

2007-2008 Report of the Clinical Pharmacology Division of IUPHAR

The aims of the Division are to develop clinical pharmacology and therapeutics by:

- a) stimulating research in clinical pharmacological world-wide,
- b) arranging scientific meetings, workshops and courses in clinical pharmacology and therapeutics in different parts of the world,
- c) improving and harmonising the teaching of the rational use of drugs at both undergraduate and postgraduate levels, particularly in emerging countries,
- d) promoting the utilization of clinical pharmacological services in health care delivery, particularly in emerging countries,
- e) enabling individual countries to benefit from the international diversification of clinical pharmacology and therapeutics,
- f) utilizing the skills of clinical pharmacology and therapeutics in counteracting misuse of prescription drugs and other chemical substances,
- g) promoting problem- and patient-oriented drug information for physicians and other health professionals,
- h) promoting high professional standards in drug prescribing,
- i) promoting high ethical standards in clinical drug research and drug utilization, and
- j) encouraging collaboration with other agencies interested in the rational use of drugs, particularly WHO.

Accordingly, the Division has focused its activities on clinical pharmacology in Latin-American Countries, Egypt and Eastern Europe by organising meetings, congresses, and visits and strengthening its ties with WHO. In addition, the Division has fostered paediatrics clinical pharmacology.

The actual composition of the Division is as follows:

Chairman:	Patrick du Souich (Canada)
Vice-chairman:	Don Birkett (Australia)
Secretary:	Kim Brøsen (Denmark)
Treasurer:	Petra Thürmann (Germany)
Past President:	Folke Sjöqvist (Sweden)
Councillors:	Darrell R. Abernethy (USA)
	Gilberto Castañeda-Hernández (México)
	Luigi Cubbedu (Venezuela)
	Mohammed Ibrahim A. Ibrahim (Egypt)
	Shinichi Kobayashi (Japan)
	Emilio Perucca (Italy)
	Wim du Plooy (South Afrika)
	Hyung-Keun Roh (South Korea)
	David Webb (UK)
	Fan-Dian Zeng (China)

Sub-Committee for Drug Utilization and Pharmacoepidemiology

Chairman: Emilio J. Sanz (Spain)

Sub-Committee for Paediatric Clinical Pharmacology

Chairman: Kalle Hoppu (Finland)

Sub-Committee for Clinical Pharmacology in less developed countries

Chairman: Lars L. Gustafsson (Sweden)

Sub-Committee for Pharmacogenetics

Chairman: Ingolf Cascorbi (Germany)

Sub-Committee for Drug development, clinical trials and drug regulation

Chairman: Phillip A. Routledge (UK)

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1. REPORT OF THE TREASURER

To be distributed during the meeting

2. REPORTS OF THE MEMBERS OF THE COUNCIL

Report of Professor Gilberto Castañeda Hernandez (México)

Course on Pharmacokinetic-Pharmacodynamic modeling. Course given at the Universidade Federal do Rio Grande do Sul in Porto Alegre, RS, Brasil. October 8-10, 2007.

The course was offered for the first time in 2004 at the Universidade Federal do Rio de Janeiro. Due to its success the course was repeated in 2006, as a pre-congress event to the 38 Congresso Brasileiro de Farmacologia at the Univesidade de Sao Paulo in Ribeirao Preto. The course will be newly offered in June 2008 at the Univesidade de Sao Paulo in Ribeirao Preto.

Lecture: Use del Modelaje Farmacocinético-Farmacodinámico para Optimizar el Tratamiento de la Osteoporosis. Given at the XII Congress of the Asociación Centroamericana, Caribe y Países Andinos de Reumatología (ACCA). May 24, 2007.

Report of Professor Emilio Perucca (Italy)

During the last 12 months, Professor Perucca collaborated in many educational activities intended to promote knowledge in clinical pharmacology and to improve use of medicines in epilepsy, his main area of interest, taking also advantage of his position as First Vice-President of the International League against Epilepsy. These include the organization of several residential courses, teaching sessions, symposia and congress sessions in many parts of the world on topics such as clinical pharmacokinetics, drug interactions, clinical drug development, outcome assessment, critical interpretation of drug trials, generic medicines, and rational drug therapy. He also participated in the production of guidelines on the rational application of therapeutic drug of antiepileptic drugs¹ and on the treatment of seizure disorders in people with HIV infection (in preparation). A more challenging, recent initiative has been the coordination of an international effort involving WHO, professional societies, the pharmaceutical industry, and other non-governmental organizations, to provide sustained and affordable access to epilepsy medications in underprivileged African nations. This project is coupled with educational initiatives for local health personnel and for patients, and with a research programme assessing the outcome of these interventions.

1. Patsalos PN, Berry DJ, Bourgeois BF, Cloyd JC, Glauser TA, Johannessen SI, Leppik IE, Tomson T, Perucca E. Antiepileptic drugs-best practice guidelines for therapeutic drug monitoring: A position paper by the subcommission on therapeutic drug monitoring, ILAE Commission on Therapeutic Strategies. *Epilepsia*. 2008 Apr 3 (Epub ahead of print)

Report of Professor Shinichi Kobayashi (Japan)

After the Congress of IUPHAR held in Beijing, the 3rd Japan and China Joint Meeting on Pharmacology and Clinical Pharmacology was held in Aug 23-24, 2007 in Dalian, China. More than 30 Japanese and 100 Chinese participated. The next meeting will be held in March 2009 in Yokohama Japan.

The 2nd Japan-Korea Joint Symposium of CPT was held in Jeju Island, Korea November 11, 2006. The 3rd Symposium has held November 30, 2007 in Utsunomiya Japan. These joint symposiums between Japan and Korea are held on the last day of the annual meeting in each society in every other year. The 4th will be held in December 2008 in Japan.

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The participants to the Annual Meeting of JSCPT have been more than 2000. Interestingly, the participation of co-medical persons, nurses and pharmacists as well as clinical research coordinators is increasing. They are very active as CRC and are very interested in clinical research and trials. JSCPT started the certification examination for the certified CRC four years ago and about 800 CRC have been certified in the last 4 years.

REPORT: SCIENCE FOR HEALTH AND WELL-BEING (ICSU)

This report is a summary of the relevant points from meetings held in Paris and two meetings held in South Africa. I could only attend one ICSU in South Africa. The rest of the information I extracted from Minutes/reports of the meetings.

1. A SHWB Executive Committee was established after an *ad hoc* scoping group was formed to assess the current strengths available to ICSU in relation to Health and Well-Being.
2. The Steering Committee for the initiative *Science for Health and Well-Being* has been constituted. The steering committee comprise of representatives of the different unions affiliated to ICSU of which IUPHAR is one.
3. One recommendation from the executive committee was to establish a coordination mechanism between SHWB activities and health-related activities of ICSU bodies (IUPHAR).

There is still no clear indication of how we as IUPHAR can take part in this initiative.

Five broad areas in SHWB were identified at an ICSU regional meeting held in South Africa in September 2006. More information can be found at www.icsu-africa.org/2icsu. It should be noted that these were areas identified for Africa and the needs of different regions will obviously differ.

The areas for Africa are: (1) Understanding the Scientific Basis of Diseases in Africa, (2) Health Promotion and Disease Prevention, (3) Health Systems Analysis and Development, (4) Traditional/Complimentary and Alternative Medicine and (5) Promotion of Human Well-Being.

From these (2) – vaccines and (4) might be relevant to us.

Compiled by W du Plooy
Representative of the Division of Clinical Pharmacology
19 Feb 2007.

REPORT OF THE SUBCOMMITTEE FOR CLINICAL PHARMACOLOGY IN DEVELOPING COUNTRIES

Background

A major issue is the profound lack of expertise in clinical pharmacology in developing countries. Such expertise is needed to establish sustainable clinical pharmacological research and education of importance for health care in developing countries. Clinical pharmacologists are also needed for cost-effective use of Essential Medicines and for composing national lists of Essential Medicines and establishing clinical guidelines for drug treatment.

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In 2006 at the World Congress in Pharmacology in Beijing Professor Lars L. Gustafsson at Karolinska Institutet, Stockholm, Sweden was appointed chairman of the subcommittee. Three senior colleagues (Professor Chris van Boxtel, Amsterdam, The Netherlands, Professor Folke Sjöqvist, Stockholm, Sweden and Professor Anthony Smith, Newcastle, Australia) accepted to serve as advisors and ambassadors of the subcommittee. Since July 2007 Professor Joan-Ramon Laporte, Barcelona, Spain has joined the group.

Achievements

1. Recruitment of Subcommittee

During the period July 1, 2006 to June 30, 2007 members of the subcommittee were recruited from Africa, Asia and Latin-America:

MD PhD Paul Waako, Chairman Dept. of Pharmacology & Therapeutics, Makerere University, Kampala Uganda (pwaako@med.mak.ac.ug)

MD PhD Philip Sasi, Dept. of Clinical Pharmacology Muhimbili University Health College Dar-es-Salaam Tanzania and Kemri-Wellcome Trust Collaborative Research, Kilifi Centre Kenya (psasi@kilifi.mimcom.net)

Professor Andrew Walubo, Dept. of Pharmacology, University of the Free State, Bloemfontein, South Africa (waluboa.md@mail.uovs.ac.za)

Professor Akin Sowunmi, Dept. of Pharmacology & Therapeutics, University of Ibadan, Nigeria (akinsowunmi@hotmail.com)

Professor Laal Kayody, Chairman Dept. of Clinical Pharmacology, University of Colombo, Sri Lanka (jayAkodyrl@hotmail.com)

Professor and Dean, Grace Gonzaga, Dept. of Clinical Pharmacology, Medical School of the University of Santo Tomo, Manila, The Philippines (gracegarayblasgonzaga@yahoo.com)

Professor Fan-Dian Zeng, Dept. of Pharmacology, Tongji Medical College of Huazhong, University of Science and Technology (fdzeng@163.com)

Professor Mabel Valsevia, Dept. of Clinical Pharmacology, Corrientes University Argentina (jrl@icf.uab.es)

Members of the subcommittee including advisors participating in World Congress in Clinical Pharmacology in Quebec in 2008 will meet and plan for future activities. The chairman is organizing this meeting.

2. Development of a tentative work program for the Subcommittee

A tentative work program for 2007-2012 has been developed with the following aims:

1. Develop and maintain a well-functioning subcommittee in the clinical division of IUPHAR focusing on the support of clinical pharmacological teaching, research and clinical services in drug information, continuous education of rational use of drugs and of drug and therapeutic committees in developing countries.
2. Establish and support networks of research based clinical pharmacological and pharmacotherapeutic experts that communicate between countries and share experience and collaborate in areas like:
 - guideline development and distribution using electronic media and internet
 - drug evaluation
 - clinical trials
 - development and maintenance of therapeutic drug monitoring laboratories.

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3. In cooperation with WHO provide assistance in capacity building of national health systems which benefit from the expertise that clinical pharmacology can offer such as promotion of Rational Use of Drugs (RUD), drug regulation, pharmacovigilance and clinical research
4. Assist in strengthening the teaching of clinical pharmacology in developing countries in collaboration with national academic institutions and scientific associations and support development of relevant course material including textbook in clinical pharmacology.
5. Liaise with other relevant international and national organizations who share the vision to promote RUD and scientifically solid clinical research with high ethical standards, such as World Medical Organization (WMA) and Council of International Organizations of Medical Sciences (CIOMS) and International Network for Rational Use of Drugs (INRUD)

In accordance with the aims and mandate promote collaboration with other relevant organizations, potential possibilities for fundraising and implementation that can assist in strengthening public health oriented clinical pharmacology and its services in developing countries

3. Exploration of options for funding

All costs for meetings and travels have either been covered by funds from WHO or from own research accounts. A budget for travel, meetings and planned activities is needed. Lack of funds has hampered development of our activities. The Subcommittee and in particular the advisors have been active in funding issues and experienced that a number of overseas departments and international organizations are willing to support small and focused activities.

Thus, focused activities in line with instructions of funding and charity organizations can be developed. Long-term supports of general courses, capacity building of a general nature or explorative meetings are generally not supported. The following organizations should be subject to continued discussions on funding of our activities: Overseas departments in Australia, Scandinavia and United Kingdom; Wellcome Trust; World Bank and its affiliated branches (Washington DC, US).

4. Collaboration with World Health Organization (WHO)

4.1. Meeting at WHO Headquarter October 2006

In October 2006 the IUPHAR liaison scientist with WHO, Professor Folke Sjöqvist invited the chairman of the subcommittee to accompany him to a two-days meeting with Professor Lembit Rägo at WHO, Geneva. Professor Rägo is Head of “Quality Assurance and Safety” within the Department of “Medicines Policy and Standards, WHO Geneva, and is nominated by WHO as liaison scientist with IUPHAR.

The meeting covered the following topics:

- 1) Information about recent changes within IUPHAR and WHO
- 2) Mutual information about the progress of ongoing collaboration between IUPHAR and WHO
- 3) Suggested collaboration within the area of Rational Use of Drugs (RUD)
- 4) Other ideas and discussions
- 5) Visibility of IUPHAR at the Headquarter

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Agreed working plans

a. An update of the 1970 WHO recommendations on clinical pharmacology (WHO TRS No 446)

This document from WHO has been fundamental in defining the role of clinical pharmacology in teaching, research and health care delivery across countries. There is now a need to update it. A working plan was developed in a meeting between representatives of WHO and IUPHAR in November 2007. See separate report from Professor Sjöqvist.

b. Mailing list of clinical pharmacologists

Dr Rågo reported that WHO has problems to get access to experts in the area of clinical pharmacology. There is a great need for this competence not only at headquarters but also at the regional offices. It is of particular interest to recruit competent staff in developing countries. Furthermore the organization needs to distribute information on various training courses carried out by WHO or in collaboration with other bodies to stakeholders within the clinical pharmacology community.

IUPHAR and its 60 country associations will provide names of clinical pharmacologists and list their expertise.

c. WHO will provide an input into the workplan of the subcommittee

4.2. Consultation between WHO and IUPHAR in November 2007 in Copenhagen to update the 1970 WHO document on clinical pharmacology

November 23-24 2007 a consultation meeting on the renewal of the WHO clinical pharmacology program was carried out under the leadership of Professors Lembit Rågo and Folke Sjöqvist. Several members of the subcommittee were invited to participate. Due to late notice only Drs Waako and Gustafsson could attend.

Dr Waako was assigned to review the type and extent of clinical pharmacology teaching in undergraduate medical programs across African medical schools.

For a report of the details of the meeting see the report from Professor Sjöqvist.

5. Specific involvement of other international, regional, national or related activities related to clinical pharmacology

a. Present and future PhD-programs in clinical pharmacology in East Africa

Dr Paul Waako at Dept. of Pharmacology & Therapeutics from Makerere University in Kampala Uganda and professor Amos Y Massele at Dept. of Clinical Pharmacology at Muhimbili University in Dar-es-Salaam Tanzania have met their partners at Division of Clinical Pharmacology, Karolinska Institutet Stockholm Sweden to discuss a joint East African PhD-training program in clinical pharmacology in collaboration with Karolinska Institutet. Presently a joint PhD program in clinical pharmacology exists between the Ugandan and Swedish partners with 7 students (1 graduated, 3 will graduate in 2008). The Ugandan program will finish June 30 2009. The idea is to suggest a 8-year PhD program in clinical pharmacology jointly between Tanzania, Uganda, Sweden and potential other partners and in collaboration with IUPHAR. The interest of the donor SIDA/SAREC to support this idea is explored.

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b. Contacts with clinical pharmacologists in Egypt 2006-2008

The chairman of the subcommittee has gained further experience in the conditions of clinical pharmacology in developing countries by participating (in his capacity as professor at the Karolinska Institutet) in a Tempus sponsored 3-years project entitled "Clinical Pharmacology for Rational Drug Prescription in Egypt". The participating countries are Egypt, Denmark and Sweden. The principle investigators are all affiliated with IUPHAR, the late Professor Mohamed Ibrahim, Egypt (after his death in 2007 replaced by Professor Mahmoud Khayyal), Professor Kim Brösen, Denmark and Professors Anders Rane and Folke Sjöqvist, Sweden.

The program has included advanced courses in clinical pharmacology for Egyptian professors in Stockholm, a course in drug utilization research and pharmacoepidemiology in Cairo and a new curriculum for teaching of Egyptian undergraduates in clinical pharmacology. Moreover the concepts and working strategies for DTCs (Drug and Therapeutics Committees) have been subject to workshops in Egypt. For details see separate report from Professor Sjöqvist.

c. Stockholm Challenge on Innovative IT-projects May 18-20, 2008

Stockholm Challenge is a global event to award innovative IT-projects improving quality of life. Since a few years the focus is on applications of importance for developing countries. Lars L. Gustafsson on behalf of the subcommittee is chairman in May 2008 of finalists within the area of health. This involvement of the subcommittee can give contacts of importance for funding ICT facilities in Africa, Asia or Latin-America for the effective dissemination of drug information or for establishment of e-learning tools in developing countries.

d. Consultation on the scientific program of WorldPharma 2010

The subcommittee and its individual members have provided ideas for the scientific program and tentative speakers.

4. Critical evaluation of achievements and priorities for the next two years

No activity that is costly has been started due to lack of funding. Economic resources are the key for the impact of the subcommittee. The subcommittee has already a core group of members from Asia, Africa and Latin-America. The subcommittee has succeeded to develop a preliminary work plan and identified potential donors and got good contacts with WHO and has been consulted and participated in several meetings and postgraduate programs.

During the World Congress in Quebec members of the group will meet physically for the first time and plan core activities for 2008-2010. Funding from IUPHAR will be of importance for our possibilities to gain external funding.

On behalf of the subcommittee

Lars L. Gustafsson, MD, PhD

Professor of clinical pharmacology, Chairman "Subcommittee for Clinical Pharmacology in Developing Countries"

Division of Clinical Pharmacology

Department of Laboratory Medicine

Karolinska Institutet, Stockholm Sweden

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Subcommittee on Pharmacogenetics Report 09.07.2008

Members:

Ingolf Cascorbi, Kiel, Germany (Chairman)
Laurent Bequemont, Paris, France
Kim Brøsen, Odense, Denmark
Ann Daly, Newcastle, UK
Magnus Ingelman-Sundberg, Stockholm, Sweden
Julia Kirchheiner, Ulm, Germany
Vural Özdemir, Montreal, Canada
Mathias Schwab, Stuttgart, Germany
Guilherme Suarez-Kurtz, Rio de Janeiro, Brazil
Toshiyuki Someya, Niigata, Japan
Andrew Somogyi, Adelaide, Australia
Bryn Williams-Jones, Montreal, Canada

The subcommittee on pharmacogenetics was re-established in the summer of 2006 after the IUPHAR2006 conference in Beijing, China. It consists of currently 14 distinguished scientists from different continents, covering expertise from molecular biology to ethical aspect of pharmacogenetics .

Committee Meetings:

A first meeting of the subcommittee took place on the occasion of the ASCPT2007 meeting in Anaheim, CA on March 23, 2007. Since only a few members could attend, some European colleagues met on the second meeting on August 31, 2007 on the occasion of the EACPT2007 congress in Amsterdam, The Netherlands. The next meeting will take place in Sao Paulo on September 29, 2008.

PhD course on Pharmacogenetics Denmark

Prof. Kim Brøsen, Odense, Denmark, invited the subcommittee to co-organize a PhD course on pharmacogenetics to be held in Denmark as an official collaboration.

The course will last from August 26-28, 2008 in Lo-Skolen, Helsingør near Copenhagen, Denmark, up to 25 participants are expected. The course is organized jointly between Danish Clinical Intervention Research Academy (DIRAC) and the International Union of Basic and clinical Pharmacology (IUPHAR) with support of the European Association for Clinical Pharmacology and Therapeutics (EACPT). For further information please visit

<http://www.diracforsk.dk/Kurser/7.htm>

Sao Paulo Research Conference on "Molecular Medicine and Pharmacogenetics

By initiative of Prof. Guilherme Kurtz-Suarez and co-organized by Prof. Paul Vargaftig, an International Symposium on Pharmacogenetics, "Translation into Clinical Practice and Ethnic Diversity" in conjunction with the Sao Paulo Research Conference on Molecular Medicine will take place September 18-20, 2008 in Sao Paulo, Brazil.

IUPHAR will support the meeting with 5,000 US\$ (IUPHAR 2,500 US\$, Clinical Division 2,500 US\$). The subcommittee appreciates this support. Due to the generosity of the local organizers, the sub-committee was able to invite a significant number of distinguished speakers and to create a highly attractive program with four symposia covering advances in pharmacogenomics of cytochrome P540 and transporter and particular the topics pharmacogenomics in clinical practice

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and in special populations For further information please visit
<http://www.eventus.com.br/bioconferences/sprc11/>.

The subcommittee cooperates with the Pacific Rim organization on Clinical Pharmacogenetics (PRACP), a society associated with IUPHAR and with the European Network on Pharmacogenetics, a subcommittee of the European Federation of Pharmaceutical Societies (EUFEPS).

Professor Ingolf Cascorbi (Germany)
Chairman of the Subcommittee on Pharmacogenetics

REPORT OF THE SUB-COMMITTEE OF PAEDIATRIC CLINICAL PHARMACOLOGY

Members:

Gabriel Anabwani, Botswana
Madlen Gazarian, Australia
Kalle Hoppu, Finland EMEA
Gregory L. Kearns, USA
Hidefumi Nakamura, Japan

2007-2008 – Paediatric medicines enter the world stage with a little help from IUPHAR

The year 2007 was pharmacopolitically probably one of the most significant years for children's medicines globally. After the US, where the paediatric legislations were renewed for a 3rd 5-year period in September 2007, the EU joined in as of 26 January 2007 when the new European Union Paediatric Regulation entered into force (a separate report to be provided by prof Hannsjörg Seyberth). The issue of children's medicines was discussed on a global scale by the member states of the WHO at the 60th World Health Assembly held in Geneva, Switzerland 14-23 May 2007. The WHA adopted resolution 60.20 'Better medicines for children' urging member states and requesting the WHO to work to improve the situation of paediatric medicines. On 25th October the First WHO Model List of Essential Medicines for Children was adopted by the 16th WHO Expert Committee on the Selection and Use of Essential Medicines, and on 6 December the WHO launched its global campaign 'Make medicines child size'.

The IUPHAR, its Clinical Pharmacology Division, and the Sub-Committee for Paediatric Clinical Pharmacology have been one of the most important providers of expertise and support for the developments at the WHO starting from providing expert advice to the Finnish government who made the proposal to put children's medicines on the agenda of the WHO, and to several governments preparing their standpoints for the WHO discussions. The 120th session of the WHO Executive Board in January and the 60th World Health Assembly in May in Geneva, Switzerland were attended by the chairman of the IUPHAR Paediatric Sub-Committee as an official delegate representing the IUPHAR and he presented a statement on behalf of the IUPHAR in both meetings. The IUPHAR supported the launch of the 'Make medicines child size' –campaign at Great Ormond Street Children's Hospital in London, UK on 6 December by sending an official representative (chairman of the Paediatric Sub-Committee), and IUPHAR is listed as a supporter of the campaign on its web-site (<http://www.who.int/childmedicines/en/index.html>).

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Less visible, but at least as important has been the expert resources the IUPHAR Paediatric Sub-Committee has been able to provide to the WHO to help in the various activities relating to the children's medicines. The First Meeting of the WHO Subcommittee of the Expert Committee on the Selection and Use of Essential Medicines held in Geneva, 9-13 July 2007 was attended by IUPHAR Paediatric Sub-Committee members Dr Kalle Hoppu and Dr Greg Kerns as invited Member/Technical Advisor. In addition IUPHAR Paediatric Sub-Committee member Dr Madlen Gazarian prepared a document for the WHO Subcommittee meeting. IUPHAR Paediatric Sub-Committee members Dr Kalle Hoppu, Dr Greg Kerns and Dr Hidefumi Nakamura attended the WHO Informal Consultation on Research Priorities for Children's Medicines –meeting on 23 October 2007 and the 16th Expert Committee on the Selection and Use of Essential Medicines on 24-25 October 2007 in Geneva, Switzerland as invited Member/Technical Advisors. The WHO asked the IUPHAR Paediatric Sub-Committee to find a presenter on paediatric clinical pharmacology topics for the 1st Training workshop on Pharmaceutical Development with focus on Paediatric Formulations held in Cape Town, SA 16- 20 April 2007. The workshop has since been repeated in Tallinn Estonia on 15 - 19 October 2007 and in Mumbai, India on 28 April - 2 May 2008. The presentations were made by Dr Kalle Hoppu. On the initiative and under the leadership of the IUPHAR Paediatric Sub-Committee a group consisting of representatives of IUPAHR, WHO, UNICEF, NIH, and Institute of Pharmaceutical Innovation, Bradford UK is currently working to promote innovative paediatric formulations.

In its work for children's medicines in the global setting, the IUPHAR Paediatric Sub-Committee has collaborated with IPA (International Pediatric Association). Dr Kalle Hoppu was invited to give a presentation at the IPA 25th International Congress of Pediatrics held August 25-30, 2007 in Athens, Greece in the symposium 'Better medicines for children at country level throughout the world'. Dr Hoppu was also appointed by the IPA as a Technical Advisor in the area of Better Medicines for Children in April 2008, which will provide an unprecedented opportunity for IUPHAR to work together with IPA globally for paediatric medicines and therapeutics.

The IUPHAR Paediatric Sub-Committee together with the new IUPHAR member ESDP submitted a proposal for a focused stream in paediatric clinical pharmacology for consideration by the program committee for WorldPharma 2010.

The IUPHAR Paediatric Sub-Committee has together with Dr Shinya Ito from Toronto, Canada and Dr Emilio Sanz from Tenerife, Spain been working since 2007 to set up a Paediatric Pharmacology e-learning Pilot Course, primarily aimed at middle to low income country participants which is planned to be ready for enrolment within a year.

Although the term of the Paediatric Sub-Committee expires at the CPT2008 the activities to assist the WHO will continue. Dr Kalle Hoppu and Dr Greg Kerns will participate as invited experts in an expert meeting on paediatric TB medicines to be held in Geneva, Switzerland 8-9 July 2008. Current Sub-Committee members have also been invited to the 2nd Meeting of the WHO Subcommittee of the Expert Committee on the Selection and Use of Essential Medicines to be held in Geneva, end of September 2008.

Professor Kalle Hoppu (Finland)
Chairman of the Sub-Committee for Paediatric Clinical Pharmacology

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REPORT ON THE COLLABORATION WITH WHO 2006-2008

The most recent plans for the collaboration between IUPHAR and WHO were worked out at a meeting in Geneva in October 2006 (see attachment). The meeting was organized by the two liaison scientists between WHO (Dr Lembit Rägo) and IUPHAR (Prof. Folke Sjöqvist). The recently elected chairman (Prof. Lars Gustafsson) of the Subcommittee for clinical pharmacology in developing countries within the Clinical Division, IUPHAR, accompanied Prof. Sjöqvist to this meeting.

Activities during 2007-2008

1. Core curriculum in Clinical Pharmacology (CP) and renewal of WHO Technical Report Series No. 446 (TRS 446).

The highest priorities for the work during 2007-2008 have been to develop a core curriculum in CP and to renew the 1970 WHO recommendations in clinical pharmacology (TRS 446). For these purposes a meeting was arranged in November 2007 in Copenhagen with participants from WHO and the Clinical Division, IUPHAR, particularly representatives of its Subcommittee for clinical pharmacology in developing countries. The meeting was supported by grants from WHO, IUPHAR and the Karolinska Institutet. Prof. Kim Brøsen volunteered as local host for the meeting.

As a concrete result of the deliberations the following persons were asked to participate as editor and authors of the different chapters in the revised recommendations about CP.

Prof. Michael Orme, UK, as general editor,
Prof. Folke Sjöqvist, Sweden, as author of the chapters on Definition and History of CP,
Prof. Michael Rawlins, UK, as author of the chapter Global Medicines Scene,
Prof. Kim Brøsen, Denmark, as author of the chapter on The role of CP in research,
Prof. Simon Maxwell, UK, as author of the chapter on The role of CP in teaching,
Prof. Lars Gustafsson, Sweden, as author of the chapter on The role of CP in patient care,
Prof. Donald Birkett, Australia, as author of The role of CP in industry,
Prof. Lembit Rägo, Geneva, as author of The role of CP in governments.

Other chapters will include the organization of CP (Kim Brøsen), the relationships of clinical pharmacologists to other drug experts (Folke Sjöqvist), training (Paul Waako, Uganda), the merging roles of CP (Petra Thürmann and Ingolf Cascorbi, Germany) and the contributions of CP to global public health (Prof. Anthony Smith, Australia).

Two addenda are planned. The first will be a core curriculum in clinical pharmacology for undergraduate training (Prof. Simon Maxwell) and the second a model curriculum for specialization in clinical pharmacology (Prof. Kim Brøsen and Prof. Andrew Walubo, South Africa).

All authors have later accepted to participate in the project. The next meeting of key persons will be arranged in Stockholm, Sept. 28-29, in connection with the board meeting of EACPT. This meeting will be supported by WHO and grants from IUPHAR, EACPT and The Swedish Foundation for Clinical Pharmacology and Therapeutics.

The final draft will be submitted for revision to the Clinical Pharmacology Division in good time before World Pharma in Copenhagen in 2010.

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2. Supporting the development of clinical pharmacology in Egypt.

Between 2005 and 2008 the TEMPUS organisation within EU has supported a project entitled “Clinical Pharmacology for Rational Drug Prescription in Egypt”. The project was initiated by Prof. Mohamed Ibrahim, Menoufia and supported by Prof. Mohamed Khayyal, Cairo, member of the IUPHAR executive committee. Through the two professors TEMPUS asked Professor Folke Sjöqvist at the Karolinska Institutet in Stockholm to organize a Danish-Swedish-Egyptian task force to assist Egypt in its ambition to develop clinical pharmacology. Denmark has been represented by Prof. Kim Brøsen, Odense, Sweden by Professors Sjöqvist, Anders Rane, Lars Gustafsson and Ulf Bergman, and Egypt by Professor Ibrahim and Prof. Mahmoud Khayyal. Thirteen Egyptian universities have participated in the project, which has had three major aims:

1. To develop clinical pharmacology in the undergraduate teaching of medical students and in the continued training of physicians.
2. To introduce the concept of Drug and Therapeutics committees (DTC:s) guiding drug selection and rational drug use (RUD).
3. To introduce drug utilization (DU) studies and pharmacoepidemiology as bases for RUD.

The program has included bilateral visits to the participating countries, advanced courses in clinical pharmacology, initiation of research projects in Egypt and introduction of clinical pharmacology in the teaching of medical students in Egypt.

The advanced courses in CP have focused on methods and principles in drug utilization research and principles in drug evaluation. The former course was held in Cairo in May 2007 in collaboration with the WHO Collaborating center for drug statistics in Oslo (Head Dr Marit Rønning) and the WHO Collaborating Center for Drug Utilization Research and Clinical Pharmacological Services in Stockholm. At this course about 25 Egyptian physicians and pharmacists were examined and approved. Programs for monitoring drug use have been introduced in two university hospitals in Cairo.

One week courses in drug evaluation have been given both in Stockholm and Cairo for Egyptian professors in pharmacology. In October 2007 an intense research oriented course was held in Stockholm for five selected Egyptian professors. Rating scales for evaluation of the quality of clinical drug trials have been introduced.

In June 2008 a final Egyptian-Swedish workshop on teaching methods in clinical pharmacology was held in Cairo at Ain Shams University under the chairmanship of Prof. Ahmed M. Abdel-Tawab and 20 participating Egyptian teachers. Drs Ylva Böttiger and Georgios Panagiotidis were responsible for the European input.

The project has not only had considerable effects on Egyptian pharmacology but has also awakened an interest in other Arabic countries such as Jordan.

Eastern Mediterranean office of WHO (EMRO) in Cairo has participated in several of the meetings in Cairo and the project leaders have had continuous contacts with and paid visits to this office, particularly Dr. Zafar Mirza and the regional director Dr. Abell Aziz Saleh. Dr Mirza considers that this program is suitable for introducing the principles of RUD both in health care institutions and academic medicine in the EMRO region.

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In the midst of these activities the Egyptian coordinator Prof. Mohamed Ibrahim, a member of the clinical division IUPHAR, died suddenly and was replaced by Prof. Mahmoud Khayyal. The collaboration is expected to continue as an academic effort after the support from Tempus has ended in June 2008.

3. Various activities

During my tenure I have continuously supported IUPHAR related activities in the developing world when consulted. An important example is continued support of projects in paediatric clinical pharmacology and drug use in children guided by Prof. Kalle Hoppu, Helsinki, Finland. Contributions have also been made to the WHO Drug Information Journal, edited by Dr. Răgo.

4. I am willing to continue my work until the integrated pharmacology-clinical pharmacology meeting (World Pharma) takes place in Copenhagen in 2010.

Stockholm in June 2008

Folke Sjöqvist, MD, PhD, FRCP

Professor emeritus in clinical pharmacology

Karolinska Institutet

CLINICAL DIVISION OF IUPHAR

The meeting of the 2004-2008 Council of the Clinical Division of IUPHAR will be held on Monday July the 28th at 9.45 – 12.15 in Room 304A of the Convention Center.

Agenda

1. Apologies for absence
 2. Adoption of the agenda
 3. Chairman's report
 4. Vice chairman's report
 5. Treasurer's report
 6. New projects
 7. Suggestions regarding members of the new council, 2004-2008
 8. Report from subcommittees
 9. Collaboration with WHO
 10. Report about CPT2008
 11. Report about IUPHAR/CPT 2010
 12. Report about IUPHAR/CPT 2014
 13. Other business
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CLINICAL DIVISION OF IUPHAR

The General Assembly of the Clinical Division of IUPHAR will take place on Wednesday July the 30th at 12.00 -14.00 in Room 202 of the Convention Center.

Agenda

1. Adoption of the agenda
2. In memoriam
3. Chairman's report
4. Vice chairman's report
5. Secretary's report
6. Report of the Sub-Committees
7. Election of the council 2004-2008
8. Future activities:
 - * IUPHAR/CPT 2010 in Copenhagen
 - * IUPHAR/CPT 2014 in Cape Town
9. Other business

CLINICAL DIVISION OF IUPHAR

The meeting of the 2008-2014 Council of the Clinical Division of IUPHAR will be held on Thursday July the 31st at 9.45 – 12.15 in Room 304A of the Convention Center

Agenda

1. Apologies for absence
2. Adoption of the agenda
3. Introduction of new members
4. Functioning of the Council
5. Summary of projects undergoing
6. New projects
7. IUPHAR/CPT 2010
8. IUPHAR/CPT 2014
9. Other business

Respectfully submitted,
Patrick du Souich
Chairman
Clinical Pharmacology Division
IUPHAR

**INFORMAL JOINT MEETING OF WHO AND IUPHAR ON CLINICAL
PHARMACOLOGY AND RELATED ISSUES**

23-24 November 2007, Copenhagen (WHO EURO premises)

Meeting report

The objective of the meeting was to review with experts from IUPHAR the WHO document on Clinical Pharmacology (WHO TRS No 446 from 1970) with the aim of developing an action plan for its update. Another objective of the meeting was to explore potential areas of cooperation between IUPHAR and WHO, especially providing expertise for proper planning of clinical trials of medicines of public health importance in developing countries and building regulatory capacity (assessment of efficacy and safety, pharmacovigilance) in these countries.

All participants agreed that the document from 1970 had played an important role in its time. It stimulated the development of clinical pharmacology in many countries and was used as a reference document in order to promote teaching of clinical pharmacology as a discipline and profession, promoting the rational use of drugs (RUD) in different societies. The WHO document also promoted inclusion of clinical pharmacology in undergraduate training of medical doctors. This was seen as important for providing medical doctors with the knowledge and skills necessary for implementing principles of RUD. It was also mentioned that several clinical pharmacologists have played important roles in developing drug policies and promoting rational use of medicines on national and Global levels.

Since 1970 many important developments of clinical pharmacology have taken place. Although the document was considered to still be of great value it was agreed that it would need to be updated taking into consideration all the changes that have occurred both in clinical pharmacology as a scientific discipline and in the environment in which it operates. It was agreed that minor updating is not sufficient and that the whole document ought to be re-written. Further discussions were held on how to update the document and what it should contain. As a major change from the previous document it was decided that it should also have model core curricula attached both for undergraduate training and for postgraduate specialist training. The latter task was considered to be more difficult due to international variations in how specialist training is carried out. However, it was concluded that recognizing and considering the potential differences in educational systems it is still possible

to provide a useful model core curriculum that might help to strengthen existing specialist training programs and initiating new ones.

Detailed discussions followed about the content of the new edition of the TRS 446.

The need for a *general editor* was discussed and it was decided that the General Editor's role will be offered to Professor Michael Orme, who has subsequently accepted the task.

Regarding the **format** of the document it was decided that it should have an Executive summary (1 page) and not exceed 50 pages (double spaced).

It was discussed and agreed that the document should have the following Chapters (the proposed author and length of each individual Chapter are given in brackets).

1. **Definition of Clinical Pharmacology and Therapeutics** (Professor Folke Sjöqvist – 0.5 page)
2. **History of Clinical Pharmacology** (Professor Folke Sjöqvist – 2.5 pages)
3. **Global Medicines Scene** (Professor Michael Rawlins – 4 pages)

Drug Scene Globally is changing and the following issues were pointed out during the discussions. Costs for new drug research and development are increasing. Non-affordable drugs (such as new generation of HIV/AIDS to fight emerging resistance) may challenge Global public health needs. Increasing complexity and safety concerns of new biological medicines. Changes in the disease pattern and turning focus from communicable diseases as the biggest killer to non-communicable diseases. Unavailability of medicines continued to be a problem. Unintended events and increased complexity of new medicines create new challenges - increased use of fixed dose combination (FDC) medicines; effects of Direct to Consumer (DTC) marketing; weak health care systems and service delivery in many resource poor/limited countries; changing Global regulatory environment; market forces contradicting health care needs and “market failure”; role of Public Private Partnerships (PPPs) in research and development for medicines for which there is no market; continuing irrational use of medicines in all of its forms including polypharmacy; the ADR problems appear to increase.

4. **Roles of Clinical Pharmacology**

4.1. *Research* (Professor Kim Brösen – 5 pages)

4.1.1. Biomedical

4.1.2. Clinical

4.1.3. Society

4.2. *Teaching* (Professor Simon Maxwell – 4 pages)

4.2.2. Undergraduate

4.2.3. Postgraduate

4.2.4. Continuous education

4.3. *Patient care* (Professor Lars L. Gustafsson – 5 pages)

4.3.1 Individual

4.3.2. Special Populations and Diseases

4.3.3. Society level – clinical pharmacologists as experts to address issues raised by politicians. Pharmacoepidemiology, pharmacovigilance, drug utilization, drug and therapeutic committees, ethics committees (reference to WHO relevant documents to be made)

4.4. *Industry* (Professor Donald Birkett – 4 pages)

Role of clinical pharmacologists in research and development including new therapies.

4.5. *Governments* (Dr. Lembit Rägo – 4 pages)

Regulatory authorities, insurance – drug reimbursement boards, national drug policies, input for creating scientifically useful electronic patient health records, electronic prescription databases and other databases.

5. **Organization** (Professor Kim Brösen – 3 pages)

6. **Relationship to other drug experts** (Professor Folke Sjöqvist – 3 pages)

- Clinicians (pharmacotherapeutic experts)

- Pharmacists

- Drug analytical expertise

7. **Training** (Professor Paul Waako – 2 pages)
 - to be considered in conjunction with addenda I and II; to be used as an introduction to the two addenda

8. **Emerging Roles of CPT** (Professor Petra Thürmann; Professor Ingolf Cascorbi – 3 pages)
 - Biologicals and biosimilars
 - Use of new types of data, drug informatics

9. **The Contribution of Clinical Pharmacology to the Global Public Health** (Professor Anthony Smith; with input from Professor Lars L Gustafsson's group of experts from developing countries in terms of bullet points – 5 pages)

10. **Conclusion** (General Editor – 2 pages)

Addenda.

Addendum I. Model Core Curriculum in Clinical Pharmacology for Undergraduate Training

Addendum II. Model Curriculum for Specialization in Clinical Pharmacology

General concluding remarks.

It was pointed out that authors of different chapters should not only describe past and present, but also have a future vision.

The drafts will be distributed not only to all authors but also to all working group members including those who for various reasons could not attend the meeting.

The following proposals were made regarding the Addenda.

Addendum I: Offering drafting to Professor Simon Maxwell (other valuable resource persons: David Nierenberg, USA and Ylva Böttiger, Sweden). A small group meeting of key persons for this topic will meet in Stockholm 28-29 September, 2008.

Addendum II: Model Curriculum for Specialization in Clinical Pharmacology Offering
drafting to Professors Kim Brösen and Andrew Walubo.

