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Uppsala

REPORTS

For everyone concerned with the issues of pharmacovigilance and toxicovigilance



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Greetings from *Uppsala*

Based here in our small city in Scandinavia, we are lucky enough to have friends all over the world for whom we provide various services. We meet many people during our travels - and some of you visit us too - and there is always much to learn, to explore, to discuss - and even to laugh about. Sadly, there are many of our international colleagues whom we don't see - so Uppsala Reports is one way of compensating for the lack of such contact. We hope you'll enjoy it!



Members want to know more

Our recent research among member countries has made it clear that we need to communicate more effectively what we are doing here at the Centre and to provide answers to questions about our work which are being quite widely asked.

Like many organisations, we have assumed that what we do, why and how we do it is obvious to everyone but, of course, that's just not the case!

Uppsala Reports is our attempt:

- to explain the Centre's work regularly and clearly to member countries and our wider audience;
- to report and examine significant current issues in drug safety;
- to share useful developments

and discoveries from around the world;

- to keep up to date with more personal and informal news.

You may feel there are already more than enough publications which you have to plough through at your desk. Uppsala Reports will be successful only if it's positively useful for you and you positively want to read it!

Let us know!

For us to achieve that we need your help:

- please let us know if there are issues or questions you'd like us to deal with;
- send us information about developments and achievements in your department;
- tell us if you feel that Uppsala Reports is worthwhile for you;

- send us letters or articles for publication.

Apart from this modest new publishing venture, we are keen to serve everyone involved in the international causes of pharmacovigilance and toxicovigilance actively in all respects: please keep in touch with us and let us know how we can better serve you and your work.

Best wishes.

Ralph Edwards

A handwritten signature in cursive script that reads "Ralph Edwards".

Director

The Uppsala Team: *Back row, left to right:* Liza Storm, Cecilia Biriell, Anna-Karin Flygare, Monica Pettersson, Minna Harengerd, Helena Fucik, Mohamed Farah; *Front row:* Marie Lindquist, Ralph Edwards, Sten Olsson, Anna Lindquist.



What does the Centre *do*?

We are often asked about the range and purpose of our work at the Collaborating Centre. Even some of our longest-established colleagues are occasionally unaware of some aspects and there are always new staff joining national centres. So, for the record, here is the mission statement of the Centre and a list of its primary activities:

The Mission of the Centre

To develop international systems and relationships in the service of science and the welfare of the people of the world in the fields of drug safety and the prevention and management of poisoning;

- To ensure that the programme will always be alert to toxic events and in a position to record them;
- To maintain and develop leading-edge excellence in the collection, processing and dissemination of drug safety and poisoning information;
- To promote the development of knowledge and tools in safety and risk-benefit analysis to contribute to improved therapy.

Further Objectives:

- To encourage the establishment of new National Centres;
- To encourage existing National Centres to participate actively in the WHO programme, to improve the quality of all their

pharmacovigilance and toxicovigilance activities, and to use available information productively; in particular to encourage them to improve the quality, frequency and accuracy of event reporting in their own countries, and to exploit fully the resources of the Centre;

- To encourage the development of coherent, integrated systems worldwide for pharmacovigilance and toxicovigilance and communications;
- To develop productive relationships with all relevant audiences for the support and facilitation of the Centre's objectives;
- To develop new products, services and tools on the basis of the Centre's existing information and expertise;

The Activities of the Centre:

- Receipt, analysis and recording of worldwide adverse event data;
- Maintenance and screening of

international database (currently over 1.5 million records);

- Publication of previously unknown adverse events in SIGNAL;
- Quarterly publication of drug safety issues from National Centres in the Adverse Reaction Newsletter;
- Editing, updating and publishing the WHO Drug Dictionary;
- Developing and supplying DD ACCESS software for searching the Drug Dictionary;
- Maintaining and publishing the WHO Adverse Reaction Terminology (WHOART);
- Carrying out special searches of the database by request and providing on-line access to the database;
- Publishing a range of special reports;
- Assistance to potential members of the programme in developing their pharmacovigilance systems;
- Running annual training course for staff from National Centres;
- Organising annual meeting for member and associate member countries;
- Publishing scientific articles;
- Contributing to international conferences.

Updated version of Critical Terms list *now available*

The WHO Adverse Reaction Terminology has been developed and expanded quite extensively in the last fifteen or so years. Accordingly it was felt necessary also to revise the list of Critical Terms.

National Centres have contributed with their comments to the draft prepared by the WHO Centre. The approved new Critical Terms List was finalised in January 1996. It now contains 464 different terms and will be amended as new terms are introduced in the WHO Adverse Reaction Terminology.

In the near future the computerized WHOART will have an indication of

the terms included on the Critical Terms List. It may now be obtained in paper print from the Centre and further information may be obtained from Cecilia Biriell.

Background: Based on the selection of terms made by professionals at National Centres in the 1980s, the WHO Centre compiled a Critical Terms List.

Some of the output from the WHO

drug monitoring programme has focused on drugs associated with these critical terms, since any such report may warrant special attention and may lead to more decisive action than reports on other terms. The terms do not necessarily refer to serious conditions in themselves, but may indicate events which may be part of or lead to a serious syndrome.

The Centre's Annual Training Course

Our fourth course will be held from 20-31 May 1996 here in Uppsala. The deadline for applications is 14 April.

Each year we have had very positive comments about the course and the considerable professional benefits participants feel they have gained. It is also a rich opportunity for learning about what is happening in other countries - to say nothing of some very agreeable social activities and the chance to make new friends!

National Centres Staff

Since 1993 we have organised an annual training course on adverse reactions and adverse reaction monitoring together with the Swedish Medical Products Agency. It is the only training course available specifically targeted to support health professionals working at national drug monitoring centres or in the process of setting them up. Every year 25 people take part in this course and representatives of 47 different countries have attended so far.

Course Content

The syllabus is divided into three separate parts:

Part I

Provides insight into the mechanisms of ADRs, why they occur and how they manifest themselves clinically. This part has a duration of two and a half days. It is based on lectures given by Swedish clinical experts involved in the national ADR monitoring programme.

Part II

Gives the theoretical basis and practical skills for setting up and operating a national centre for spontaneous adverse reaction reporting. This section includes lectures, a lot of group discussions and computer-based work with recording and retrieval of ADR information. Every participant is

asked to make a poster and to present pharmacovigilance activities in her/his home country to the rest of the group.

Part III

Is a two-day introduction to pharmacoepidemiology. The merits and drawbacks of the different methods available for follow-up of ADR signals are discussed. Published studies are analysed and criticised. The aim of this short course is to provide participants with a critical mind when assessing pharmacoepidemiological studies.

Interaction between participants is considered an important feature of the course. Participants from countries without an established drug monitoring system can easily talk with new staff members from well-established monitoring systems and with staff of the WHO Centre. This contributes to making course participants feel part of the international pharmacovigilance network which is one of the main aims of the course.

Sten Olsson

If you would like further information about the course, please contact me, Sten Olsson, here at the Centre.

18TH ANNUAL MEETING IN BANGKOK

The 18th Annual Meeting of the WHO International Drug Monitoring Programme took place in Bangkok in December. Around 53 representatives from 31 countries attended, and the meeting was generally assessed as being very positive and productive. Photograph: Members of the VIP group at the opening ceremony of the WHO International Drug Monitoring Annual Meeting.



Thai Hospitality

Participants in the meeting were treated to the most splendid hospitality and meticulous organisation by the Thai team. Their efforts helped to ensure the success and pleasure of the event, assisted not a little by the generous and attentive service at the excellent Imperial Hotel. The meeting was honoured by the presence of the Minister of Public Health and the Permanent Secretary of Health (seen centre in our photograph of the VIP group).

Lisbon 1996

This year's annual meeting will be held in Lisbon from 15-18 September, immediately prior to the annual ESOP meeting in the same city. Details of this event will be available soon.

National Centre meetings are open only to representatives of National Centres and associates.

Product and Publication *News*

For further information, price lists, order forms or sample diskettes (where available) please contact Liza Storm here at the Centre.

WHO DD and WHOART

New editions (December 1995) of the paper print versions of WHO Adverse Reaction Dictionary (WHOART) and the WHO Drug Dictionary are available from the Centre from March 1996.

DD Access

The WHO Centre has developed a new product DD Access that provides the information contained in the WHO Drug Dictionary together with software that allows the user to make convenient retrievals in a Windows environment.

DD Access is a stand-alone product that may easily be installed on a PC. It is available in two versions, standard and professional. New versions will be released annually and quarterly respectively.

ON-LINE

WHO Adverse Reactions Data Base On-line is a service which, in its new version, is now available to a larger audience of those with an interest in drug product safety.

Pharmaceutical companies, for example, may subscribe to this software giving on-line access to adverse reaction reports submitted to WHO since 1968 from approximately 30 countries. These are the countries which are willing to release their reports to any relevant enquirer, provided the conditions of a standard Caveat Document are accepted.

National Centres participating in the WHO drug monitoring programme

have access to all 1.58 million case reports stored in the WHO database without any restrictions or charges. A manual describing the software facilities and the technicalities in arranging for an on-line connection can be obtained from the Uppsala team - please contact Liza Storm.

Special Searches

Custom Searches on Request is a service offered by the Centre to third party enquirers with relevant interests within the governmental, academic or industrial sectors. The Centre staff undertakes to perform retrievals in the WHO Adverse Reaction Data Base tailor-made to the needs of the enquirer.

A substantial number of standard presentations are available. Pharmaceutical companies may, for example, subscribe to regular printouts arranged according to the layout of the CIOMS II line listing for drug safety updates. Companies are offered this service at a charge. A manual describing the facilities is available from the Centre.

Did you see us in Philadelphia?

We had a stand at the DIA (Drug Information Association) conference on Worldwide Issues and Solutions for Clinical Data Management in Philadelphia, USA, 24 - 27 March, 1996. Centre staff demonstrated the use of the DD Access software and how to make on-line retrievals in the WHO Adverse Reactions Data Base.

Computer support for small drug regulatory authorities

We are frequently approached by representatives of small drug regulatory authorities with limited budgets for development of Information Technology. The request is usually for support with computer facilities for management of adverse reaction reports and also for other functions undertaken by the authorities.

Since we do not keep system development capacity in-house it has so far not been possible to be as helpful as we would have wished. The computer consultancy supporting the team here is, however, now developing a product aimed at suiting the needs of small drug regulatory authorities. The product, Regulator-Light, will become available in July or August 1996. It will also include a module for management of ADR reports. More information may be obtained from PharmaSoft AB, Uppsala, tel +46-18-185400, fax +46-18-109200.

Find us on the INTERNET

The first version of our Internet home page <http://www.pharmasoft.se/who> is available from April 1996. Through the home page you may conveniently get information about the WHO drug monitoring programme, the Centre here and the services and products available. The home page will be continuously developed and expanded, and will include edited highlights from each edition of Uppsala Reports.

PLEASE CONTRIBUTE TO UPPSALA REPORTS

Do let us have your news, views and opinions - even 50 words from you will be welcome - over the phone, by fax or e-mail. Sten Olsson is co-ordinating material, but any member of the team will be pleased to take down information from you for the next edition. In any case, just let us know if you think Uppsala Reports is a worthwhile venture.

If there are issues you'd like us to deal with, questions you want answered, problems you'd like to air - let us know!

News from *Around the World*

Ireland

From January 1996 the Irish drug control authority changed its name to the Irish Medicines Board from the National Drugs Advisory Board.

Poland

The Director of the Polish adverse reactions monitoring centre, Dr Andrzej Czarnecki, was appointed Professor of Clinical Pharmacology in 1995.

Costa Rica

Dr Albin Chavez, head of the ADR monitoring centre in Costa Rica since the country joined the WHO programme in 1992, is currently and up to July 1996 a visiting scientist at the United States Pharmacopoeial Convention, Division of Information Development, 12601 Twinbrook Parkway, Rockville, MD, USA. The position as head of the drug monitoring centre in Costa Rica is now held by Dra Zahira Tinoco Mora.

Sri Lanka

When Sri Lanka became an associate member of the WHO drug monitoring programme, the contact was Dr Ravindra Fernando at the National Poisons Information Centre, General Hospital, Colombo. In November 1995, the Ministry of Health, Highways & Social Services decided that the National Centre would be relocated to the Department of Medical Technology and Supplies Division within the Ministry. The Director is Dr U. Ajith Mendis.

Canada

Dr Curt Appel, who resigned as head of the Canadian drug monitoring centre in 1995, has now established his own company, Kusuri Canada Corp, dealing with training in the pharmacovigilance area.

Chile

In January 1996, we received the first ADR reports from the new national centre in Santiago, Chile. The contact at the centre is Dr Q.F. Cecilia Morgado-Cadiz, Centro Nacional de Información de Medicamentos, Avda Marathon 1000. Chile was the 47th country to join the WHO drug monitoring programme.

Australia

Dr Alain Rohan has served as head of the Australian drug monitoring centre for many years. In August 1995 he took leave from his post for a one-year assignment with the Canadian Bureau of Drug Surveillance. On two occasions, in 1994 and 1995, he visited the Philippines as a consultant assisting in the development of the Philippine national drug monitoring system.

Netherlands

In January 1996 the Ministry of Welfare, Health and Cultural Affairs in the Netherlands decided to change the organization of the national system for spontaneous adverse reaction reporting. The formal responsibility for the

programme now rests with the Medicines Evaluation Board, not with the Pharmaceutical Inspectorate. It is expected that Netherlands Pharmacovigilance Foundation, LAREB, will have the responsibility for collection and processing of adverse reaction case reports for the Medicines Evaluation Board.

South Africa

Mrs Nanette O'Connor has left the national centre in South Africa. She was replaced by Ms Ushma Mehta as of 1 February 1996.

Philippines

Kenneth Hartigan-Go, who runs the ADR Monitoring Programme, is taking a number of initiatives to increase ADR awareness and reporting rates. He has just published the third edition of SIGNALS - a lively and informative newsletter (which usually includes a quiz to test doctors' knowledge of ADRs), and the first edition of the Guide to Participating Hospitals which includes comprehensive information about ADR diagnosis and reporting.

Please let us have any interesting national, professional or personal information for this section - anything that will interest and inform colleagues round the world. Tell us by phone, fax or e-mail.

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