing the WHO Adverse Reactions Newsletter, but instead carry the full responsibility for the adverse reactions and safety aspects of the WHO Pharmaceuticals Newsletter. By ensuring that all National Centres are included on the mailing list of the WHO Pharmaceuticals Newsletter all recipients should now get a much improved drug information service!

**More Internet Based Seminars & Training Courses**

In August 1999, we made our first three lectures, including sound recordings and visual material, available on the UMC website (www.who-umc.org/presentations). We were curious to know if our clients would appreciate this new technology for distribution of information and knowledge.

Unfortunately we had very little feedback to this initiative so far, either positive or negative. We imagine that we would have received negative comments if our target audience had experienced technical difficulties in accessing the seminars, so we’ve decided to keep on adding new presentations on to our website.

If the offer is accepted by National Centres, the UMC will assist Reactions Weekly in gaining up-to-date access to published material from national pharmacovigilance centres. This information will be reviewed by ADIS and included in the weekly journal. Accordingly, National Centres are offered a quicker distribution of material from National Centres and coverage of everything written about adverse drug reactions in approximately 1,800 journals/newsletters from around the world.

**National Pharmacovigilance Systems (NPS) 3rd Edition**

Included with Uppsala Reports 11 was a flyer announcing the availability of the 2nd edition of our publication National Pharmacovigilance Systems, describing the pharmacovigilance set-up in 57 countries. The response was very positive and we had a lot of requests for the publication.

**PLEASE LET US KNOW!**

To guide us in deciding whether Internet-based training and information sharing is a technology for the future we need your views, comments and experiences. All types of comments, positive or negative, technical or content related are most welcome.

Please present your comments to our website, which will be published in 2001. We are considering how to amend the contents to make the publication more informative and up-to-date. We are also thinking about other ways of distributing the information (e.g., on CD-ROM or on Internet). If you have suggestions regarding the content or the format of this valuable reference source (and your suggestions are most welcome!), please contact Sten Olsson at the UMC.

**Collaboration with the University of Cape Town on Traditional Medicines**

On 8 February 2000, Professor Peter Folb, Department of Pharmacology, University of Cape Town (UCT), South Africa visited the UMC to discuss collaboration between the UCT and the UMC in the area of traditional medicines. It was agreed that the two parties...
will share information in their respective databases with the aim of making the supporting structures compatible. The components that will be shared initially are: the ATC herbal register; the UMC herbal substances register; the botanical, therapeutic, chemistry and pharmacology information available to UCT.

The aim is to expand the interventions in a Pan-African initiative in the course of time and to see if other countries in the WHO drug monitoring programme might like to join the collaboration. An important component of the collaboration will be student exchange and training with the view of building capacity in this field.

**Governmental Review**

As mentioned in Uppsala Reports 10 and 11, the WHO Collaborating Centre for International Drug Monitoring (the Uppsala Monitoring Centre) was subjected to an official review in 1999, commissioned by the Swedish Government. The review team presented its report to the Government in September 1999. This report, 80 pages (Swedish Governmental Official Report SOU 1999:99) is now available in English and may be obtained from the UMC.

**Discussion on the National and International Management of Adverse Events following Immunization (AEFI)**

In early February 2000, the UMC hosted a discussion about vaccine safety with participants from WHO Headquarters and the University of Cape Town, South Africa. WHO was represented by Philippe Dulucq and Julie Mintzle (Vaccine and Biologicals) and Mary Cooper (Essential Drugs and Medicines Policy). Ushma Mehta and Prof Peter Folb represented the University of Cape Town. Ralph Edwards and Ronald Meyboom attended on behalf of the UMC.

Among other things it was agreed that:

- *general, national, international principles* are the same as those adopted in general clinical decision-making. Therefore, vaccine safety and AEFI signals do not differ significantly although the public response might be quantitatively different. Vaccine safety monitoring has the added dimension of not only protecting the patient but also the immunization programme. In the case of vaccines there is a more urgent need to investigate something which might impact on patient safety or the immunization programme.
- there is a need to cross-fertilise the fields of vaccine safety and pharmacovigilance. Closer collaboration should be established between the vaccine and biologicals department at WHO and the UMC.
- the Cape Town group will develop a training manual which will provide regulatory authorities with the information and skills necessary to deal with vaccine safety issues
- the UMC training programme (which is run every alternate year) will include a session on the special monitoring issues relating to vaccines
- the UMC would promote the idea among National Centres that for, various, unexpected ADRs, a field evaluation would need to be done before a probable causal association is entered into the database.
- the Annual Meeting of National Centres would include a session on vaccines
- the use of data-mining tools to identify signals in the UMC database could be useful in specific relation to vaccine signals.

**Organizational changes at the UMC**

As of January 2000, we have modified our internal organization to improve our operational efficiency. Our aim is to have a performance oriented, flexible organization with clear responsibilities, but without a rigid hierarchical structure. In addition to our main areas - External Affairs, Public Sector Clients; External Affairs, Commercial Clients; Data Management & Research; Information Technology Systems and Internal Affairs - we have a number of identified programmes. For each of these, we have a programme leader who is responsible for the ongoing activities within the programme.

We hope that the new organizational structure will help us achieve our goals of a first class and scientifically sound contribution to worldwide medicines safety, and an excellent and timely service to all our clients.

**Staff changes**

From April 2000, Malin Nord will be on maternity leave from the UMC for a while. Fortunately we have managed to find a competent replacement in Anne Kiuru. Anne has a MSc in pharmaceutical biociences from the University of Uppsala, has studied at the Uppsala Graduate School in biomedical research and has experience within several areas of research and development in both pharmaceutical and biomedical research. She will be handling incoming reports from National Centres, corresponding with National Centres about their reporting to the UMC and updating the WHO Drug Dictionary with new drugs on request from member countries and external inquirers. Anne speaks Swedish, English and Finnish. Her e-mail address is: anne.kiuru@umc.org

**Promoting Adverse Reaction Reporting!**

In 1997, we distributed a folder to National Centres with examples of educational and promotional material used in various countries to stimulate reporting of adverse drug reactions. The thought was to share ideas and designs within our network and thus facilitate the adaptation of existing material into, for example, other language versions. Our mission is (on a global scale) to utilize educational and promotional material as efficiently as possible, avoiding unnecessary duplication of work.

We now want to update our collection of material and proceed to another level. With the increasing use of the Internet we have seen it become common practice to download material from an Internet website for local use, manipulation or printing. Our ambition is to develop our website into a repository for educational and promotional aids in pharmacovigilance. We would like it to be used by anyone who is interested in this area.

**PLEASE HELP!**

To accomplish this we need your help! We kindly ask everyone involved in trying to promote adverse reaction reporting to send us one copy of every piece of material produced and currently in use. Here are some examples of materials currently used:

- printed material (posters, stickers, calendars etc)
- educational videos or audio tape
- educational slide shows e.g. in MS PowerPoint or other format
- educational video or audio tape
- other materials like: pens, rulers, magnets, notebooks, coasters etc.

Please e-mail us digital versions of your materials, or post actual items to Sten Olsson at the UMC. We’re most interested in materials produced in the local language and not only English versions.

The origin of the material received as well as any specific authorship will of course be clearly stated as we make it available to others. If you prefer not to have your computerized material made available directly from the UMC website, but kept on your own Internet server, we can set up a direct link.

**Results of educational or promotional interventions**

When educating newcomers to the field of pharmacovigilance on how to encourage reporting, we refer to the variety of activities that have been undertaken in our member countries. It is, however, difficult to find documentation on the effects of the different educational or promotional interventions. We are not sure which methods are effective and which are not, or why.

To remedy this situation we would like to collect information about any documented results of interventions in this field, and will be happy to carry out this study. We are interested in published reports as well as internal documents. The intention is to make the results widely known through Uppsala Reports and to use them in our training activities. If you have any documented results of your own activities in this area or know of other studies, please do let us know.
Further information about the conference may be obtained from: Lena Westin or Jan Albinson, KILEN, Kammakargatan 7, S-111 40 Stockholm.
Tel: +46 8-60 60 100
Fax: +46 8-60 60 110
E-mail: kilen@kilen-institutet.se
Internet: www.kilen.org

The VII World Conference on Clinical Pharmacology and Therapeutics of IUPHAR - division of clinical pharmacology, and the 4th Congress of the European Association of Clinical Pharmacology and Therapeutics (EACPT) will be held in Florence, Italy, 15-20 July, 2000. For more information contact:
Prof Giampaolo Velo
Tel: +39-45-809 8611/807 4899
Fax: +39-45-581111
E-mail: ctp2000@sfm.univ.it

The International Society for Pharmacoepidemiology (ISPE) will hold its 16th International Conference on Pharmacoepidemiology in Barcelona, Spain, 20-23 August, 2000. For more information contact ISPE:
Tel: +39-45-718 6500
Fax: +31-365-0699
E-mail: ispe@paimgmt.com

The 8th Annual Meeting of the European Society of Pharmacovigilance (ESOP) will take place in Verona, Italy, 21-23 September, 2000. For more information contact:
Prof Giampaolo Velo
Tel: +39-45-809 8611/807 4244
Fax: +39-45-581111
E-mail: esop@sfm.univ.it

The Drug Information Association (DIA) is organizing the following events of interest to drug safety and pharmacovigilance:
The DIA 36th Annual Meeting held in San Diego, USA, 11-15 June, 2000. One of the main themes is Critical Safety/Pharmacovigilance.
A workshop on Safety Information and Labeling in New Orleans, USA, 4-5 December, 2000.
A workshop entitled Improving Pharmacovigilance Working Practices to be held in Washington DC, USA, 11-12 December, 2000.
For more information on the DIA events contact:
Tel: +1-215-628 2223
Fax: +1-215-641 1229
E-mail: dia@diahome.org
Or
Tel: +41-61-386 9393
Fax: +41-61-386 9390
E-mail: diaeurop@stepnet.de

The 3rd edition of this standard reference textbook, edited by Brian Strom, University of Pennsylvania Medical Center, will be due in June 2000. The normal price is £120. Members of the International Society of Pharmacoepidemiology (ISPE) are offered a special price of £90. This book (880 pages) (ISBN 0471 89925 9) is published by John Wiley & Sons. Information may be requested from: John Wiley & Sons Ltd, 1 Oldlands Way, Bognor Regis, West Sussex, PO22 9SA, United Kingdom.
Tel: +44-1243-843 294 Fax: +44-1243-843 296
E-mail: cs-books@wiley.co.uk
Internet: www.wiley.com

OPINION AND EVIDENCE: DRUG SAFETY

The 2nd edition of this book (with Ralph Edwards from the UMC as Guest Editor) is now available from ADIS International Ltd. It contains an analysis of drug safety trends, reports from international pharmacovigilance meetings, summaries of over 125 papers and an alphabetic drug database with references to more than 2000 case reports of adverse drug reactions listed in the literature. In the 1999 book is available at US$49.95 from:
ADIS books, Private Bag 65901, Mairangi Bay, Auckland 10, New Zealand
Fax: +64-9-4770787, on-line order from www.adis.com

REPORTING ADVERSE DRUG REACTIONS - DEFINITIONS OF TERMS AND CRITERIA FOR THEIR USE

ISSN (Council for International Organizations of Medical Sciences) recently published this book which includes 180 medical terms used in the reporting of adverse drug reactions representing 20 different system organ classes, based on the WHO adverse reaction terminology. For each term a preamble, providing comments that may be of help to validators of ADR reports, a definition and basic requirements for use of the term are provided. The book, including internet version, is available at SFS3 from CIOMS, c/o WHO, 1211 Geneva 27, Geneva, Switzerland.

IMMUNIZATION SAFETY

Issue number 2, 2000 (78:153-280) of this bulletin produced by the World Health Organization has immunization safety as its special theme. Articles include the following:

- Immunization safety: a global priority (editorial).
- M. Schlott & R. Dudas
- New challenges in assuring vaccine quality.
- N. Delienne, E. Griffiths & J.B. Milstein
- Developing a national system for dealing with adverse events following immunization, U.Meha, J.B. Milstein, R.Dudas & P. Foll
- Monitoring signals for vaccine safety: the assessment of individual adverse event reports by an expert advisory committee, J.P. Collet, N. Macdonald, N. Cashman, R. Pless & The Advisory Committee on Causality Assessment
- The vaccine safety datalink: immunization research in health maintenance organizations in the USA. R.T. Chen, E. de Vries, R. Davis et al.
- Simian virus 40, poliovirus vaccines and human cancer: research progress versus media and public interests. J.S. Bates
- Vaccine adverse events in the new millennium: is there reason for concern? B.J. Ward.

ADVERSE DRUG REACTIONS JOURNAL

In June 1999, the first issue of the Adverse Drug Reactions Journal (ISSN 1008-5734) was published in Chinese. The page content is translated into English. This quarterly journal is sponsored by the Beijing centre for adverse drug reactions monitoring. Chief Editor is Dr Cheng Jinhu.
UMC's long-term strategy: "Our ambition is to develop ways of distilling the information we are getting and linking it with other sources, so that researchers can go to one site and get all the relevant information rather than do a literature search, Internet search and other research work. We are actively exploring ways to assist National Centres and others to access pharmacovigilance information on one site." For people around the world, the UMC will harness the latest IT technology to speed up the process of signal analysis in order to give maximum assurance to patients and health professionals.

The world's largest ADR resource

Since 1978 the UMC has been the centre for independent global pharmacovigilance. Our ADR data resource is the largest and most comprehensive in the world, and is developed and maintained by the UMC on behalf of the World Health Organization. The data held is collected from the National Centres of 58 affiliate countries and comprises over 2,000,000 reports, to which 35,000 new reports are added quarterly. Many of the signals that prompt the National Centres to take action are generated by the UMC’s clinical reviewers using this information.

A new and unique service

The combination of the BCPNN and the WHO database by the UMC has resulted in a powerful tool that is unique to pharmacovigilance. Now, that capability is being made available to you for the first time through a new service called ADRespherics. The primary objective behind ADRespherics is to give you the opportunity to monitor specific drugs to detect ADR signals as early as possible, so that your company has much more time and information to make the best decision about the continued use and labelling of a product. ADRespherics puts the power to know, and know early, at your disposal.

To find out more about ADRespherics please contact Mats Persson at the UMC.

Proof of Concept

Retrospective test runs on the WHO database have shown that ADRespherics can detect signals earlier than other analytical approaches. Specifically, when ADRespherics was used to analyse reports on captopril (see box), the study found that the association with coughing would have been indicated as early as 1981, and strongly highlighted in summer 1983; in reality this signal was not reported until 1986.

Three Flexible Services

Your specific needs are provided for with a portfolio of the following services:

1. Cumulus - Data Mining Tables
   This service allows you to track new drugs after launch, Cumulus provides you with ADR information from real patients to compare with your own research findings.

2. Stratus - Selective Comparison
   This service allows you to identify whether a drug has a specific problem that makes it stand out from others in its class.

3. Nimbus - Customised Comparison
   This service incorporates drug usage data in addition to raw numbers of spontaneous reports and allows for comparisons of reporting frequencies across countries and over time.

Why the name ADRespherics and the cloud formations?

"While we're all enjoying the spring sunshine here we keep an eye out to see clouds on the horizon so that we can reach for our umbrella, raincoat and wellies in time. We chose the theme of clouds to illustrate the service as it shows the universal concern in the pharmacovigilance community to anticipate events, so as to have time to act. The name of the service will be ADRespherics to reflect the weather theme."

All systems of pharmacovigilance rely on the ADR information that comes in and the UMC needs your continued supply of ADPs; the UMC is part of a network, and all National Centres will benefit equally from the new data-mining service.
News from Around the World

**Ethiopia**

The UMC has received this report (below) from Mr Gidey Amare, Drug Administration and Control Authority, Ministry of Health, Ethiopia, describing the pharmacovigilance activities undertaken in his country:

Two workshops have been conducted so far. The first workshop (a national one) was organized by the Ministry of Health and was held to work in teaching institutions; in medical professional associations; in regional health bureaux and hospitals.

The second one was organized for pharmacovigilance professionals mainly working in the inner city of Addis Ababa and referral hospitals.

In both workshops a total of 55 medical doctors, 6 pharmacists, 1 epidemiologist, 1 pharmacy manager and health officer participated. Both the workshops were successfully completed as planned. The participants attended the workshops with great interest and active participation. Generally speaking the performance and participation were beyond our expectations. Participants strongly recommended that similar workshops to be conducted to introduce professionals, working at different levels and regions, to the topic of pharmacovigilance and thereby establish a functional ADR monitoring system in the country.

We are planning to continue with the awareness creation campaign if our scarce resources allow it. We believe that the efforts to disseminate the information on the need to establish ADR monitoring will be of great importance to the major regional national states. We propose to conduct ADR reporting training workshops before the end of our fiscal year using the individuals who participated in the national workshop as a bridge to facilitate the administrative arrangements.

We have already developed an ADR reporting form and are now in the process of arranging and discussing with the postal service to print postage prepaid ADR reporting forms, to facilitate reporting. We have also reached agreement with the Federal Health Ministry and ADR monitoring will be established within the organizational structure of the drug administration and control authority.

I was working in the task force

formed to prepare a draft of the functions, responsibilities and organizational structure for the authority. This gave us a good opportunity to convince the task force to consider ADR monitoring as one of the main functions of the authority. At this level it is fully acceptable that its left to the approval by the office of the Prime Minister. Hopefully it will be approved

The UMC would like to thank Mr Gidey Amare. This continued work of his continued success! We always welcome individual reports (and pharmacovigilance material) from him at any time, so please do send us your material!

**Peru**

A national technical committee on pharmacovigilance, coordinated by the Ministry of Health, has started implementing a national pharmacovigilance system for Peru. A regulatory framework and administrative material have been developed and distributed throughout the country. The first case reports have been received from the medical profession and from pharmaceutical companies. Pharmacovigilance training courses for health professionals are being planned.

Activities are coordinated by Dr Susana Vasquez, Centro Nacional de Farmacovigilancia, Informacion de Medicamentos, Direccion Regional de Medicamentos, Insumos y Drogas, Ministerio de Salud, Lima.

Tel: +51-14-716246
Fax: +51-14-716353
E-mail: cenafim@digemid.gob.pe

**The Netherlands**

Dr Arthur P. Meiners, Head of Pharmacovigilance at the Medicines Evaluation Board in The Netherlands recently launched an initiative to develop an open-source software for management of adverse reaction data, compatible with the best standards recommended by ICH (International Conference on Harmonized System). Here is a summary of his reasoning and project proposal:

**POSISYS project announcement 2000.02.19** (the pharmacovigilance/ pharmacovigilance open source initiative system)

Nearly all pharmacovigilance/pharmacovigilance software systems currently in use by regulators, pharmaceutical companies and academic centres are either commercial products with specific extensions requested by the buyers, or home grown products. For commercial companies the buyers are relatively few. The fact that most systems are relatively unique increases the cost of maintenance and updating. These factors are seriously limiting the speed at which such systems can be implemented, and the high cost of systems limits their availability to smaller organisations and developing regions.

The growing success of the free, unix compatible, operating systems, Linux, clearly indicates that this trend allows a different approach to systems development. One which is based on open standards and results in highly standardised, high quality systems which can be obtained and used by all users of unix. Under such conditions commercial companies can still offer many national quality services, but they cannot dictate the cost or speed of progress any more.

In view of the above, I propose to develop the post-system, the Pharmacovigilance (/epidemiology) open-source initiative system, to be based on international open standards and to be made available free of charge to any interested party. Of course, I cannot develop such a complete system alone within a reasonable period of time. Help is clearly needed!

Help can be in the form of submission of useful routines any of the parts of this article have developed and are allowed to submit as freeware under the general public licence, help in the form of take the form of testing and documenting the post-system as it is developed. Or it can be in helping in hosting one or more web-servers to and from which the project components can be uploaded. Additionally the POSISYS website (http://home.planet.nl/~ameiners/posisys.html) is a private site. Please note also, that this is a non-profit effort, to which direct financial support is currently not possible, but we support from any interested parties is welcome.

If you are interested in supporting this project, please fill in and submit the POSISYS project response form located at:

http://home.planet.nl/~ameiners/posisys/posisys_proj_reply.html

Dr Arthur P. Meiners
Tel: +31-70 356 7550
Fax: +31-70 356 7515
E-mail: a.p.meiners@planet.nl.

**New member Countries!**

In March, the UMC received the first contributions of adverse reaction reports from Cyprus and the Federal Republic of Yugoslavia. Both countries had previously submitted their formal applications for becoming members of the WHO International Drug Monitoring Programme and they have now fulfilled the requirements.

The WHO International Drug Monitoring Programme now includes 58 full-member countries. Five countries are awaiting full membership status while the issue of technological requirements for the WHO reporting requirements is being resolved.

Correspondence with the new Centres should be directed to:

**Federal Republic of Yugoslavia**

Vaso Antunicov
Clinical Centre of Serbia
National Centre for Adverse Drug Reactions
Telefax: 26
Yu 11000 Belgrade
Yugoslavia, Fed Rep of
Tel: +381-11 361 5531
Fax: +381-11 361 5630

**Cyprus**

Dr. Christos Tsionitides
Clinical Pharmacist
Drug Information
Poison Control Centre
Lefkosia General Hospital
Lefkosia, Cyprus
Tel: +357 236 9005
Fax: +357 236 7194
E-mail: dipic@cytanet.com.cy

Here is a description of the pharmacovigilance system in Cyprus:

The Department of Pharmaceutical Services of the Ministry of Health established the Cyprus Pharmacovigilance Program in 1993. It was developed in consultation with the Drug Information and Poison Control Centre (DIPCC).

The computer and communication resources and library services are shared with the DIPCC, which minimized infrastructure costs and allowed the Program to operate almost immediately after its establishment.

The adverse drug reaction (ADR) reporting form was proped based on the WHO reporting form and is produced in Greek and English. The form was initially sent to all physicians, dentists and pharmacists accompanied with a letter explaining the goals of the program. Similar information was sent to the National Medical, Dental and Theraeutical and Nursing associations. In all communications we emphasized the WHO and EU support to such programs and their role in drug safety.

The program is pursued through:

a) the newsletter Clinical Pharmacy News
b) by mailing the ADR form to healthcare professionals at regular intervals
c) through presentations of the program to organized groups.

The newsletter is published by the division of Clinical Pharmacy four times a year and deals with drug and poison information as well as pharmacovigilance issues. Pharmacovigilance issues usually include the presentation of interesting local or international reported cases.

An ADR form is sent along with the newsletter, which is distributed for free every three months to all physicians and pharmacists in Cyprus.

In an effort to involve as many healthcare professionals as possible and as there is currently no Medical or Pharmacy School in Cyprus, we approached the American School Directrial Education, who agreed that nurses can play a major role in ADR surveillance. She promised to incorporate a series of lectures on Pharmacovigilance in the Nursing School curriculum.

Currently there is no legislation for ADR reporting in Cyprus. This, however, will change soon as the Cyprus legislation is being revised and will be harmonized with the European legislation in view of the accession of the Cyprus to the European Union.

Since the beginning of the Program, 60 reports have been received. The reports are evaluated by the staff of the Division of Clinical Pharmacy and an oral or written feedback is provided to the reporters.

Serious reports are forwarded to the Drug's Council, which is the regulatory authority that governs the use and licensure of all drugs in Cyprus. The 1997 reports were submitted to the WHO Collaborating Centre in March 1998 and now they are in the possession of the WHO Drug Monitoring Programme is expected soon.

The future plans of the Program include a nationwide campaign for the promotion of pharmacovigilance that will include the production of a poster, an improved design of the ADR form and lectures to all government hospitals for the year 2001.

**Dictionary**

**Users' Group Meeting**

The latest WHO dictionaries users' group meeting was held at the DIA meeting in Philadelphia, USA. During this meeting, Professor Peter Murray-Rust presented XETER, a web-based software to be used for browsing, searching and comparing different terminologies and versions of terminologies.

For further information on the users' group, please contact Lisa Storm at the UMC, or visit our website on: www.who-umc.org

The Internet training course regarding adverse reaction terminology, and the drug dictionary will be launched within 6-8 weeks. We will send you further information about this in due course.

**Product News**

The new versions of the computerized Drug Dictionary and Adverse Reaction Dictionary, containing the first quarter of 2000, are now available. In this version of the Drug Dictionary we have also included the revised ATC-code.

In December 1999, Dr Zbigniew Bankowski retired from his post as Secretary General of CIOMS (Council for the International Organizations of Medical Sciences). During the last fifteen years CIOMS has, under the leadership of Dr Bankowski, made important contributions to progress in the science of pharmacovigilance particularly by convening a great number of meetings and publishing a series of influential monographs on various drug safety related subjects.

In February 2000, Ms Sevgi Öksüz retired from her position as head of the national pharmacovigilance centre in Turkey after having served at the Ministry of Health for 25 years. Ms Öksüz was the main organizer of the 22nd Annual Meeting of Representatives of National Centres, held in Ankara in September 1999. She is still active in the scientific committee of ESOP (European Society of Pharmacovigilance).

In February 2000, it was announced that Dr Peter Honig has been appointed Director of the Office of Post-Marketing Risk Assessment (OPDRA) at the FDA Center for Drug Evaluation and Research. He has worked for the FDA since 1993 and became Deputy Director of OPDRA in October 1999.

In India, Professor (Mrs) Nilima A. Kshirsagar, Head of the Special WHO Centre on Pharmacovigilance in Mumbai, India, has been appointed Dean of the T.N. Medical College. She has moved her Department of Clinical Pharmacology from the Seth G.S. Medical College and K.E.M Hospital to her new base, now at T.N. Medical College & BYL Nair Hospital, Dr Al Nair Road, Mumbai Central, Mumbai (Bombay) 400 008, India. Tel: +91 22 308 5379, 308 1490/91/92/93 Fax: +91 22 307 5243 E-mail: dclphkm@bom7.vsnl.net.in

In New Zealand, Dr Michael Tatley recently joined the New Zealand National Centre in Dunedin as a Medical Assessor. He came to the centre from Cape Town, South Africa.

In Tanzania, Mr Henry Irunde left the National Centre at Tanzania Drug and Toxicology Information Service, to take up new studies. The current contact person is: Ms Mary Masanja.

In USA, Dr Peter Honig has been appointed Director of the Office of Post-Marketing Risk Assessment (OPDRA) at the FDA Center for Drug Evaluation and Research. He has worked for the FDA since 1993 and became Deputy Director of OPDRA in October 1999.