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Permanent Secretariat Opened



The Executive Committee pictured at the entrance of the Headquarters of the Swedish Pharmaceutical Society/Academy of Pharmaceutical Sciences (SAPS), also door to the EUFEPS Secretariat. They are, from left to right: Prof. Björn Lindeke, Secretary-General & Treasurer, Dr Anders Grahnén, Vice-President, Prof. Malcolm Rowland, President, Prof. Atilla Hincal, Prof. Douwe D. Breimer, Past-President, Dr Michel Veillard, and Prof. Tony Fell.

On February 20, 1999, the permanent secretariat of EUFEPS was officially opened. It is located in the premises of the Swedish Pharmaceutical Society in Stockholm, Sweden.

Members of the Executive Committee, as well as of the Board of the Swedish Pharmaceutical Society/Academy of Pharmaceutical Sciences (SAPS) attended the inaugural reception and opening ceremony. The opening was held in conjunction with the February Executive Committee Meeting (see page 2).

Pictured at the Opening Ceremony, from left to right: Prof. Stig Agurell, former Secretary-General of EUFEPS, as well as former President of the Swedish Pharmaceutical Society/SAPS, Prof.

Conny Bogentoft, current President of the Swedish Pharmaceutical Society/SAPS, Prof. Folke Sjöquist, President of the European Association of Clinical Pharmacology and Therapeutics (EACPT), and Prof. Jörgen Vessman, Chairman of the EUFEPS Committee on Industrial Relations (CIR).



As is well-known to the readers of this Newsletter, EUFEPS was founded in 1991 in Strasbourg, France, by a number of national societies and associations for pharmaceutical sciences in Europe, one of which is SAPS (see pages 4-5). Since then, the number of Member Societies of EUFEPS has grown substantially, and additional forms of membership have also been established.

Currently, EUFEPS links 25 Member Societies in 22 European countries. In addition, there is approx. 480 Individual Members, as well as 25 Corporate Members of EUFEPS.

Urgent need

From the inauguration of EUFEPS, SAPS has been providing secretarial assistance to EUFEPS. As the activities of EUFEPS have increased, so too have the administrative and managerial requirements on the Secretariat. To meet these needs, a permanent location for the Secretariat has been sought, and, in 1997, the EUFEPS Council accepted an offer by

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SAPS that the EUFEPS Secretariat be permanently housed in its premises in Stockholm.

Mutual happiness

Against this background, the President, Prof. Malcolm Rowland, at the Opening Ceremony in February, said that EUFEPS was very pleased that a permanent home for the EUFEPS Secretariat has now been physically established. In addition, he thanked the Academy for providing substantial financial support, for a period of two years. And, he expressed a hope that this will challenge other Member Societies of EUFEPS to increase their support, too.

The President of the Swedish Pharmaceutical Society (SAPS), Prof. Conny Bogentoft, said that he was well pleased with this outcome. International co-operation and collaboration are of utmost importance for the development of new drugs. Without extensive

research, there would not be many new effective medicines, if any. Also, most of the medicines produced are developed for the international market. Collaboration between national regulatory agencies is growing, and a European Agency was recently created. In addition, drug companies in one country are merging with drug companies in other countries.

In other words, internationalisation and globalisation seem to be inevitable, and, in this perspective, it is a matter of course that the Swedish Pharmaceutical Society, through SAPS, firmly supports EUFEPS and its efforts to advance the pharmaceutical sciences and innovative drug research in Europe, Prof. Bogentoft reported.

Facilities and staff

Three suitable, newly and nicely renovated, rooms have been reserved for the EUFEPS Secretariat, on the same floor as the Scien-

tific Secretariat of SAPS. Equipment includes up-to-date computer work-stations, telephone, fax, printer, copy machine etc.



Hans H Lindén Anita Ljung Jenny Hagberg

The staff of EUFEPS Secretariat include: Hans H. Lindén, co-ordinator (Executive Committee, sub-committees, meetings etc.), as well as Newsletter Editor, Anita Ljung, Secretary to Prof. Björn Lindeke, part-time for EUFEPS (Membership administration and fees, Council, Newsletter Calendar and distribution etc.), and Jenny Hagberg, since February 1999, also part-time for EUFEPS (Conference and workshop administration, address database, documentation etc.). ■

EXECUTIVE SUMMARY

May 1999

The Executive Committee met on February 19-21, 1999, in Stockholm. As reported in this issue of the Newsletter, the new EUFEPS Secretariat was officially opened at a small ceremony, held in conjunction to this Executive Committee meeting.

Membership increasing

We are happy to announce some good news about our membership. First of all, the Asociación de docentes de Farmacia Galénica, or Spanish Society of Pharmaceutics and Pharmaceutical Technology, has submitted the supplementary information about their Society, as requested by the EUFEPS Council in Milan in September 1998. It will be the 25th Member Society of EUFEPS.

The Individual Membership has risen to about 500 persons. Nominations for the Individual Membership Representative to Council have been finalised. Elections are in progress.

Finance

The Treasurer has noted with pleasure that twelve Member Societies paid their fees for 1999 already by early February. The accounting records and the administration for the year 1998 have been approved by the Authorised Auditor. In 1998, as in 1996, expenses exceeded income, resulting in a net loss. The accumulated assets, balanced for currency changes, dropped by EUR 23 953. As indicated earlier, major deviations on the income side are due to insufficient contributions from congresses, about half of the budget. On the other hand, income from financial management rose significantly. In 1998 it corresponded to about half the amount of the revenues obtained from Member Societies. A

major obstacle on the expense side is, as has been the case for several years, substantially increasing costs for mailing and shipping, which is under review

Equipment transfer

Regarding the Equipment Transfer Project for European pharmaceutical research institutions in need, equipment required and institutions requiring equipment have been identified, as has recently also some equipment. When a list of equipment now becomes available, as well as when we know what the needs are, the commitment of the EUFEPS Executive Committee will be restricted to identifying the destination for a certain piece of equipment. Neutrality as to destination is essential. Secretariat assistance for co-ordinating such activities will also be needed.

Additional activities

The report by the Working Party on Council has been submitted by Prof. D. Duchêne, Chair of the Working Party. Some of the considerations will be very useful for the further developments of the rules and procedures. The document will be further discussed by the Executive Committee and representatives for the Working Party at a meeting in June 1999.

Profs. Malcolm Rowland and Björn Lindeke had an informal meeting with Prof. H.P.T. Ammon, President of DPhG (Deutsche Pharmazeutische Gesellschaft) in Tübingen on March 25, 1999. Various issues of mutual interest were discussed, notably DPhG and its relationship to EUFEPS, the Second European Graduate Students' Meeting 2000 and grants aimed at aiding participation in meetings organised by EUFEPS.

Within CIR discussions concerning the

School of Excellence are continuing. A position paper is being drafted. Some "seed-activities" are also being looked into. With regard to the Questionnaire on Training Needs, the EUFEPS Executive Committee supports the idea of running a second more extended study.

The 7th European Congress of Biopharmaceutics and Pharmacokinetics (ECBP) and 5th Congress of EUFEPS on "mechanistically based drug design and development: integrating the biological revolution" was successfully organised in Jerusalem, Israel, recently. A report on the highlights will be published in the next issue of this Newsletter.

On June 21-22, 1999, a conference will be held in London on "Regulatory Guidelines for Validation of Bioanalytical Procedures: Towards Developing a European Consensus on the FDA Proposals for Bioanalytical Validation", i.e. BIOVAL '99. It will be the first major international review of these issues since the pivotal Washington Conference on Bioanalysis in 1990. Additional ones are to follow (see e.g. "EUFEPS 2000" on page 3).

The planning of the 6th European Congress of Pharmaceutical Sciences in Budapest on October 3-5, 2000, proceeds well (see page 3). The 6th EUFEPS Conference, a follow-up to the 5th Conference on optimising drug development in Wiesbaden in 1998, will be run in Basel, Switzerland, from November 30 - December 2, 1999 (see page 5).

Next meeting

The next Executive Committee meeting will take place in London on Saturday, June 19, 1999, in conjunction with BIOVAL '99. ■

Björn Lindeke,
Secretary-General & Treasurer



EUFEPS 2000

Update on 6th European Congress of Pharmaceutical Sciences

Plans are well advanced for EUFEPS 2000 on Saturday – Tuesday, September 16-19, 2000, in Budapest, Hungary, the heart of Central Europe. This Congress follows the highly successful series covering advances in the pharmaceutical sciences, first launched in Amsterdam (1992), then Berlin (1994), Edinburgh (1996), Milan (1998) and the 5th Congress held in Jerusalem in 1999.

Venue and organisation

The venue will be the outstanding Budapest Convention Centre – which is attached to the Novotel, our congress Hotel located near downtown Budapest. The scientific programme will comprise Plenary Lectures, Mini-Symposia on selected themes, and submitted papers – presented either as Posters, thematically linked, or in thematic Podium Sessions - each starting with an invited Keynote Lecture. There will also be a couple of Hot Topic Sessions to discuss critical contemporary themes. As with previous Congresses in this series, Posters will form the heart of the scientific programme, and will be supported by a light lunch and refreshments provided as part of the Registration Package.

Programme strands and topics

A few details of the main programme strands are given here – the full preliminary programme will be distributed in mid-August this year, and will also appear on our website (see below) together with an Abstract Form for direct on-line submission of Abstracts.

The Plenaries will focus on *Drug-polymer conjugates as a new approach to targeted therapy*, *The impact of multiple synthesis*

methods and high-throughput screening on drug development, *Optimization of lead compounds: The pharmacokinetic challenge and Anti-angiogenesis as a new strategy for cancer treatment*.

Four Mini-Symposia will be devoted to *New Perspectives in Natural Product Chemistry*, *Modelling During Drug Development: in vitro/in vivo modelling of absorption, metabolism, receptor binding, Material Science and Drug Design and Genome mapping – Implications for Genome-Based Drug Discovery*.

The Keynote Lectures will head up thematic sessions, each presenting 6 submitted papers: *ICH: 2000 and beyond*; *Novel Concepts for New Drugs/Progress on the Development of New Drugs*; *Industrial Analytical Strategies for Drug Design and Development*; *Chiral Issues in Drug Development*; *Oral Delivery of Low Solubility Drugs*; *Pharmacokinetics/Pharmacodynamics*; *In vitro Toxicology*; *Novel Concepts in Dosage Form Design*; and *Advances in Phytotherapy*.

IPEC & BIOVAL

Within EUFEPS 2000 there will be a special one-day Symposium organised by the *International Pharmaceutical Excipients Council*, whose programme will be dedicated to in industrial and international problems in that arena.

At a one-day *Satellite Symposium BIOVAL 2000* before the Budapest Congress, leading international specialists will review the outcomes of discussions on the FDA proposals for *Bioanalytical Methods Validation for Human Studies*, as presented at the January 2000 FDA/AAPS Workshop to be

held in Crystal City, Washington, USA. There will also be a number of Short Courses on topical themes.

Social Programme

As for the Social Programme, the special *Registration Package* will include a *Welcome Reception* at the elegant National Gallery of Art - with a magnificent Buffet Table and fine Hungarian wines; plus an adventurous *River Boat Party* with dinner on the Danube on the Monday evening.

Lunches and refreshments will also be included in the package – which will cost about \$450 for industrial delegates, \$390 for academics and \$200 for students and unwaged persons etc. – an unbeatable bargain for those wishing to visit Budapest in late summer to update on leading-edge developments in their field, and renew friendships in the best network there is for pharmaceutical scientists worldwide.

A range of visits to the most famous venues in and outside the city will also be available for accompanying persons.

You are invited

All scientists working in any area of the pharmaceutical sciences are warmly invited to submit one (or more) abstracts for presentation at EUFEPS 2000. Information on the programme and format for submission of abstracts can be obtained by visiting our website: www.pharmweb.net/conference/eufeps2000.html

Tony Fell, *Co-Chair, EUFEPS 2000 Organising Committee*

Sándor Görög, *Chairman, International Scientific Programme Committee*
Szabolcs Nyiredy, *President, EUFEPS 2000*

Corporate Membership support acknowledged

Generous support from these companies is gratefully acknowledged:

Astra Arcus AB, Sweden

Astra Hässle AB, Sweden

Astra Pain Control AB, Sweden

Chemical Works of Gedeon Richter Ltd,
Hungary

GlaxoWellcome SpA, Italy

Janssen Pharmaceutica NV, Belgium

Lilly Development Centre,

Mont-Saint-Guibert, Belgium

Melacure Therapeutics AB, Sweden

Novo Nordisk A/S, Denmark

Organon Teknika BV, The Netherlands
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Pharma Bio-Research International BV,
The Netherlands

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Yamanonchi Europe, The Netherlands

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Correction



Regardless of what was stated in the report from the 5th EUFEPS Conference, in the previous issue of this Newsletter, these nice looking gentlemen are, from left to right: Dr Thierry Lavé (F. Hoffmann-La Roche, Basel, Switzerland) and Dr David Rance, (Pfizer, Sandwich, UK). We apologise for the mix-up.

The Swedish Pharmaceutical Society

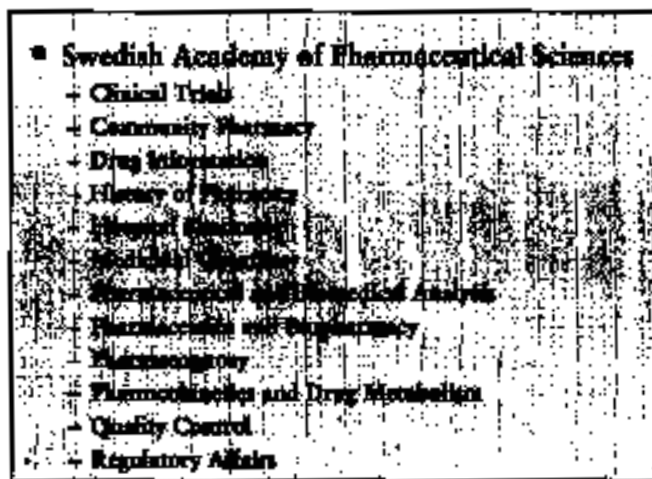
Ever since the very beginning of EUFEPS, its secretarial functions have been temporarily handled by the Swedish Pharmaceutical Society ("Apotekarsocieteten"). This lasted up until the end of 1998 when it was finally decided that the EUFEPS Secretariat should reside within premises provided by the Society. In the series of presentations of Member Societies in this Newsletter, it is now appropriate to present the Swedish Pharmaceutical Society, and its scientific group, the Swedish Academy of Pharmaceutical Sciences (SAPS).

Competence on medicinal drugs

The modern history of the Swedish Pharmaceutical Society starts in 1971, when all Swedish pharmacies were integrated into a national company (Apoteket AB) with the State as the majority owner. Since then the activities of the Society have been focused on scientific matters, education and publishing. Legally, the Swedish Pharmaceutical Society of today is a non-profit organisation for people engaged in the field of medicinal drugs. From originally having been a Society comprising pharmacists only, the organisation has grown into encompassing anyone who has a keen interest in the field and who would like to join. The major objective of the organisation is to further developments in pharmaceutical research and to promote high professional standards. The slogan presently in use is *competencies acting together for a better knowledge about medicinal drugs*.

Membership and organisation

The membership of the Society, approximately 8000 individuals, is divided geographically into 11 regional divisions, each governed by a regional committee. The Society as a whole embraces the Swedish Academy of Pharmaceutical Sciences (SAPS) – comprising 12 specialised and scientific sections (see figure) – the Swedish Centre for Continuing and Post-Graduate Studies in Pharmacy and the Swedish Pharmaceutical Press. As with the regional divisions, each section is governed by its own board. SAPS, through its sections, comprises the Society's expert body within the specialised areas of the sections and is highly instrumental in creating programs for symposia, courses etc. It also reviews a number of official reports which pertain to pharmaceutical or educational issues that are referred to the Society from the Government



Listed above are the Speciality Sections of the Swedish Academy of Pharmaceutical Sciences (SAPS).

and its various bodies for consideration.

The Council of the Swedish Pharmaceutical Society, which presently comprises 54 members meets, unless otherwise called for, every second year. It elects a nine-member Executive Committee headed by the separately elected President. A Central Secretariat, encompassing the educational and press departments, supervised by an Executive Director employs a staff of just a little over 30 people. Globally, the Society is an organisation dominated by women. In 1998, 76 per cent of the membership comprised the female gender and, since recently, also more than 50 per cent of the total body of elected representatives constitute women. A core activity run by the organisation is the annual Swedish Pharmaceutical Congress (*Läkemedelskongressen*) run together with the exhibition *PharmExpo*.

Finance

It is considered important that the Swedish Pharmaceutical Society stays neutral and independent. One way to achieve this is when parts of incurred costs can be financed by yields on one's own capital. Accordingly, for many years the Society has run an active financial management programme. Thus, while of the total expenditure for 1998, about EUR 4.5 million, EUR 2.9 million, were defrayed by revenues from membership and participation fees, publication subscriptions etc., the rest was balanced by revenues from capital investments. Also, by awarding scholarships and grants of approximately EUR 400 000, the Society provides support for pharmaceutical research and education.

Education and training activities

The Swedish Centre for Continuing and Post-Graduate Studies in Pharmacy is a leading national provider of continuing education and post-graduate courses. The centrally organised activities which encompass a broad spectrum of subjects – from generally oriented topics to specific science oriented subjects – attract about 5500 participants annually. About 55 per cent of the participants

emanate from the pharmaceutical industry and 18 per cent stem from the national pharmacy corporation. The Centre also co-operates with universities and other providers of education inside and outside of Sweden.

The educational programme is based on a tradition which goes back a couple of hundred years. Already in 1821, Apotekarsocieteten established a foundation (SAPS) to promote the progress of the pharmaceutical sciences and elective courses in experimental chemistry were given during the years 1820-22. In 1837, the Society founded the Pharmaceutical Institute and was solely responsible for the training of apothecaries until the Swedish State, in 1881, took over this responsibility. In 1968, the Pharmaceutical Institute became the Faculty of Pharmacy at the Uppsala University.

Journals and textbooks

The Swedish Pharmaceutical Press publishes a variety of products. The Journal *Läkemedelsvärlden* (Swedish Pharmaceutical Journal) has recently celebrated its 100th anniversary. In addition to textbooks in Swedish, various books are also being published in English. For sales outside of Sweden, the Swedish Pharmaceutical Press presently co-operates with Taylor & Francis in London.

Scientific symposia and award in science

Drawing on a well developed network and large resources of knowledge, SAPS is ideally suited to contribute ideas for programmes

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6th EUFEPS Conference

Optimising Drug Development: Streamlining Proof of Concept

November 30 – December 2 • 1999 • Basel • Switzerland

Aim

Following on from previous EUFEPS conferences on optimising drug development, and uniquely bringing together industrialists, academics, and regulators, this two and a half day Conference, held at the Basel Convention Center, aims to critically examine key issues and streamlining of proof of concept for gaining time and value in fast tracked and front loaded informative drug development.

Focus

Proof of concept trials (typically in Phase IIA) represent the most important decision point for full drug development in big pharma, as well as a maximum value gain for the

biotechnology industry. The focus of this Conference will be on concepts rather than on specific therapeutic area variations.

Format

Using a similar format to previous EUFEPS conferences, key segments of this value chain will be broken down into eight sessions, each with lectures and discussions. Session topics will also form the basis for open discussion in evening workshops. Workshop summary reports will be integrated and presented by rapporteurs on the third morning of the Conference.

Sessions & Exhibition

- Role of proof of concept in drug development

- How will genomics affect proof of concept?
- Proof of concept: ADME and safety properties • Preclinical proof of concept – value for man? • Facilitating proof of concept in early clinical development • Development and evaluation of biomarkers • Designing and analysing the proof of concept trials
- Regulatory issues on proof of concept and lean pivotal trials • Exhibition featuring current technological developments, forming an integral part of the Conference.

Additional information

For additional information, contact the Conference Secretariat at the EUFEPS Secretariat, PO Box 1136, SE-111 81 Stockholm, Sweden. Telephone +46 8 7235000. Telefax +46 8 4113217 Email eufeps@swepharm.se ■

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for international symposia, seminars and work-shops. Thus, since 1971, when these activities started, more than 70 international symposia and workshops have been organised or co-organised by SAPS.

Each year, since 1961, a particularly prominent and internationally renowned pharmaceutical scientist has been appointed the Scheele Laureate in memory of the famous chemist and pharmacist Carl Wilhelm Scheele. The Scheele Laureate is awarded a prize of ECU 11000, a medal and a diploma.

Peaceful co-existence

The Swedish Pharmaceutical Society owns some property in central Stockholm from where the Central Secretariat (and also the EUFEPS Secretariat) operates. A museum of Pharmacy is housed in these premises as is a comprehensive Library, comprising about 10 000 volumes covering pharmacy, medicine and natural sciences, many of which date back to the 15th-16th century.

Embraced within the Swedish Pharmaceutical Society, pharmaceutical practice and pharmaceutical sciences, the latter with its many specialities, have managed to thrive in peaceful co-existence for several decades; a situation which we hope will remain for many years to come. ■

Prof. Björn Lindeke
Executive Director

Current EMEA Information

The European Agency for the Evaluation of Medicinal Products

February – April 1999

These documents are also available at website: www.eudra.org/emea.html

CPMP

- * CPMP/573/99 Public Statement on Trovan IV & Turvel IV
- * CPMP/QWP/583/99 Workplan for the joint CPMP/CVMP Quality Working Party 1999/2000 Status January 1999-03-22
- * CPMP/QWP/054/98 Decision Trees for the selection of Sterilisation Methods – Annex to Note for Guidance on development Pharmaceuticals (CPMP/QWP/155/96)
- * CPMP/BWP/2257/98 Concept Paper on the Development of a Committee for Proprietary Medicinal Products (CPMP) Points to Consider on Human Somatic Cellular Therapy
- * CPMP/BWP257/99 EMEA Workshop on Application to Pharmaceuticals of Assays for Markets of TSE – held on 19-20 January 1999 – Report to the CPMP from the Biotechnology Working Party
- * CPMP/SWP/166/99 Concept Paper on the Revision of the Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Carcinogenic Potential
- * CPMP/WP/197/99 Concept Paper on the Development of a Committee for Proprietary Medicinal Products (CPMP). Points to Consider on Endpoints in Clinical Studies with Haematopoietic Growth Factors for Mobilisation of Stem Cells
- * CPMP/EWP/482/99 Concept Paper on the Development of a Committee for Proprietary

- Medicinal Products (CPMP). Points to Consider on Biostatistical/Methodological issues arising from recent CPMP Discussions on Licensing Applications: Superiority, Non-Inferiority and Equivalence
- * CPMP/EWP/863/98 Draft – Points to Consider on Wording of Helicobacter Pylori Eradication Therapy in selected SPC sections
- * CPMP/EWP/707/98 Draft – Points to Consider on Clinical Investigation of Medicinal Products for Prophylaxis of Intra- and Post-Operative venous Thromboembolic Risk
- * CPMP/EWP/570/98 Draft – Points to Consider on the Clinical Investigation of New Medicinal Products for the treatment of unstable Angina Pectoris or non-Q-wave Myocardial Infarction
- * CPMP/EWP/235/95 rev. 1 draft – Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Cardiac Failure
- * CPMP/EWP/563/98 draft – Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Venous Thromboembolic Disease
- * CPMP/180/99 Scientific Advice – Role and responsibilities of the Scientific Advice Review Group
- * CPMP/2024/98 Procedure for Developing CPMP Guidelines and Points to Consider Documents
- * CPMP/PhVWP/175/95 rev. 1 – Note for Guidance on Procedure for Competent

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Authorities on the Undertaking of Pharmacovigilance Activities

- * CPMP/ICH/365/96 – ICH Topic Q6B – Note for Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products
- * CPMP/BWP/305/99 Draft – Explanatory Note: the Expiry date of Products Incorporating Plasma-Derived Products as Stabilisers or Excipients
- * CPMP/BWP/328/99 Draft- Development Pharmaceuticals for Biotechnical and Biological Products
- * CPMP/BWP/733/99 – Preliminary EU Recommendations for the Influenza Vaccine Composition for the Season 1999/2000
- * CPMP/2527/1998 EN - Becaplermin
- * CPMP/2556/1998 EN – Antihæmophilic Factor (Recombinant)
- * CPMP/2748/1998 EN – Cetrorelix (as acetate)
- * CPMP/156/99 EN Deferiprone
- * CPMP/2773/1998 EN – Haemophilus b conjugate (Meningococcal Protein conjugate) and Hepatitis B vaccine
- * CPMP/2796/1998 EN – Rotavirus vaccine
- * CPMP/BWP/1021/99 – Final EU Recommendations for the influenza vaccine composition for the season 1999-2000
- * CPMP/BWP/1230/98 – Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products
- * CPMP/EWP/908/99 – Concept Paper on the development of a Committee for Proprietary Medicinal Products (CPMP) Points to Consider on Biostatistical/Methodological Issues Arising from Recent CPMP Discussion on Licensing Applications: Adjustment for Multiplicity and Related Topics
- * CPMP/EWP/519/98 draft 11 – Note for Guidance on Clinical Investigation of Steroid Contraceptives in Women
- * CPMP/ICH/285/95 draft – ICH topic M2 – Recommendations on Electronic Transmission of Individual Case Safety Reports Message Specifications
- * CPMP/456/99 EN - Efavirenz
- * CPMP/435/99 EN - Efavirenz
- * CPMP/86/99 EN - Ribavirin
- * CPMP/572/99 EN - Eptifibatid
- * CPMP/QWP/8567/99 – Operation of two-year transition period for application of note for guidance on residual solvents to marketed products
- * CPMP/QWP/2809/98 corr. – Concept Paper on the Revision of Note for Guidance on Radiopharmaceuticals
- * CPMP/PhVWP/108/99 – Note to Marketing Authorisation Holders Pharmacovigilance Guidelines

EMEA

- * EMEA/42968/98 rev. 2- Procedure on the Granting of Marketing Authorisation by Central and Eastern European Countries for Medicinal Products for Human use authorised in the European Union following the Centralised Procedure and the Variation and

Renewal of Such Marketing Authorisations

- * EMEA/HMPWG/25/99 – Report from the Ad hoc working group on Herbal Products 1997/98
- * EMEA/9880/99 – EMEA Discussion Paper on Antimicrobial Resistance
- * EMEA/27164/98 Rev. 1 – Report on the Experts Round Table on the difficulties related to the use of new Medicinal Products in Children held on Dec 18, 1997
- * EMEA/H-30313-98 Rev. 1 – Procedure for Notification of Parallel Distribution of Centrally Authorised Medicinal Products
- * EMEA/9880/99 Rev. 1 – EMEA Discussion Paper on Antimicrobial Resistance

EPAR

- | | |
|-------------------|--------------|
| CPMP/527/96 | Norvir |
| CPMP/1882/98 | Triacelluvax |
| CPMP/1755/98 | Humalog |
| CPMP/EPA4/2387/98 | Forcaltonin |
| CPMP/2422/98 | Emadine |
| CPMP/2741/98 | Temodal |
| CPMP/549/97 | BeneFIX |
| CPMP/1502/98 | Simulect |
| CPMP/1304/98 | Trovan IV |
| CPMP/1243/98 | Optruma |
| CPMP/130/97 | Teslascan |
| CPMP/245/98 | Optison |
| CPMP/012/97 | Vistide |
| CPMP/960/97 | Quadramet |
| CPMP/1283/98 | Humaspect |
| CPMP/1884/98 | Coaprovel |
| CPMP/1096/97 | Viramune |
| CPMP/527/96 | Norvir |
| CPMP/290/96 | Rilutek |
| CPMP/790/98 | Echogen |
| CPMP/933/98 | Fortovase |
| CPMP/2394/98 | Infergen |
| CPMP/1136/98 | Viagra |
| CPMP/1251/98 | Patrex |
| CPMP/896/96 | Insuman |
| CPMP/646/96 | Zyprexa |
| CPMP/897/99 | Sonata |
| CPMP/2979/98 | Cetrotide |
| CPMP/584/96 | Invirase |

EMEA General Documents

- * EMEA Status Report 1/3/99
- * Catalogue of EMEA Public Documents (March 1999)
- * EMEA Status Report – 30/3 1999
- * EMEA Organigram
- * Information Concerning Calendar of Events at the EMEA
- * Outcome of the third audit meeting on the European marketing authorisation system, chaired by dr Martin Bangemann
- * Catalogue of EMEA Public Documents (April 1999)
- * EMEA Status Report – 28/4 1999
- * Catalogue of EMEA Public Documents (May 1999)
- * EMEA/INS/241/99 – Policy on Financial Transactions and Payments for GMP Inspections requested in order to Complete the Assessment of Applications under the Centralised Procedure ■

3rd Central Symposium on Pharmaceutical Technology

September 23-24 • 1999
• Portoroz • Slovenia

Aim

The aim of this Symposium is to promote the advancement of pharmaceutical technology, industrial pharmacy and biopharmaceutics/pharmacokinetics as component parts of pharmaceutical sciences. Also, it attests to the increasing importance of scientific collaboration among academic, industrial and regulatory institutions within the Central European region and between this and other European regions.

Topics

At the Symposium, papers will cover Pharmaceutical Dosage Forms, and Pharmaceutical Processes, as well as Transport and Interaction Studies, including a number of Plenary Lectures, and Oral & Poster Presentations.

Format & Location

It is a two days meeting to be held in Avditorij Portoroz, starting on Thursday at 8 a.m., and ending on Friday by 6.30 p.m. On Wednesday evening, there will be a Welcome Party, and on Thursday evening a Symposium Banquet.

Portoroz is a tourist resort at the north Adriatic Coast, 120 km from Ljubljana, 30 km from Trieste (Italy), and 259 km from Klagenfurt (Austria), all of which having regular, international air connections.

Information & Registration

For additional information, consult the website: www2.arnes.si/lsjlf1/events.html or Dr Jelka Dolinar, Symposium Secretariat, Slovenian Pharmaceutical Society, Dunajska 65, SLO-1000 Ljubljana, Slovenia. Phone and fax: +386 61 1330445. Email jelka.dolinar@guest.arnes.si

EUFEPS Council

The 1999 EUFEPS Council will be held in conjunction with this Symposium, in the afternoon of Friday, September 24, 1999. ■

Many more Individual Members

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 Craig Yarwood, *Morristown, USA*
 Per-Henrik Zingmark, *Södertälje, Sweden*

CALENDAR

Advances in Tissue Engineering

August 22-26, 1999, Houston, TX, USA

Contact: CRS Administrative Headquarters,
1020 Milwaukee, Ste. 335, Deerfield, IL 60015, USA
Fax +1 847 8087073
Email crs@crsadmhdq.org

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12th Camerino-Noordwijkerhout Symposium

September 5-9, 1999, Camerino, Italy

Contact: Secretariat, 12th Camerino-
Noordwijkerhout Symposium, Dipartimento di
Scienze Chimiche, Università di Camerino
Via s. Agostino 1, IT-62032 Camerino, Italy
Fax +39 0737 637345
Email angeli@camserv.unicam.it

*

12th International Symposium on Microencapsulation

September 6-8, 1999, London, UK

Contact: Dr T.L. Whateley, Dept Pharmaceutical
Sci, SIBS, University of Strathclyde
Glasgow G4 0NR, Scotland, UK
Fax +44 141 552 6443
Email t.l.whateley@strath.ac.uk

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Biosensors – Fundamentals Techniques and Applications

September 22-24, 1999, Cranfield, UK

Contact: J.A. Clements, Room 403,
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397
Email jclements@rpsgb.org.uk

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International Course on PK/PD Modeling – Concepts and Applications

September 22-25, 1999, Amsterdam, The Netherlands

Contact: F.J. Velthorst, LACDR, Box 9502
NL-2300 RA Leiden, The Netherlands
Fax +31 71 5274277
Email velthorst@lacdr.leidenuniv.nl

*

Summer School on Biology of Free Radicals

October 3-8, 1999, Aussois, France

Contact: Mrs Arlette Alcaraz, CHU Grenoble
Laboratoire de Biochimie C. PO Box 217
F-38 043 Grenoble Cédex 09, France
Fax +33 4 76765664
Email arlette.alcaraz@ujf-grenoble.fr

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Tabletting Technology

October 11-13, 1999, Cambridge, UK

Contact: J.A. Clements, Room 403, Royal
Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397
Email jclements@rpsgb.org.uk

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ESCP 28th European Symposium on Clinical Pharmacy

October 14-16, 1999, Berlin, Germany

Contact: ESCP International Secretariat
Theda Mansholtstraat 5 B
NL-2331 JE Leiden, The Netherlands
Fax +31 71 5722431
Email secretariat@escp.nl

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Traditional Chinese Medicine

October 26-27, 1999, London, UK

Contact: J.A. Clements, Room 403
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397
Email jclements@rpsgb.org.uk

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VIII School of Medicinal Chemistry

October 26-29, 1999, Noordwijkerhout, The Netherlands

Contact: F.J. Velthorst, LACDR, Box 9502
NL-2300 RA Leiden, The Netherlands
Fax +31 71 5274277
Email velthorst@lacdr.leidenuniv.nl

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Practical Computer Validation

October 27-29, 1999, York, UK

Contact: J.A. Clements, Room 403
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397
Email jclements@rpsgb.org.uk

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Biotechnology Processes: Developments, Applications and Regulatory Issues

November 15-17, 1999, York, UK

Contact: J.A. Clements, Room 403
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397
Email jclements@rpsgb.org.uk

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Clinical Trials in Perspective

November 22-24, 1999, Bath, UK

Contact: J.A. Clements, Room 403
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397
Email jclements@rpsgb.org.uk

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Certificate of Suitability of Monographs of the European Pharmacopoeia: New Aspects of the Procedure "How to prepare your dossiers"

November 11-12, 1999, Berlin, Germany

Contact: Dr C Le Tarnec, Council of Europe
EDQM, B.P. 907 FR-67029 Strasbourg Cedex 1, France
Fax +33 3 88412771

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AAPS Annual Meeting and Exposition

November 14-18, 1999, New Orleans, LA, USA

Contact: AAPS, Fax +1 703 6847349
Email meetings@aaps.org

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Asian Conference and Exhibition of Controlled Release

November 29-December 1, 1999, Hong Kong

Contact: CRS Administrative Headquarters 1020
Milwaukee, Ste. 335, Deerfield, IL 60015, USA
Fax +1 847 8087073
Email crs@crsadmhdq.org

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6th EUFEPS Conference – Optimising Drug Development: Streamlining Proof of Concept

November 30-December 2, 1999, Basel, Switzerland

Contact: EUFEPS Secretariat, PO Box 1136
SE-111 81 Stockholm, Sweden
Fax +46 8 4113217
Email eufeps@swepharm.se

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International Symposium on Induction of Drug Metabolism: From Molecular Mechanisms to Drug Approval

December 9-10, 1999, Stockholm, Sweden

Contact: Märít Johansson, Swedish Academy of
Pharmaceutical Sciences, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Fax +46 8 205511
Email marit.johansson@swepharm.se

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14th GTRV Annual Meeting

December 9-10, 1999, Marseille, France

Contact: Groupe Thematique de Recherche sur
les Vecteurs, Centre d'Etudes Pharmaceutiques
5 rue J.B. Clement Dr J.A. Clément
F-92296 Chatenay-Malabry, France
Fax +33 1 4683585
Email gillian.barratt@cep.u-psud.fr

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Drug-Drug and Drug-Food Interactions: Mechanisms, Predictions and Regulatory Implications

December 9-10, 1999, Washington, USA

Contact: Dr Shiew-Mei Huang, CDER, FDA,
HFD-850, WOC2, 1451 Rockville Pike,
MD 20852, USA
Fax +1 301 5942503
Email huangs@cdcr.fda.gov

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5th US-Japan Symposium on Drug Delivery Systems

December 12-17, 1999, Hawaii, USA

Contact: CRS Administrative Headquarters,
1020 Milwaukee, Ste. 335, Deerfield, IL 60015, USA
Fax +1 847 8087073
Email crs@crsadmhdq.org

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46th Annual APV Congress/APGI 9th International Conference on Pharmaceutical Technology/3rd World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology

April 3-6, 2000, Berlin, Germany

Contact: APV, Kurfürstenstrasse 59
DE-55118 Mainz, Germany
Fax +49 6131 97690

or

APGI, Rue Jean Baptiste Clément
FR-92290 Chatenay Malabry, France
Fax +31 146 835308

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Pharmaceutical and Biomedical Analysis – BPA 2000

May 14-18, 2000, Basel, Switzerland

Contact: Prof. Wolfgang Lindner, Institute of
Analytical Chemistry, University of Vienn,
Währingstrasse 38, A-1090 Wien, Austria
Fax +43 1 33151826
Email wolfgang.lindner@univie.ac.at

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IXth International Symposium on Luminescence Spectrometry in Biomedical and Environmental Analysis – Spectroscopic and Imaging Detection Techniques

May 15-17, 2000, Montpellier, France

Contact: Prof Dan A. Lerner, Université of
Montpellier, Ecole Nationale Supérieure de
Chimie, 8 Rue de l'Ecole Normale
FR-34296 Montpellier Cedex 5, France
Fax +33 04 67144349
Email lerner@enscm.fr

*

2nd International Symposium on Microdialysis in Drug Research and Development

June 14-17, 2000, Stockholm, Sweden

Contact: Märít Johansson, Swedish Academy of
Pharmaceutical Sciences, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Fax +46 8 205511
Email marit.johansson@swepharm.se

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CRS Workshops

July 7-8, 2000, Paris, France

1) In Vitro/in Vivo Correlations Applicable to
Extended-Release Formulations 2) Gene Therapy
and Liposome 3) Cyclodextrines

Contact: CRS Administrative Headquarters
1020 Milwaukee, Ste. 335
Deerfield, IL 60015, USA
Fax +1 847 8087073
Email crs@crsadmhdq.org

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27th International Symposium on Controlled Release of Bioactive Materials

July 7-13, 2000, Paris, France

Contact: CRS Administrative Headquarters
1020 Milwaukee, Ste. 335
Deerfield, IL 60015, USA
Fax +1 847 8087073
Email crs@crsadmhdq.org

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EUFEPS 2000 – 6th European Congress of Pharmaceutical Sciences

September 16-19, 2000, Budapest, Hungary

Contact: EUFEPS 2000, c/o Research Institute
for Medicinal Plants, H-2011 Budakalász
PO Box 11, Hungary
Fax +36 26 343195 or 340426
Email eufeps2000@mail.mata.hu

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