EURO DURGbulletin

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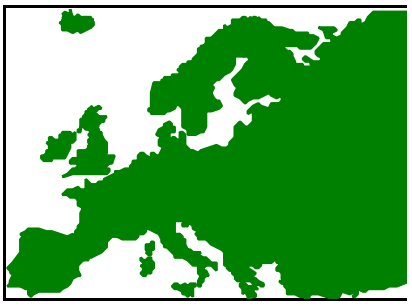
EUROPEAN DRUG UTILIZATION RESEARCH GROUP

Editors. *This issue was prepared by the following members of the Executive Committee of EURO DURG: Nicola Montanaro, Flora Haaijer-Ruskamp, Robert Vander Stichele, Liselotte von Ferber, Ulf Bergman.*



Report from the Nominating Committee

Dear National DURGs in Europe, Dear individual EURO DURG members,

According to our EURO DURG constitution in August 1998 in Berlin the new Executive Committee is due to be elected. Elections of the Executive Committee are prepared by a Nominating Committee, consisting of Annemarie Hoffmann, Germany, Ludvik Stika, Czech Republic and Ingegerd Agenas, Sweden. Members who have served in a position for two consecutive terms i.e. 4 years, shall not be eligible for re-election for the following two terms, i.e. 4 years. To maintain continuity it would be wise to bring some new members into the committee in 1998.

The members of the Executive committee should come from different European regions. Candidates can be proposed by countries or by individual members. The Executive Committee (Chair, Vice Chair, Secretary, Scientific Secretary, Treasurer and six members at large) shall be elected at the General Assembly by members present at the meeting on the basis of one country one vote. Members from one country appoint their representative and make this known to the Chair at the start of the General Assembly. The election shall be by secret ballot. Decisions are taken by simple majority vote. The Nominating Committee asks all National DURGs in Europe as well as the individual EURO DURG members to propose candidates for the 1998 election. Deadline will be the Europe Day 1998, i.e. May 5. In the June 1998 Bulletin the names of the candidates for the 1998 election will be published.

Proposals should be sent to:

Prof. Dr. Annemarie Hoffmann,
Klinikum der Friedrich Schiller Universitaet Jena, Institut fuer Klinische Pharmakologie,
Postfach, D 07740 Jena.
Phone. +49-3641-93 77 74
Fax: +49-3641-93 77 88
e-mail:
ahoffmann@bach.med.uni-jena.de

Announcement BERLIN 1998

The scientific meeting in 1998 will be in collaboration with the 14th ICPE of the International Society of Pharmacoepidemiology (ISPE) where we have 3 joint sessions. All members are urged to send in abstracts stating their EURO DURG membership (deadline March 2 1998). In view of the late information, we have asked for an extension of the deadline for ICPE abstracts, but have received no answer as yet.

Preceding the joint ISPE/ EURO DURG meeting we will have a meeting of the working groups and a General Assembly where we'll have elections (see Report from the Nominating Committee) for the new executive committee 1998-2000. The meeting of the working groups is intended for interested active members of the working groups who want to participate actively in joint research and the work of the working groups. Working groups are: Confidentiality (coordinator Liselotte Von Ferber); Quality of Drug Use (coordinator Hugh McGavock); the User Perspective (coordinator Ebba Holme Hansen); Mapping Europe (coordinator Robert Vander Stichele).

We propose that all EURO DURG members attending will stay at the Hotel President, where we were able to negotiate very reasonable prices - also for days of the 14th ICPE. It is only 20 minutes walking distance from the hotel Inter Continental where the ICPE meeting is held. Being in one hotel gives us the opportunity for easy (social) interaction and strengthen our EURO DURG group.

Registration is separate for the EURO DURG workshop (August 15-16 1998) and the 14th ICPE. Attached you'll find a registration form for the EURO DURG workshop. For the registration for the ISPE meeting we ask our members to add the notification of affiliation with EURO DURG (see attached form). Eastern European DURG members who are not ISPE members are eligible for scholarship, provided they submit a request authenticated by EURO DURG (see attached registration form). Information and registration forms for the 14th ICPE will be sent to the chairs of the national DURGs, who are asked to forward it to their members, and the individual EURO DURG members. In summary, if you intend to attend both the EURO DURG workshop and the 14th ICPE you are requested to fill in 3 or 4 forms:

1. Registration form for the EURO DURG workshop (to be sent to Dr Marion Schaefer)
2. ISPE registration (to be sent to ISPE Katrina Crist)
3. Notification of affiliation (to attach to the ISPE registration)
4. For EURO DURG members from Eastern European countries: Request for scholarship for the ISPE meeting (to attach to the ISPE registration)

IN THIS ISSUE

Welcome to new National DURGs in Europe

According to the Constitution, EURO DURG is an association of national DURGs. During our meeting in Berlin 1997 we were able to welcome new members.We are very glad that researchers in different countries have formed national groups and have decided to join the European group. We look forward to an active and enthusiastic collaboration. The new groups are:

DURG Greece
Chair: Dr A.Iliopoulou
Section of Clinical Pharmacology
Department of Clinical Therapeutics
Athens University
Alexandra Hospital
80 Vas Sofias Str115 28 Athens
GREECE
tel. + fax: 30 1 7771 731

ISDURG (Iceland)
Almar Grimsson
The Icelandic Pharmaceutical Society
ICELAND
tel.: 354 5616 166
fax : 354 5616 682
e-mail: pharmaci@itn.is

DURG Hungary
Chair: Zsusa Szpezdi
National Institute of Pharmacy
PO Box 450
H-1372 Budapest
Hungary
tel: 36 1 215 89 77
fax 36 1 118 11 67

Two more countries are in the process of becoming members:

DURG Israel
Prof Micha Levy, M.D.
Dep of Medicine
Hadassah University Hospital
Jerusalem 91-120
ISRAEL
tel.: 972 2 6776 449
fax : 972 2 6422 384

DURG Norway
Marit R nning
WHO Collaborating Centre for Drug Statistics Methodology
PO Box 100, Veitvet 0518 Oslo Norway
tel.: 47 22 16 98 10
fax: 47 22 16 98 18
email: marit.ronning@nmd.no

EURO DURG WORKSHOP
BERLIN August 15-16 1998

Place: Hotel President, An der Urania 16-18, Berlin

August 15
12.30 - 14.00 Lunch
14.00 - 17.30 Meeting of working groups

August 16
09.00 - 11.00 General Assembly
Elections of new Executive Committee (1998-2000)

Costs:
Early registration (before July 1 1998) 90,-- DM
Late registration (after July 1 1998): 140,-- DM

Hotel costs (Hotel President) for the duration of the EURO DURG workshop and the 14th ICPE:
single room: 172,--DM per night (1 person)
double room: 212,--DM per night (2 persons)

A cheaper alternative (about half an hour with the underground) is:
Hotel Albatros, Rudolstaedterstrasse 42, Berlin. Tel +49-30-897830
costs: single room 110 DM pp per night

Please send the registrartion for the EURO DURG to: Dr Marion Schaefer, Humboldt-Universitat zu Berlin, Inst fur Pharmazie, Goetherstrasse 54, D-13086 Berlin, Germany. Tel :49-30-965 92 415; fax:49-30-924 8280
email:marion=schaefer@pharma.hu-berlin.de

14th International Conference on Pharmacoepidemiology (ICPE)
Berlin, August 16-18, 1998
Hotel Intercontinental Berlin, Germany

JOINT SESSIONS ISPE / EURO DURG

August 16 educational session
August 17 plenary session
poster session

In order to attend these joint meetings one has to register for the ICPE meeting on separate registration forms. Please add the notification of EURO DURG affiliation with the ICPE registration form.

Registration fees before July

academic ISPE member	$ 425,--
non-ISPE member	$ 525,--
reduced fee (students/ Eastern EURO DURG members)	$ 225,--

Eastern European DURG members who are not ISPE members are eligible for scholarship provided they submit a request authenticated by EURO DURG. See attached registration form.

All EURO DURG members are urged to send in abstracts for the ICPE conference. The deadline is March 2 1998. **Abstracts and registration forms are available from your national chair or ISPE**: for further information about the ICPE please contact:

Katrina Crist, Executive Secretariat ISPE
2000 L street, suite 200
Washington DC 20036, USA
tel 1-202-4161641; fax 1-202-4161744
email: kcrist@slackinc.com
or: ISPE@slackinc.com

Berlin 1997 EURO DURG workshops
(to be continued in the next issue)

Confidentiality Working Group Questionnaire

Christian von Ferber, University of Cologne

The questionnaire action of EURO DURG is an expert based survey started in June 1997. This questionnaire was dispatched to members of EURO DURG in ten countries within the European Union and Eastern Europe. The experts were requested to complete the questionnaire themselves, or to ask somebody who was more familiar with the issue to do so.
Thirteen answers were received from the following ten countries

Countries	No.[a]	Answers[b]	
		yes	no
Belgium	1		●
Denmark	2		●
Germany	2	●	
Italy	1	●	
Netherlands	1	●	
Spain	1		●
Sweden	1	●	
United Kingdom:	2	●	
Scotland			
Northern Ireland			
Czech Republic	1		●
Hungary	1		●

[a]No. of reports

[b]Have you been aware of hindrances as a result of confidentiality laws in the last two years (1995 onwards)?

The aim of the survey was to acquire more substantial information on the following three topics:

1. Do obstacles to research by confidentiality laws exist?
2. Specifying the public health functions of drug utilization research.
3. Activities to ease the impact of the European Directive protecting the individual rights when health data become processed.

The first topic will be discussed on national and international level at present.

1. Hindrances of research by confidentiality laws

The legal principles of confidentiality restrict access to individual health data for drug utilization research and pharmacoepidemiology. The European Guideline of October 1995 allows the processing of health data as an exemption from a general ban only, and from 1998 onwards the Guideline will become obligatory for all countries within the European Union. It is therefore vital for EURO DURG to know more about how drug utilization is affected by confidentiality laws at present and in the near future under the rule of the European Directive.
In the majority of countries within the European Union obstacles to research already exist (Folie 1).
In those countries , in which at present no obstacles exist, it is felt that the implementation of the European Guideline will worsen the situation.
Our colleagues from Eastern Europe have up to now been rejoicing in a state of apparent innocence.

2. Public health relevance of drug utilization research and pharmacoepidemiology

Drug utilization research and pharmacoepidemiology have both to demonstrate the public health functions of their research in order to gain access to personal health data in the future. The exemptions which, according to the European Guideline, allow the processing of personal health data for research, are open to a spectrum of legal interpretations narrowing or broadening the scope of research. The process of specifying exemptions for research in national laws of confidentiality is currently being carried out.
The founding of the EURO DURG last year in Balaton offers the chance that drug utilization research and pharmacoepidemiology acquire the same conditions throughout the European Union. Besides the protection of individual rights, one of the primary goals of the European Guideline is to facilitate the exchange of data, not only for commercial purposes, but also for purposes of public health.
The proposal for equal status in accessing personal health data for research in the European Union at the same time demands equal standards when respecting confidentiality, and also when relating to methods, contents and relevance for public health.
Access to personal health data that are collected and stored by health insurance funds or the National Health Service will become licensed for research only when the results benefit public interests. This situation requires that the objectives and the public functions of the research can be identified not only from the inside by the scientific community, but also from the outside by the laymen, politicians and members of the authorities.
A first step to convince the laymen will be to specify those common areas of research that lie in the public's interest. Preparing this step for our discussion today the questionnaire put forward the following suggestion:

"Members of the association or institution (for whom the reporter is completing the questionnaire) are active in the following areas of research of drug utilization research or pharmacoepidemiology"

As the answers show priorities of research lie in the quality of prescribing and the cost containment in our welfare based health care systems. In these areas the interests of patients, politicians and DURGers are identical. I propose that it should become necessary to stress this point in discussions about confidentiality with respect to drug utilization research in the same way as ISPE has for drug safety and for the findings of adverse drug reactions by pharmacoepidemiologists. You will find some excellent examples in the memorandum of ISPE of August 1997.
To improve the quality of prescribing, as well as to contain costs, drug utilization research, requires access to the personal health data of patients and documents in the hands of physicians and hospitals. If these requirements cannot be fulfilled the issue of confidentiality is in danger of becoming misused in order to hide malpractice and prodigality.
The evaluation of the advantages and disadvantages of confidentiality from the patient's perspective has to be made an issue in the discussion of the European Guideline.

3. Actual activities to ease the impact of confidentiality laws.

With respect to this third topic the questionnaire aimed to collect information on the activities carried out by the national DURGs to influence the implementation of the European Guideline into national legislation. The reporters suggested three strategies:

- *seeking cooperation with other scientific associations.*
- *initiation of a dialogue with the confidentiality authorities.*
- *contacting legislative bodies in order to be heard in the legislative process.*

Most countries, especially those who are already suffering from restrictions have become active in each of these directions, although with varied success (Folie 3). Cooperation with other scientific associations has been

established and suggestions to the administrative bodies for confidentiality have been made. However only one actually succeeded in influencing the process of legislation itself.

4. Conclusions. What can be learned from this expert based survey?

First of all we have to thank all the reporters from the ten countries for their valuable information and helpful comments.

Secondly - to start with the crucial point - in order to gain influence on the implementation of the European Guidelines it is necessary to specify and elaborate those areas of research for which the interests of patients, politicians and researchers are identical. Also assuring the quality of prescribing, containing costs and - for pharmacoepidemiology - drug safety and monitoring adverse drug reactions.

EURO DURG Confidentiality Working Group Questionnaire	
Activities to influence the implementation of the European Guideline Is your association active in the following ways? (No. of countries assenting to the question)	
A. Cooperation with other scientific associations to achieve an easing of research in the public interest:	
6 Started	4 already in order
B. Targeting the Confidentiality administrative bodies:	
6 initiated dialogue	1 cooperation by the implementation established
5 developed suggestions	3 agreement about principles for facilitating research
C. Targeting the legislative bodies in order to be heard	
5 made contact with	1 (+1?) will be heard in the legislative process

" Together we will become stronger" - the slogan of the self help movement. The national EURO DURGs should join with other associations in their efforts. National EURO DURGs are mostly small groups; only two of our informants reported more than 50 members belonging to their associations. That means that all national groups in our survey combined represent a maximum of approximately 300 to 500 members- obviously not powerful enough to exert political pressure or to influence legislation.

Answering the question put forward at the beginning of our session, if our working group should prepare a separate memorandum, I prefer to propose that EURO DURG should adapt to the principles and proposals of ISPE. However EURO DURG should add some points which would specify and explain in detail to the public the achievements of drug utilization research in the interest of public health. Drug utilization is promising real progress in assuring the quality of prescribing and drug counseling, as well as in containing costs for our European welfare based health care systems.

I hope you will find some excellent examples to support these theses in our meeting's presentation.

Working Party on Confidentiality Proposals presented to the Executive Board of EURO DURG at the Business Meeting, Sept. 16 1997

1. EURO DURG may accept the ISPE memorandum as a platform for further action. The Memorandum covers in an excellent form the field of pharmacoepidemiology by describing the achievements for public health and by presenting a common stock of methods, study designs and devices for protecting privacy of the patients. As far as drug utilization in its own scope overlaps with pharmacoepidemiology everything has been said in the memorandum. Therefore EURO DURG can join the proposals and may use them in the ongoing discussions shaping the new national laws on confidentiality.

2. The ISPE memorandum restricts itself to pharmacoepidemiology. Therefore it is necessary to formulate an amendment specifying:

- the achievements of drug utilization research for public health. Every member of EURO DURG should name outstanding examples for research assuring quality of prescribing and promoting cost containment
- designs of studies, that are specific for drug utilization research and not covered by the ISPE memorandum p.e. the Compass or the pharmacotherapy quality circles of physicians, databased counseling and evaluation in the continuing education of physicians and pharmacists
- proposals for Review Boards, that would review and approve studies of pharmacoepidemiology and drug utilization research with respect to Confidentiality. Overwhelmingly it was the opinion in the working party on confidentiality that research is not only done by medical doctors but by other professions too such as psychologists, epidemiologists, sociologists. Therefore multi-professional Review Boards should be established notwithstanding national traditions.

In order to formulate an amendment to the ISPE memorandum under the special needs of EURO DURG it seems to be necessary, that every national member group makes its contribution to these three topics to a task force consisting of:

Nicola Montanaro, Robert Vander Stichele, Owen Wade, Ludvik Stika, Ulf Bergman, Hugh McGavock, Annekatrin Bertelsmann, Liselotte von Ferber, Christian von Ferber.

NEWS

JERUSALEM 1999

The EURO DURG meeting 1999 will be a joint meeting of EURO DURG and the 3rd congress of the EACPT (European Association of Clinical Pharmacology and Therapeutics) and the 4th Jerusalem Conference on Pharmaceutical Sciences and Clinical Pharmacology.

The meeting will be in Jerusalem at the Jerusalem International Convention Center (ICC) and the adjacent Holiday Inn Crown Plaza Jerusalem Hotel, October 3-8, 1999. The Executive Committee of the meeting is chaired by Professor M. Levy.

Affiliation with the European Association of Clinical Pharmacology and Therapeutics (EACPT)

EURO DURG and the EACPT have much in common. It was therefore in the business meeting of September 16 1997 (Berlin) decided to work towards a more formal link between the two organisations. At present we are thinking of an 'affiliated status' which would allow both parties to retain their identity. More details are being worked out at present.