For everyone concerned with the issues of pharmacovigilance and toxicovigilance

- 22nd Annual Meeting of WHO Drug Monitoring Programme
- Uppsala Training Course on Adverse Drug Reactions
- Review panel for signal analysis
- Case reports Now – 2 million!
MESSAGE FROM THE DIRECTOR

If anyone doubts our international credentials, I recently completed the most extensive and complicated trip of my professional life! I went from Sweden to Prague, to London, to Mexico, to Brazil, to Denmark, to South Africa, back to Sweden - for less than a week - to Geneva and finally back to Sweden. The month before I started this trip I had been in South Africa for a week, and in Turkey for our National Centres meeting.

All the meetings were important in their different ways, all achieving something, and allowing me to meet many of our international colleagues. The global community challenges us all to think about the best way for us to work efficiently together, and to address the ever-growing range of issues in our specialist field.

At our recent internal planning meeting in Prague, we made some changes to our management structure in order to simplify the management of the Centre. Marie Lindquist will be our General Manager (for a trial period to see if she likes it!). Other senior staff will remain area heads, but not spend time with management issues. There will be co-ordinators for various on-going programmes (e.g. managing the Drug Dictionary). Time-limited projects will also have co-ordinators. These changes are not intended to be cosmetic, but to address key defects, which we have jointly identified. We hope you will see the positive effects in improved service to you.

More changes are likely to result from the positively-phrased Swedish government review of our future status and funding, which has been sent out for feedback. (See page the back page for further information.)

As a result of these changes we would like to receive your suggestions on how the UMC can best, and more particularly, effectively serve pharmacovigilance in the next millennium. Keep in touch!

Best wishes to you all,

Ralph Edwards

22nd Annual Meeting of WHO Drug Monitoring Programme

For twenty two years now, representatives of the national pharmacovigilance centres that take part in the WHO monitoring programme have come together to discuss issues of common interest.

Last year the meeting was held in Ankara, Turkey (20-22 September) in spite of some safety concerns caused by the terrible earthquake in Turkey shortly beforehand. Eighty participants from 43 countries, representing all parts of the world attended.

For the first time the meeting was followed by a tutorial, which covered background information about the WHO programme and what is expected of a national centre, for newcomers. The meeting had several breakout sessions where technical and methodological topics like reporting of efficacy failure by patients and pharmacovigilance training were discussed.

Major discussion items in the plenary session were monitoring of adverse events following immunisation, and safety problems with traditional medicines. The consequences of the recent review into the organisation of the UMC, undertaken by the Swedish government also attracted much attention. Sevgi Öksüz, head of the Turkish pharmacovigilance centre, and her team, organised a truly splendid meeting from the scientific, social and cultural points of view!

The WHO meeting was followed by the Seventh Annual Meeting of the European Society of Pharmacovigilance (ESOP) which attracted 200 participants.
During last year, the UMC put a lot of effort into improving the procedure for signal analysis, and developing new tools to detect signals quickly and effectively. This meeting was an opportunity to present the new ideas, to provide a forum for feedback on the results, and for discussions among the group, as to whether the new approach will aid the signal review panel in its work.

The expert panel enables the UMC to carry out its main aim - identifying new adverse reaction signals - and is thus an integral part of the network supporting the WHO programme for International Drug Monitoring.

The following reviewers (about half of the review panel) attended the meeting:
- Dr Wybo Bruinsma, the Netherlands
- Dr Ana Maria Corrêa-Nunes, Portugal
- Dr Peter de Smet, the Netherlands
- Dr Martin Pfeiffer, Germany
- Prof Frederick T Fraunfelder, USA
- Dr Robert Pless, USA
- Prof Milan Kriska, Slovak Republic
- Dr Alain Rohan, USA
- Dr M Laurie Mashford, Australia
- Dr Ruth Savage, New Zealand
- Dr Ronald Meyboom, the Netherlands
- Dr Molly Thomas, India
- Dr Ed Napke, Canada

Some conclusions and action points arising from the meeting:

**Methods**
- It is possible to identify safety differences between different medicinal products. However, the current quarterly screening is done on the substance level
- The use of the data-mining tool will be developed to aid the detection of syndromes and interactions
- the UMC will work towards identifying predictive terms/indicators of critical adverse drug reactions
- the UMC will undertake to make a special study of vaccine ADRs using the data-mining approach
- Since the second half of 1999, the routine report screening output, the Combinations and Associations Database, has a new field showing how many of the reports on each drug-ADR combination fulfil the different documentation grading criteria used in the WHO database. This allows reviewers to get an impression of the quality of the signal
- Further research at the UMC should investigate if useful information can also be gathered by looking at concomitant medication.

**Process**
- the UMC will continue to appoint new experts for areas that are not currently assigned to any specific reviewer. the UMC will also ensure that there is ongoing validation of the signal detection process
- the UMC will work towards establishing on-line contact to the WHO database for all reviewers

- Dr Meyboom and Dr Rohan will develop a review assessment template which will serve as an aid for reviewers
- the UMC will develop a strategy for re-introduction of a previously signaled drug-ADR association into the review process. This is to ensure that drug-reaction associations are not forgotten once signaled, but followed up for possible further actions
- the UMC will look into the possibility of reviewers joining the national centres’ Vigimed e-mail list for up-to-date pharmacovigilance information.

**Output**
- the UMC will look into the feasibility of accepting reports from industry and professional societies, and providing relevant information to them about signals
- the UMC will ask National Centres to consider wider distribution of the SIGNAL document to relevant professional groups in their countries and to reinforce that there is no restriction of an individual National Centre’s use on the total WHO data
- the UMC will consider how to deal with associations which have been reviewed, based on information available not considered signals
- the UMC should also send out signals emanating from one country only. The national centre concerned should be asked for feedback
- For reasons of credibility the UMC should keep the policy of having named authors of signals
- the UMC will ensure that a caveat (or warning) document (to accompany signals) is produced.

**Summary**
All participants have adopted the data-mining approach to signal detection, and prefer using the new output documents (the Combinations and Associations Database) for the review process.

It was agreed that an assessment template would be developed in order to improve the harmonisation and robustness of the information presented in the SIGNAL document. In addition a caveat statement will be added to SIGNAL as an aid to the proper use of the data. The reviewers’ panel is committed to playing an active role in the further development of the international signal detection system.

**New signal reviewers**
Our request for new volunteers to join our panel of signal reviewers (published in Uppsala Reports 10) resulted in six people showing interest in joining the group. We are very happy to welcome Dr Curt Appel (the Kusuri Corp, Canada) and Dr Robert Chen (Centres for Disease Control, USA) as new consultants. Curt Appel was formerly in charge of the national pharmacovigilance centre in Canada and is still active in the pharmacovigilance area doing training courses and consultancy work. We are now at the stage of clarifying what the tasks are with the other panel members.

We are still very interested in having additional clinical experts with an interest in adverse drug reactions joining this group of volunteers. If you are attracted to the idea of becoming a consultant to the UMC, please let us know. Contact xxxxxxx at the UMC.
IBC Global Conferences are organising a meeting on The Clinical Significance of Drug to Drug Interactions in London, UK, 20-21 January 2000. For more information contact IBC at Tel: +44-20-74535496 Fax: +44-20-76366858 e-mail: cust.serv@ibcuk.uk

IIR organises its ADRs 2000 meeting in London, UK, 24-25 January 2000. Entitled Ensuring Regulatory Compliance and Improving Standards in Global Pharmacovigilance. For more information contact IIR at Tel: +44-171-9155055 Fax: +44-171-9155056 e-mail: registration@iir-conferences.com

Management Forum is arranging a Workshop on Periodic Safety Reports, in London, UK, 11 February 2000. For more information contact Management Forum at Fax: +44 1483 536424 E-mail: registrations@management-forum.co.uk

A training course on Drug Safety Surveillance and Epidemiology, organised by DIA, will be held in Philadelphia, USA, 6-8 March 2000. For more information contact DIA at Tel: +1-215-6282288 Fax: +1-215-6411229 e-mail: dia@diahome.org

The DIA 12th Annual EuroMeeting 2000 will be held in Nice, France, 7-10 March 2000. One of the main themes is Clinical Safety/Pharmacovigilance. For more information contact DIA at Tel: +41-61-3869393 Fax: +41-61-3869390 e-mail: diaeurope@stepnet.de

IIR is organising a training course on Pharmacovigilance & Adverse Event Reporting in London, UK, 29-31 March 2000. For more information contact IIR at Tel: +44-171-9155055 Fax: +44-171-9155056 e-mail: registration@iir-conferences.com

The VII World Conference on Clinical Pharmacology and Therapeutics of IUPHAR – Division of Clinical Pharmacology, and the 4th Congress of the European Association for Clinical Pharmacology and Therapeutics (EACPT) is organising a conference in Florence, Italy, 25-20 July 2000. For more information contact Prof Giampaolo Velo on Tel: +39-045-8098611/8074899 Fax: +39-045-581111 e-mail: cpt2000@sfm.univr.it

The 8th Annual Meeting of the European Society of Pharmacovigilance (ESOP) will take place in Verona, Italy, between 21-23 September 2000. For more information contact Prof Giampaolo Velo on Tel: +39-045-8098611/8074899 Fax: +39-045-581111 e-mail: esop@sfm.univr.it Internet: www.sfm.univr.it/esop

Case reports
Now – 2 million!

On 11 November 1999 we reached a level of two million adverse reactions case reports in the WHO database. It took 14 years (1968-1992) to collect and process the first million. With an ever-increasing number of countries - now 56 - submitting case reports to the UMC, we expect the three million level to be reached within the next five years. At present we are struggling with a backlog of some 200,000 reports from the USA which have been delayed because of the introduction of the AERS database at the US FDA. They will all be introduced into the WHO database within the next few months.

Dictionary Users' Group Meeting

Fifty members of the WHO Dictionary Users' Group met in Brussels (3-5 November 1999) in connection with the annual European DIA Clinical Data Management Meeting.

Representatives from the centre were Anna-Karin Flygare, Malin Nord, Inger Forsell and Liza Storm. The Centre’s project to develop dictionary courses for the Internet was presented, and received a very warm reception from the audience.

Product news

Current versions of the computerised Drug Dictionary, Adverse Reaction Terminology and DD Access Professional, contain information up to and including the third quarter of 1999.

In the next version (1999:4), which will be available in February/March 2000, all terms in the Adverse Reaction Terminology will be translated into English, French, German, Portuguese and Italian. We also hope to translate all terms into Spanish very soon.

If there are any exciting or important issues concerning pharmacovigilance happening in your country which you would like to communicate to other national centres, please contact Sten at the UMC.
WHO Headquarters
Dr Lembit Rägo, formerly head of the drug regulatory authority of Estonia, has been appointed Special Adviser on Quality Assurance and Safety at the WHO cluster of Health Technology and Pharmaceuticals. In this role he will be responsible for quality assurance issues in three departments:

1. Essential Drugs and Other Medicines
2. Vaccines and Other Biologicals
3. Blood Safety and Clinical Technology

Dr Lembit will be the liaison person for the UMC at the WHO headquarters. He will take up his new post by the start of the new Millennium.

Sweden
Bent-Eric (Beje) Wiholm has been in charge of the pharmacovigilance unit of the Swedish Medical Products Agency (MPA) for about 20 years. He has been an influential proponent of an epidemiological approach to pharmacovigilance and has also served as the Chairman of ISPE, the International Society for Pharmacoepidemiology. Beje is now leaving his position at MPA for a post with Pharmacia Upjohn in New Jersey, USA. He will be leading a pharmacoepidemiology group within the company. He will, however, retain his part-time position at the Karolinska Institute, in Stockholm, where he has been running a research group in pharmacoepidemiology for a long time.

Indonesia
Dr Lucky Slamet was promoted (in June 1999) from her previous position as head of the national centre for adverse reaction monitoring to Director General of the General Directorate of Food and Drug Control. She replaced Dr Andajaningsih, who has retired.

USA
The MedWatch office was recently transferred from the Office of the Commissioner of the FDA to the Centre for Drug Evaluation and Research (CDER). Diane Kennedy, Director, and Stephen Goldman, Medical Director, have moved to other positions. Vicky Babb and Mary Pat Couig will be managing MedWatch until a new permanent director is recruited.

Tanzania and Malaysia
Henry Irunde and Ntunda Msuya from the Ministry of Health, Tanzania, visited Malaysia for training in Pharmacovigilance, Drug Information and Toxicology Services between 19 July - 2 August 1999. The training was focused on the practical handling of adverse reaction reports, and various reference information sources. It also included a study visit to the National Poisons Centre.

Retirement symposia honouring Prof Jens Schou and Prof Kjell Strandberg
Jens Schou had a wonderful one-day symposium and social gathering in Copenhagen to mark his retirement from his University chair, but not from the editorship of ‘Pharmacology and Toxicology’. Jens gives much to science and regulation in drug safety, and he is one of only a few people who works actively in animal and human toxicology both in and outside the pure drug arena.

About a month later Kjell Strandberg celebrated his compulsory retirement from the Swedish Medical Products Agency, again with an impressive symposium, lasting two days. Kjell has been our (very supportive) Chairman of the Board at the UMC throughout many difficult times. It is fair to say that if he had not been farsighted and prepared to take some risks, the Centre would not have survived, let alone thrived. Professionally, Kjell is a consummate ‘pharmacodiplomat’ as well as keeping his feet well on the solid ground of pharmacological science. He will be continuing as a consultant to the UMC.

Both of our colleagues have acquired and given enormous knowledge and wisdom to pharmacovigilance. Neither is stopping their work! Indeed, we gather from both of them that they are looking towards a future of great activity, but with the luxury of choosing what they do and when they do it, we imagine!

Canada
Carole Bouchard, who acted as head of the ADR reporting unit at Health Canada some years ago, has now been appointed Manager of a new office of Controlled Substances at the same agency.

New Zealand
Dr Ruth Savage, who served on the signal review panel of the UMC for several years, has now joined the staff of the New Zealand national centre, the National Toxicology Group in Dunedin.

Republic of Korea
Ms Kyung-Min Myung (e-mail: kendy@kfda.go.kr) was recently appointed Head of the Drug Monitoring Programme, replacing Ms Young-Sook Chung, who was transferred to the Narcotics Control Division.

ANNUAL NATIONAL CENTRES MEETING- 2000!
We have pleasure to announce that Tunisia will be hosting the 23rd annual meeting of national centres in mid-November 2000 in association with the Mediterranean Congress on Pharmacology. We look forward to seeing you all there.
Europe
The Pan European Regulatory Forum on Pharmaceuticals (PERF) is a co-operative venture between the 15 members of the European Union (EU), and the candidate countries of Central and Eastern Europe (CEE). The ultimate aim is the transfer of all EU technical requirements into the national legislation of the CEE. Pharmacovigilance is one of the priority areas.

In this area the objectives of co-operation are to review:

- the current status of pharmacovigilance in each of the candidate countries
- the training required
- the establishment, monitoring and follow-up of national pharmacovigilance action plans.

The schedule of PERF activities in pharmacovigilance includes the following meetings:

**Prague** 8-10 September, 1999
**Paris** 12-14 October, 1999
**London** 24-26 November, 1999
**London** 24-26 January, 2000
**Vilnius** 1-3 March, 2000

For more information contact:
Dr Noël Wathion, EMEA.
Fax: +44-171-4188551

The regulatory authorities of the European Union have introduced a common Internet entry point to the websites of the individual agencies. The address is:
http://www.heads.medagencies.org

India
The International Congress on "Frontiers in Pharmacology and Therapeutics in the 21st Century" took place in New Delhi from 1-4 December, 1999.

Secretary General of the organising committee was Dr Suresh Gupta, who is also the head of the Indian national pharmacovigilance centre. There was a conference symposium on pharmacovigilance at which Sten Olsson (the UMC) made the introductory presentation on the need for pharmacovigilance.

Other subjects covered included principles of signal detection (Anoop Misra), the impact of genetic factors (Folke Sjöqvist), counterfeit medicines (Martijn ten Ham), the role of the clinical pharmacologist (Nilima Kshirsagar) and vaccines monitoring (Osman Mansoor). Mohamed Farah, the UMC, made a presentation at a separate symposium on traditional medicines, about the need for proper classification of herbal medicines, and the use of the scientific nomenclature.

A follow-up symposium was held at the All India Institute of Medical Sciences the following day, entitled "Establishing Pharmacovigilance in India." In addition to Sten Olsson, Mohamed Farah and Suresh Gupta, several Indian experts provided information about past experience and ideas for the future development of pharmacovigilance in India.

Japan
In May 1999 a new Internet website, (www.pharmasyrisgrjp.com), was launched by the Organization for Pharmaceutical Safety and Research, Japan. The Ministry of Health and Welfare (MHW) and pharmaceutical manufacturers and importers manage this organisation. The aim of the website is to improve the availability of drug safety information to health professionals. The site, available in Japanese only, provides information on package inserts of ethical drugs, safety information released by MHW, or by pharmaceutical manufacturers, and individual adverse reaction case reports from the national pharmacovigilance centre. The case information is provided as line listings, and more detailed description of unusual cases. Pharmasys is being developed and expanded, and will soon include information on newly approved drugs.

Switzerland
The Swiss regulatory authority, the IOM, recently set up an Internet home page: www.uicm.ch, in English, French and German. You can subscribe to new entries on the website, including messages on measures taken on the grounds of drug safety.

Swaziland
Margareth Magagula, pharmacist at the Central Medical Stores in Kwaluseni has developed a plan for the establishment of a programme for adverse reaction monitoring in Swaziland, after completing a one-month study visit to the South African national pharmacovigilance centre in Cape Town. She has now also developed a very practical and attractive training manual aimed at creating awareness of the problem of adverse drug reactions, and encouraging their identification, communication and prevention in Swaziland. If you are interested in this material, contact Margareth Magagula at Fax no +268-5186279, or, e-mail: magmu@realnet.co.sz

Venezuela
The Venezuelan drug control authority, Instituto Nacional de Higiene 'Rafael Rangel', have organised training courses in drug control methodology for Latin American countries for the last seven years. The course extends over a period of about one month. This year twenty three participants from 13 countries attended the training in Caracas, which included a three-day session on pharmacovigilance. The pharmacovigilance faculty included local experts, Carmen Lozada and Luisa-Helena Valdivieso, as well as invited lecturers from abroad, Mabel Valsecia (Argentina), Mariano Madurga (Spain), Albin Chavez (Costa Rica) and Sten Olsson (the UMC).

Bulgaria
On 29 October 1999, the National Drug Institute organised a pharmacovigilance seminar in Sofia, aiming to promote the national pharmacovigilance system to health-care professionals, and to raise awareness of drug safety issues. Approximately 300 health professionals from different parts of Bulgaria attended. The main speakers Ronald Meyboom and Sten Olsson, representing the UMC, and Marc Ceuppens from Smithkline Beecham, Belgium, covered a wide variety of topics. Iraida Bantutova, head of the national centre, presented results of the national adverse reaction monitoring programme.

Croatia
In Croatia two innovative measures have been taken to stimulate adverse reaction reporting by physicians:

- The Croatian Medical Chamber awards each physician with half a...
point for three reports on adverse drug reactions. Every physician has to collect 20 points yearly (120 points in six years) to have his/her licence renewed.

- Every hospital has to be active in the reporting of ADRs as only hospitals reporting adverse drug reactions will be licensed to perform clinical trials. It is reasoned that if hospital physicians don’t diagnose and report ADRs, perhaps they cannot be regarded as sufficiently qualified to perform clinical trials.

**Romania**

As a part of the so-called Phare-project, the European Union (EU) is supporting the development of the pharmacovigilance system in Romania. The first part of this development plan was a pharmacovigilance training course in Bucharest, 8-12 November 1999, with Sten Olsson from the UMC acting as the course provider.

The outcome of the course was a proposed action plan for stepping up the pharmacovigilance activities in Romania and to integrate the Romanian system further with EU processes and the WHO network. The next step of this Phare-project will be a visit by Dr Daniela Stanciu, pharmacovigilance co-ordinator at the Romanian National Medicines Agency, to the UMC in February 2000. The development plan also includes two promotional seminars for leading healthcare professionals in Romania in April 2000, with participation from the UMC.

**Thailand**

The Thai FDA held its first national seminar on pharmacovigilance in August 1999 in Pattaya. The UMC’s commitment to effective communications in drug safety was represented by Bruce Hugman of EQUUS in sessions on Managing Meetings and Medical Communications.

**South Africa**

A DIA meeting on pharmacovigilance covered many interesting topics, and brought together representatives from Central and Southern African countries. The key concerns among many items discussed, was the need to concentrate more on what might be called drug misadventure. This includes many avoidable adverse reactions to drugs, which cause considerable morbidity. Herbal medicines were discussed, and the difficulties in managing generic drug safety (particularly when short tender periods for government supply were involved) were noted as special concerns. Ralph Edwards represented the UMC.

**Brazil**

The Brazilian Society for Toxicology invited Ralph Edwards to act as a keynote speaker. Ralph talked about toxicology into the next millennium, stressing the importance of monitoring the needs of healthcare practitioners, using case reports to poison control and ADR centres as a way of determining professional and consumer concerns. He also emphasised the need for better feedback and communication; IT will help with this.

The Society was, and is, a good advertisement for the need for overlap between poison control and ADR monitoring centres. There was much of interest in both areas, in this well organised and attended 3-day symposium.

**Cuba**

The national pharmacovigilance centre has been transferred to Pharmacoepidemiology Development Centre, 44 No 502 esq 5a Ave, Miramar Playa, Havana. Head of the new centre is Frank Debesa, Fax: +537-240924, E-mail: frank@mcdf.sld.cu

**Uppsala Reports**

WHO

The Ninth International Conference of Drug Regulatory Authorities (ICDRA-9) was held in Berlin, Germany 26-29 April 1999, with participants from 90 countries. The conference formulated a number of recommendations under 15 different headings. One of the headings was Transparency in monitoring the safety of medicines. The following recommendations were made:

1. Countries setting up systems for drug safety monitoring should make use of existing experience, including that from WHO and other countries. In this way, scientific resources can be harnessed.

2. Networks for electronic exchange of drug information, in particular relating to safety and which allow for rapid communication should be established. WHO should take the lead in this endeavour.

3. Regulators should be prepared for crises, and guidelines should be available on how to manage a crisis situation involving drug safety.

4. Plans for post-marketing surveillance should be made during drug development.

5. All relevant stakeholders need to be involved in drug safety issues identified by drug monitoring.

6. New drug safety monitoring programmes can be instrumental in the detection of counterfeit drugs. Unexpected lack of efficacy should be considered and managed as an adverse drug reaction.

7. Authorities should co-operate with other regional authorities when important signals are detected in order to ensure the earliest possible awareness.

8. WHO should develop principles of good communication practice with input from WHO Member States and regional authorities.

Under the heading of Herbal Medicines, it is recommended among other things, that WHO should collaborate with Member States to strengthen the safety monitoring of herbal medicines.
News from the Uppsala Monitoring Centre

Governmental review

The review committee was commissioned by the Swedish Government to make an appraisal of the UMC and make suggestions for its future organisation and funding (mentioned in Uppsala Reports 10). The committee provided its report to the Government in early September 1999. The Government has now asked relevant Swedish institutions to give their views on the recommendations before 14 January 2000. Negotiations are then expected to be held between WHO and the Swedish Government, adapting the administrative set-up of the UMC to present-time demands. The original agreement between WHO and the Swedish government was signed in 1978, and has not been revised since.

OBITUARY

Dr Christian Benichou

One of our valued signal reviewers Dr Christian Benichou died on 16 November, 1999. Christian was a much respected head of drug safety in Roussel-UCLAF. His basic clinical speciality was rheumatology, but he had a broad knowledge and sharp intellect, which he used to write guidelines on adverse drug reaction monitoring and diagnosis. He was particularly enthusiastic about definitions, and made us all think more clearly about the need for understanding the terms that are used to summarise, and subsequently to search adverse drug reaction information.

He was a great friend of the UMC and CIOMS. He pushed us along in his firm but gentle way when we were too slow, and supported us enthusiastically when we were on the right track. He will be greatly missed for all his professional skills and, more than that, his engaging and friendly character.

Staff changes

Annelia Lennartsson has joined us to become the new secretary at the centre in September 1999. She is responsible for telephone service, mailings and many other administrative tasks. She is also in charge of making travel arrangements and will work as the secretary to the Director.

Anna Lindquist, who has been with the UMC for five years, has taken leave from September 1999 to undertake university studies. She’s doing a four year course in computer linguistics.

Daniel von Sydow (pharmacist) has worked during the past four years for the computer service company PharmaSoft. In October 1999 he joined the UMC as a project manager, and will help us to develop ideas on new products and services into usable finished products.

Congratulations to Malin Zaar, one of our pharmacists, who recently got married to Lars! As a result, her surname has changed to Nord. She may now be reached on: e-mail malin.nord@who-umc.org

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the Uppsala Team

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Uppsala Reports © the Uppsala Monitoring Centre 2000
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Uppsala Reports is edited, designed and produced for the Uppsala Monitoring Centre by EQUUS Communications, London, UK. (Tel: +44 (0)171 274 8724; Fax: +44 (0)171 733 3600; e-mail: info@equus-group.com; internet: www.equus-group.com)