Report 2006-2007 of the Clinical 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 Division has expanded his activities by create two Sub-Committees, one on "Pharmacogenetics" and the second on "Drug development, clinical trials and drug regulation".

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 Thuermann (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)

1. REPORT OF THE TREASURER

To be distributed during the meeting

2. DESCRIPTION OF THE SUBCOMMITTEE FOR PHARMACOGENETICS

Aims and scopes

Pharmacotherapy optimization through individual drug therapy is one of the major goals of clinical medicine. Over the last decades it has been clearly shown that genetics play a significant role in the pharmacokinetics of drugs and there is an increasing understanding of the genetic background among individuals and ethnic groups with regard to drug efficacy and response. Therefore, pharmacogenetics has developed into one of the most important subfields of clinical pharmacology.

The new subcommittee on pharmacogenetics, established in the summer of 2006, consists of a number of distinguished scientists from different continents. The subcommittee will hold annual meetings to:

- Promote exchange of pharmacogenetic knowledge by organization of symposia and workshops in the field of pharmacogenetics and –genomics
- Evaluate the clinical impact of pharmacogenetics
- Develop a drug-related pharmacogenetic database
- Create a population based "biobank" to conduct translational research in clinical pharmacogenomics
- Establish international collaborative clinical studies to investigate the benefits of pharmacogenetics.

The subcommittee cooperates with the Pacific Rim organization on Clinical Pharmacogenetics (PRACP), a society associated with IUPHAR.

A satellite meeting on pharmacogenetics has been proposed for the CPT2008 congress in Quebec.

Members

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3. REPORT ON CONGRESSES

A. The 2nd Korea-Japan Joint Symposium of Clinical Pharmacology and Therapeutics

The 2nd Korea-Japan Joint Symposium of Clinical Pharmacology and Therapeutics was held in the beautiful Jeju Island, Korea on November 11, 2006. The symposium was organized by both the Korean Society for Clinical Pharmacology and Therapeutics and the Japanese Society of Clinical Pharmacology and Therapeutics. Prof. Hyung-Keun Roh (Korea) took the chair of the organizing committee and Prof. Min Soo Park (Korea) corresponded with Prof. Eiji Uchida (Japan) in preparation for the 2nd joint symposium.

The event provided the opportunity to present common interests on global clinical trials between two countries. The program included 10 speakers and 4 chairs from both countries and consisted of two sessions for "Infrastructure for Global Trials" and "New Technology Development and Experiences". The topics including regulations of clinical trials in both Japan and Korea, education of professionals in clinical trials, clinical trials centers network, biomarkers, modeling/simulation and pharmacogenetics/-genomics were presented and discussed.

The joint symposium was attended by about 120 people and lasted for four hours at the end of the 2006 annual conference of Korean Society for Clinical Pharmacology and Therapeutics. In order to promote mutual friendship among participants from both countries, there was a small party with music after the symposium. Since both societies for clinical pharmacology agreed that Japan and Korea host the symposium every year alternately, the 3rd joint symposium will be held in Japan in November 2007.

There were some discussions about expanding our activities by increasing attendance at the joint symposium. Prof. Shinichi Kobayashi (Japan) suggested giving young researchers opportunity to present their works in this joint symposium because it is needed to let young people take interest in the field of clinical pharmacology for the future. Both countries will put a great deal of effort into the joint symposium for continuation and growth, and the joint symposium will be better if there is support from IUPHAR.

Report prepared by Prof. Hyung-Keun Roh (Korea)

B. Progress of 9th World Conference in Clinical Pharmacology and Therapeutics - CPT2008

CPT2008 will be held at the Convention Center of the city of Québec from the 27th of July to the 1st of August, 2008. (see http://www.cpt2008.com)
The preliminary program includes nine plenary lectures and 36 symposia. Each symposium will last 2.5 hours and there will be 4-5 speakers.
As per Satellite meetings, the potential ones are:

- Paediatric
- Education
- Bio Equipment
- Pharmacogenetics
- Hypertension
- Natural Health Products

	Monday	Tuesday	Wednesday	Thursday	Friday
PL	I. Progress in cancer treatment: molecular targets* USA	III. Innovations in the treatment of dislipemias* CAN	V. Antioxidants: disease prevention, therapeutic agents or the epitome of usefulness? SINGAPORE	VII. Prescribing for pregnant women: The facts and the fears* CAN	IX. Contribution of pharmacogenomics to improved outcome of drug therapy: Focus on the latest developments* USA
Stream #1 New therap.	1. New anticancer drugs and cancer treatment in 21st century JAPAN	9. ImmunopharmacologyThe TNF-alpha antagonists – lessons learned in immunopharmacology UK	17. Targeting protein kinase signalling: clinical relevancy USA	25. Substance addiction and abuse* CAN	33. Prevention of left ventricular hypertrophy (LVH) and cardiac remodelling: beyond blood pressure reduction* SWED
Stream #2 Fundam. to CP	2. Drug Hypersensitivity: Insights into Pathophysiology and Therapy* UK/USA	10. Current status of Clinical Pharmacology based on genome science JAPAN	18. Safety and Efficacy of Herbal Medicines* CAN	26. Pharmacogenetic epidemiology* SWEDEN	34. Imaging as Biomarker: Optimization for Evaluation of Drug Effect JAPAN
Stream #3 Med & Soc	3. Drugs in sport* USA	11. Pharmacology Teaching in the Undergraduate Medical Curriculum: Is it necessary?* UK	19. Academic drug trials – an endangered species due to bureaucracy and costs?* SWEDEN/CAN	27. Cardiovascular risks management. Are we going in the right direction? USA	35. Better access to essential medicines: update on recent developments* WHO
Stream #4 Spe. popul.	4. Advances in Paediatric Clinical Pharmacology* UK/CAN	12. Drug utilisation in ICUs CAN	20. Drugs in pregnancy and lactation. For the better drug information. JAPAN	28. Geriatric pharmacology* UK	36. Mechanism-based PK-PD modeling* HOLLAND
PL	II. Drug Delivery Systems* CAN	IV.Innovations in analgesia* BRAZIL	VI. Clinical pharmacology of malaria – the number one public health problem UK	VIII. Public health implications of research utilizing pharmacovigilance* databases NEW ZEALAND	
Stream #1 New therap.	5. New insights in the treatment of pain* UK/CAN	13. Eicosanoid receptors in disease: targets for therapy* USA/CAN	21. Endothelial dysfunction as a therapeutic target* SPAIN	29. Clinical Pharmacology and Therapeutic Role of New Generation Antiepileptic Drugs* ITALY/ISRAEL	
Stream #2 Fundam. to CP	6. CNS Drug Metabolism and Transporters: Potential Roles in Clinical Pharmacology* CAN/USA	14. Serotonin Receptors: Pharmacogenetics and Clinical Implications* GERMANY/CAN	22. Clinical relevance of nitric oxide and its inhibitors* UK/BELGIUM	30. FDA/EMEA	
Stream #3 Med & Soc	7. Towards Quality Use of Medicines* WHO	15. Traditional Chinese Medicine: A global approach* CHINA	23. The use of quality indicators in therapeutics. Does it improve drug prescribing?* SWED/CAN	31. Ethnical differences in drug therapy* GERMANY	
Stream #4 Spe. popul.	8. The Ethics of Drug Research* CAN/UK	16. Pharmacology Aspects of HIV Treatment* CAN/UK	24. Pharmacovigilance meets pharmacoepidemiology ITALY	32. Better medicines for children* FINLAND	

4. REPORT ON TEACHING ACTIVITIES

Professor Gilberto Castañeda Hernández gave a course on Modelaje Farmacocinético-Farmacodinámico at the Universidad de Ribeirao Preto en Sao Paulo, Brasil, the 17-18 of October 2006. Students and professors from the Medical and the Pharmacy Schools attended the course. This activity was held as prior the 38th Congresso Brasileiro de Farmacologia.

5. REPORT OF ACTIVITIES WITH ICSU

Report on Science For Health And Well-Being

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.

A. 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.

B. The Steering Committee for the initiative *Science for Health and Well-Being* has been constituted. The steering comprise of representatives of the different unions affiliated to ICSU of which IUPHAR is one.

C. 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.

6. REPORT OF THE SUB-COMMITTEE OF PAEDIATRIC CLINICAL PHARMACOLOGY

2006 – an exceptional year of activity for international paediatric clinical pharmacology

On March 6, 2006 a group of paediatric clinical pharmacologists, paediatric pharmacist and paediatricians from different parts of the world assembled in Baltimore for the NICHD Global Consortium on Pediatric Pharmacology Meeting to discuss international collaboration. Both

issues relating to collaboration between scientist working in the developed and measures to promote paediatric pharmacology in the developing world were on the agenda.

The Biannual Congress of ESDP (European Society for Developmental Perinatal & Paediatric Pharmacology) held in Stockholm, Sweden June 14-17, 2006. At the end of this very successful scientific congres, a special 'Plenary dialogue about Global Pediatric Pharmacology' was held in commemoration of Lars Boréus, one of the pioneers of paediatric clinical pharmacology and President of ESDP 1990-1992.

Preceding the 15th World Congress of Pharmacology, a Satellite Symposium 'International Challenges in Pediatric Pharmacology' was held in Shanghai, China June 28 – 30, 2006. The symposium was followed by an IPA (International Pediatric Association)/ IUPHAR workshop "Essential Medicines For Children" in Shanghai on July 1, 2006. This gathering of a group of paediatricians, clinical pharmacologists and pharmacists from all over the world, with representatives of the IPA and the Paediatric Sub-Committee of the IUPHAR Clinical Pharmacology Division, made a decision to found an International Alliance for Better Medicines for Children.

The program of the 15th IUPHAR World Congress of Pharmacology Beijing China, July 2-7, 2006 included a symposium 'Better Medicines for Children', organised by the Paediatric Sub-Committee of the IUPHAR Clinical Pharmacology Division presented the current active developments in this field to the international pharmacological community.

In Geneva a Joint WHO and UNICEF convened a meeting 'Consultation On Paediatric Essential Medicines' on August 9-10, 2006. The meeting marked an important activation of interest of the WHO in children's medicines. The chairman of the Paediatric Sub-Committee attended the meeting representing the IUPHAR Clinical Pharmacology Division.

2007 – intense activity for international paediatric clinical pharmacology is continuing

On 26 January the new European Union Paediatric Regulation entered into force. It will bring a new level of activity to research on children's medicines to Europe, already visible in the form of national networks for investigation of paediatric medicines that have been set up or are in preparation in many European countries.

The 120th session of the WHO Executive Board (EB) adopted on 29 January a draft resolution on 'Better medicines for children', which will be put on the agenda of the World Health Assembly (WHA). The chairman of the Paediatric Sub-Committee attended the meeting in Geneva representing the IUPHAR and made a presentation to the EB.

of The WHO Expert Committee on the Selection and Use of Essential Medicines. Will meet in Geneva 19-24 March 2007 to discuss among other topics the establishment of a formal Expert sub-committee on the selection and use of essential medicines for children. The Paediatric Sub-Committee is providing assistance to the WHO for the preparation of the background documents for the establishment and work of the WHO sub-committee. We are also currently helping the WHO to find paediatric clinical pharmacology experts for other WHO meetings and courses.

The Paediatric Sub-Committee of the IUPHAR Clinical Pharmacology Division will continue to be actively involved in the developments.

Kalle Hoppu
Chairman of the Sub-Committee for Paediatric Clinical Pharmacology

7. COLLABORATION WITH WHO

a. Report of Folke Sjöqvist, representative of IUPHAR

List of activities that are going to be undertaken.
Activity 1:
Areas of collaboration according to letters of intent by Dr. Hans V. Hogerzeil, August 23, 2004, and Dr. Folke Sjöqvist, May 19, 2003.

1. Renewal/update of the 1970 WHO statement on clinical pharmacology (in progress).
2. Involvement of IUPHAR members in the preparation of WHO Drug Information (example Wettermark et al, WHO Drug Information, 2006;20:78-85)
3. Further development of a core curriculum in clinical pharmacology (rational use of drugs) for undergraduate students (in progress)
4. Prepare a mailing list of all individual clinical pharmacologists in the various IUPHAR country associations for joint approaches by WHO and IUPHAR to promote the use of WHO core materials.

Activity 2:
Rational use of drugs in children: The division of clinical pharmacology, IUPHAR has a subcommittee in Pediatric clinical pharmacology, presently headed by Dr. Kalle Hoppu, Helsinki, Finland (e-mail: kalle.hoppu@fimnet.fi). Dr. Hoppu has been in touch with Dr. Lembit Rägo and Assoc. Director General Howard Zucker recently and been informed that WHO is eager to push pediatric medicines agenda forward.
In addition our two former chairmen of this subcommittee, prof. Hannsjörg Seyberth and prof. Anders Rane, have recently been in consultation with WHO (Dr. Hans Hogerzeil) regarding the new EU legislation about drug evaluation in children.
Through this subcommittee IUPHAR ha a unique overview of pediatricians – pharmacologists in the field. Dr Hoppu was IUPHAR-representative at the joint WHO-UNICEF consultations on Pediatric Essential Medicines, Aug 9-10, 2006 in Geneva.

Activity 3:
Projects aimed to promote the rational use of drugs in less developed countries (examples):

1. Swedish-Danish-Egyptian collaboration “Clinical pharmacology for rational use of drugs in Egypt” initiated by prof. Mohamed Ibrahim Mohamed and Mahmoud Khayyal, Egypt and with seeding money fron IUPHAR. Now supported by the EU Tempus program. Formation of drugs and therapeutic committees in major Egyptian hospitals. Partly in collaboration with the WHO Regional Office in Cairo. Great interests from other Arabic countries.
2. Initiative of prof. Anthony Smith, Newcastle, Australia and dr. Kris Weerasuriya, WHO Regional Office, Delhi to support RUD in Sri Lanka (workshop with teachers in pharmacology and therapeutics).

3. Participation by experts in the EDM program at HQ.
4. Ensuring that international Congresses in pharmacology devote significant time to problems caused by irrational use of drugs, particularly in emerging counties (example CPT 08, Quebec).

Activity 4:
Initiation of drug utilization research and formation of DTC:s (drugs and therapeutic committees). IUPHAR experts (prof. Don Birkett, Australia, prof. Folke Sjöqvist, Sweden) responsible for the WHO manual Introduction to Drug Utilization Research and for the drug utilization chapter in IUPHAR publication Methods in Clinical Pharmacology (ed. by Patrick du Souich et al) 2004.
Initiation of DU statistics and applications in Egypt (poster 15th World Congress of Pharmacology, Beijing, 2006).
Formation of DTC:s in Egypt (F. Sjöqvist et al, WHO Drug Information 16(3), 2007-213, 2002).

b. Report on 120th Session of the WHO Executive Board
Geneva, Switzerland, 22-30 January 2007

The undersigned had the opportunity to attend the 120th session of the WHO Executive Board (EB) as a representative of the IUPHAR, a NGO in official relationship with the WHO. On the agenda, under technical and health matters, item (4.9) 'Progress in the rational use of medicines, including better medicines for children' was of special interest to the clinical pharmacology community. The strange name is a result of combining what are essentially two issues under one heading. 'Progress in the rational use of medicines' was originally debated at the118th session of the EB, but deferred to its 120th session as it was not possible to agree on the text. 'Better medicines for children' was proposed by a Member State (Finland) November 2006. Both items had separate reports by the WHO secretariat. The two items were combined because for some reason the WHO has so far refused to have more than one agenda point concerning medicines on the agenda of the EB or World Health Assembly (WHA).

On Monday, 22 January, after the opening of the EB meeting, the new Director-general of the WHO Dr Margaret Chan, on her 19th day in office, gave her first report to the EB..

'Progress in the rational use of medicines, including better medicines for children' was scheduled for discussion on 24 January. The WHO allows NGOs in official relationship to make a statement to the EB. The request to speak has to be made at least 24 hours before the opening of the meeting at which the agenda item is expected to be discussed. The request has to be accompanied by a copy of the statement to be made, so I hade to file the request and statement (enclosed) on 23 January.

The discussion on agenda point 4.9 began late in the afternoon on 24 January. Most of the EB members (Portugal, Jamaica, Libya, Bhutan, Thailand, Sri Lanka, Denmark, Japan, Australia, USA, Rwanda, Tonga, China, Brazil, Kenya, Lesotho, Liberia, Bolivia, Salvador, and Namibia), some Member States not represented on the EB (Russia, Finland, Sweden, Malawi), Intergovernmental Organisations (European union, International Narcotics Control Board) and Nongovernmental Organisations (IFPM, FIP, IPA, and IUPHAR) made a statement so the discussions continued next day. On Thursday 25 January after making the statement on behalf of IUPHAR as one of the last speakers, I had to leave for another meeting in London, and was not able to follow the end of the discussions. A drafting group was formed and met on 27 and 28 January to compile the various comments made by the EB members into a draft resolution.

'Better medicines for children' initiative received broad support. One of the discussion items was whether 'Rational Use of Medicines' and 'Better Medicines for Children' should be combined into one resolution or kept separate. The drafting group agreed on separate resolutions, which can be considered a win for the children's issue. The final resolutions were adopted on the last day of the EB meeting, Monday 29 January. The final draft resolution on 'Better medicines for children' (name changed from the WHO Secretariat's suggestion 'Better Essential Medicines for Children') was strengthened over the original. The two items which in the preparatory discussions we considered necessary additions were included in the draft resolution: item 1.6. and especially 2.2 "to ensure that all relevant WHO programmes, including but not limited to that on essential medicines, contribute to making safe and effective medicines as widely available for children as for adults." The draft resolution can be considered an acceptable compromise and a good starting point. The resolution for 'Rational Use of Medicines' was also modified, in my opinion slightly weakened.

The topics should now appear on the agenda of the 60th World Health Assembly to be held in Geneva 14-23 May 2007. It will be important that the WHA agrees on a good program for 'Better Medicines for Children' and allocates appropriate funding in its May meeting. Funding will be difficult as especially US and Japan oppose any increase to the WHO budget.

It is clear that the informal collaboration of paediatric clinical pharmacologists from different parts of the world, serving as experts for their governments preparing for the WHO EB meeting, played a significant role in getting the 'Better medicines for children' –initiative adopted successfully, and in a strengthened form. An even more determined effort is needed to work for a good resolution, program and sufficient funding to be adopted by the World Health Assembly. Once on the agenda of the WHA. children's medicines will be a topic for discussion for the governments of all 193 Member States of the WHO, a unique opportunity.

Kalle Hoppu
Chairman of the Sub-Committee for Paediatric Clinical Pharmacology

Respectfully submitted
Patrick du Souich
Chairman
Clinical Division
IUPHAR

CLINICAL PHARMACOLOGY DIVISION
OFFICERS AND MEMBERS OF THE COUNCIL

Chairman
Patrick du Souich one term of 4 years completed in 2008 – I can be renewed if the members of the Council and IUPHAR wishes so

Vice-Chairman
Don Birkett one term of 4 years completed in 2008 – he can be renewed if the members of the Council and IUPHAR wishes so

Secretary
Kim Brøsen 8 years – needs to be replaced

Treasurer
Petra Thuermann one term of 4 years completed in 2008 – she can be renewed if the members of the Council and IUPHAR wishes so

Councillors
Darrell R. Abernethy (USA)
Gilberto Castañeda-Hernández (México) one term of 4 years completed in 2008 – he can be renewed if the members of the Council
Luigi Cubbedu (Venezuela) 8 years – needs to be replaced
Mohammed Ibrahim A. Ibrahim (Egypt)
Shinichi Kobayashi (Japan) 8 years – needs to be replaced
Emilio Perucca (Italy) 8 years – needs to be replaced
Professor Wim du Plooy one term of 4 years completed in 2008 – he can be renewed if the members of the Council
Hyung-Keun Roh (South Korea) one term of 4 years completed in 2008 – he can be renewed if the members of the Council
Professor David Webb (UK) one term of 4 years completed in 2008 – he can be renewed if the members of the Council
Professor Fan-Dian ZENG one term of 4 years completed in 2008 – he can be renewed if the members of the Council

Chairman of the Sub-Committee for Drug Utilization and Pharmacoepidemiology
Emilio J. Sanz one term of 4 years completed in 2008 – however he has not been active and might be replaced

Chairman of the Sub-Committee for Paediatric Clinical Pharmacology
Kalle Hoppu one term of 4 years completed in 2008 – he can be renewed if the members of the Council wishes so

Chairman of the Sub-Committee for Clinical Pharmacology in less developed countries
Lars L. Gustafsson
one term of 4 years completed in 2008 – he can be renewed if the members of the Council wishes so

Past President: Folke Sjöqvist
Old and useful fellow that will leave the position of past-president when I will take it.

IUPHAR PAEDIATRIC CLINICAL PHARMACOLOGY PROGRAM 2007-2008

The Paediatric Sub-Committee of the Division of Clinical Pharmacology of IUPHAR has developed a Work-plan 2004-2008 for Paediatric Clinical Pharmacology, which will be approached in collaboration with organisations and individuals sharing the aims:

1) Advocacy to increasingly incorporate paediatric clinical pharmacological knowledge in policy development, regulatory work, and clinical paediatrics all over the world.
2) Influencing the new regional (US, EU etc.) initiatives for better medicines for children to promote the benefit of children globally.
3) To find solutions for development of a sustainable global framework to train more paediatric clinical pharmacologists to fulfil the unmet needs of the developing world and the increasing demand in the developed world.
4) Creation of international networks in paediatric clinical pharmacology to foster co-operation in research.

Concrete developments and actions to be taken to move forward:

1 & 2 Advocacy: On a global level the major opportunity for advocacy has come with the initiative by the Finnish government, "Better medicines for all children", to put children's medicines on the agenda of the World Health Assembly (WHA). This has required WHO and the governments of its Member states to consider many aspects of paediatric medicines, including policy, development, formulation, investigations and availability. The preparation of Member state responses for the WHO Executive meeting 22-30 January has shown that the small size of the international paediatric clinical pharmacology community has proven to be a great asset. In almost any country there are only a few top experts in paediatric medicines a government can turn to for assistance in preparing a response. The international network of paediatric clinical pharmacologists, reinforced in 2006 by the many international paediatric pharmacology meetings, has been extraordinarily valuable in preparations for the discussions of this initiative. IUPHAR's Paediatric Sub-Committee has had a major role in the discussions. These efforts have to continue and intensify to help WHO and the Member states to develop a resolution with a good program of actions and the WHA to adopt it. Adoption will open up new opportunities for paediatric clinical pharmacologists, paediatricians pharmacists, and others to work for better medicines for children all over the world, but also requires them to rise to the challenge. There are indications that the framework of WHO also provides an opportunity to influence the regional initiatives to promote the benefit of children globally. However, local advocacy by the paediatric clinical pharmacologists, paediatricians and pharmacists will be at least as important.

The International Alliance for Better Medicines for Children was formed in Shanghai last July, by dedicated individuals and the efforts of IUPHAR and IPA (International Pediatric Association). Although not yet fully functional, it can and should be built to a forum providing a platform for collaboration of different professionals involved in providing children with better medicines. Once successfully established, the International Alliance can become a powerful advocate and enable interchange between paediatricians, paediatric clinical pharmacologists and paediatric pharmacists on a new level, enhancing possibilities in training and research. Despite its limited size, the paediatric clinical pharmacology community currently has had a strong position within the International Alliance and should continue to develop it further.

Proposed actions and required resources:

For IUPHAR to maintain its current global leadership in advocacy on children's medicines, its representatives have to be able to attend selected key international events, like the WHO Executive Board meeting and World Health Assembly when significant discussions on children's medicines take place. The status of IUPHAR as a NGO in official relations with the WHO gives IUPHAR recognition within WHO and gives its representatives the possibility to deliver a statement for the meeting and provide documents, in addition to lobbying.

Resources requested: Travel funding within Europe for attendance of 1 person at 2 WHO meetings in Geneva (Executive Board if the "Better Medicines for Children" initiative is deferred to 2008 for work on the resolution and program and the WHA). Estimated total cost 3. 000 Euro.

The International Alliance for Better Medicines for Children has to be able to find external funding, if it is to become sustainable and be able to develop and execute concrete actions. Before reaching this stage, the current ad hoc organizing committee, which has 2 IUPHAR representatives from the Paediatric Sub-Committee (Madlen Gazarian from Australia and Kalle Hoppu from Finland), has to be able to have a couple of meetings to agree on the fundamental working principles and initial program for the Alliance and to write grant application to get funding. The meetings will be scheduled in connection to international paediatric or paediatric clinical pharmacology meetings as far as possible, but as there are no major ones planned for paediatric clinical pharmacology until the summer of 2008, the IUPHAR representatives may need support to attend.

Resources requested: Travel funding for attendance at one ad hoc organizing committee meeting for 2 persons requiring intercontinental travel. Estimated total cost 4 000 Euro.

3. Global framework for training of paediatric clinical pharmacologists to fulfil the unmet needs of the developing world and the increasing demand in the developed world: The provision of children with better medicines globally requires more trained paediatric clinical pharmacologist for research, teaching, regulatory and other government work in developed and developing countries. The global paediatric clinical pharmacology community, currently consisting practically entirely of persons based in developed countries, has long expressed its willingness to provide training for students from developed or developing countries. Recruitment of students has been most difficult, and it has been almost totally impossible to get access to students in the developing world possibly interested in training in paediatric clinical pharmacology. The new developments with WHO, the collaboration with IPA and the forming of the International Alliance may provide better access to recruit students to train in paediatric clinical pharmacology. The most cost effective way to start to rapidly increase the knowledge on an international scale is by employing distance learning methods and technology, in combination with limited educational meetings when feasible. To explore these new possibilities a pilot project should be set up. It can utilize the web-site with distance learning tools set up by the Chairman of IUPHAR's Pharmacoepidemiology Sub-Committee Emilio Sainz (http://www.icbmc.net/). Members of the paediatric clinical pharmacology community have offered use of their existing web-based educational resources. However, two persons have to be recruited to take charge of coordinating the educational activities into meaningful programs and supervising the activities of the web-site to fulfil the high scientific standards of IUPHAR. The pilot project includes one regional introductory workshop on children's medicines and basic paediatric clinical pharmacology organized in collaboration with the IPA and/or WHO in middle to low income part of the world. This event will be used to recruit students to the distance learning program. Other means of recruitment should also be tested. Once suitable educational methods and tools have been developed, these can be made available for other interested groups within the IUPHAR.

Resources requested: The distance education web-site should be moved to the IUPHAR web-site and technically administered by the IUPHAR web-master, to give IUPHAR visibility and once successfully developed allow use by other groups within IUPHAR's web-site. Travel funding is needed to allow the persons responsible for coordinating the distance learning activities (1 meeting to plan the pilot project). In addition, funding is requested for 2 IUPHAR representatives to attend one regional introductory workshop (the costs of arranging the workshop to be funded by other sources). Estimated total cost 6 000 Euro + costs for the web-site when managed by the IUPHAR web-master.

4. Creation of international networks in paediatric clinical pharmacology to foster co-operation in research. Work is progressing by the US NICHD within the 'Global Consortium on Pediatric Pharmacology' activity to develop web-based tools to allow teleconferencing free of charge to the participants. Once operational this will make global networking easier and more effective, providing a big advantage to the sparse, geographically widely spread paediatric clinical pharmacology research community. IUPHAR fully supports the activity by participating in the pilot phase of the web-based tools.

Resources requested: No special funding needed.

Total funding sought for IUPHAR global paediatric clinical pharmacology –initiative for 2007-2008 from IUPHAR: 13 000 Euro (17 000 USD)

PS. This program is based on the Paediatric Sub-Committee Work-Plan 2004-2008. Items 1-3 can be combined to an application based on collaboration with the WHO.

Helsinki 10.2.2007

IUPHAR Division of Clinical Pharmacology
Subcommittee on Pharmacogenetics

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

Background:
Pharmacotherapy optimization through individual drug therapy is one of the major goals of clinical medicine. Over the last decades it has been clearly shown that genetics play a significant role in the pharmacokinetics of drugs and there is an increasing understanding of the genetic background among individuals and ethnic groups with regard to drug efficacy and response. Pharmacogenetics has developed into one of the most important subfields of clinical pharmacology and plays a significant role in the drug development process.

Aims and scopes
The subcommittee will

- Promote exchange of pharmacogenetic knowledge by organization of symposia and workshops in the field of pharmacogenetics and –genomics.
- Evaluate the clinical impact of pharmacogenetics
- Cooperate with drug-related pharmacogenetic database
- Create a population based “biobank” to conduct translational research in clinical pharmacogenomics
- Establish international collaborative clinical studies to investigate the benefits of pharmacogenetics.
- A compendium is under development addressing the following topics: Scientific basis of pharmacogenomics
  - History of pharmacogenetics
  - Basics of pharmacogenetics
  - Developments of Pharmacogenomics
  - Ethnical diversity in pharmacogenetics/genomics
  - Ethical issues of pharmacogenetic information
  - Usefulness of pharmacogenetics
  - Approval process
  - Pharmacogenetics in practice
  - Data on genetic variances relevant for drug therapy
  - Current recommendations of genotype-adapted drug therapy

First meetings of the subcommittee will take place on the occasion of the ASCPT2007 meeting in Anaheim, CA and the EACPT2007 congress in Amsterdam, The Netherlands.

The subcommittee cooperates with the Pacific Rim organization on Clinical Pharmacogenetics (PRACP), a society associated with IUPHAR.

A satellite meeting on pharmacogenetics has been proposed for the CPT2008 congress in Quebec.

Ingolf Cascorbi
Speaker, Subcommittee on Pharmacogenetics

Current Members
Laurent Bequemont, Paris, France
Kim Brøsen, Odense, Denmark
Ingolf Cascorbi, Kiel, Germany
Ann Daly, Newcastle, UK
Magnus Ingelman-Sundberg, Stockholm, Sweden
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