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IUPHAR Clinical Division

Att. Don Birkett (<u>birkprof@hdbirkett.com</u>) (Petra Thürmann (petra.thuermann@helios-kliniken.de)

Report from the "Subcommittee for Clinical Pharma-cology in Developing Countries": activities 2013 and plans for 2014-2015

1. Executive summary

1.1. Activities during 2013

- -Communication and lobbying for the IUPHAR document on the discipline: The subcommittee members have continued to present the document in their home countries and during travels. Andrew Walubo and colleagues published the article about "Clinical Pharmacology becomes a speciality in South Africa" as the first country in Africa. Walubo published the results of a review on clinical pharmacological activities in developing countries. Input for his work was provided by Subcommittee members in 2008.
- -The subcommittee is organizing a symposium at the Congress in Cape Town ("Introduction of new medicines" with presentations by Drs Nghiem Tran Dung (Vietnam), Ilse Truter (South Africa), Betahnia de Araájo Almedia (Brazil), Angela Timoney (Scotland) and Brian Godman (UK/Sweden) and co-chaired by Truter and Gustafsson (Sweden).
- Follow-up activities after the "Workshop on "Interface Management of Pharmacotherapy" in Stockholm in 2012: The subcommittee has published a report about the course that was initiated by WHO and organized by Karolinska Institutet and Stockholm Healthcare Region in collaboration with the Subcommittee, with global participation and financially supported by IUPHAR. One of the participants, Professor Jasper Ogwal-Okeng from Uganda has been one of the leaders to establish Uganda Pharmacological Society in 2013. This society has a major focus on clinical pharmacological research and services. Another participant in the course, Dr Nghiem Tran Dung from Ministry of Health in Hanoi was instrumental in organizing a number of international work-shops on Rational Use of Medicines and the selection of essential medicines in Vietnam in October 2013 with Subcommittee participation.

1.2. Activities planned during 2014

- The promotion of the clinical pharmacology strategic document will continue.
- The subcommittee members will meet in South-Africa at minimum one working session to plan for activities for the next 4 years. As preparation a telephone meeting will be organized in April 2014. In order to strengthen the work of the subcommittee it is suggested to elect a co-chairman and a secretary of the subcommittee.

-Other planned activities include:

- Application to IUPHAR about financial support for 4 to 6 short term (4 weeks) clinical pharmacological training scholarships for visits for young residents/researchers focusing on Rational Use of Medicine and critical drug evaluation principles.
- Recruitment of members/colleagues to the design of African Pharmacological Science Gateway improving IT-connectivity between colleagues
- -Recruit colleagues and institutions willing to start on-line courses on Rational Use of Medicines utilizing recent interests from various online initiatives.
- -Strengthened collaboration and exchange of visits with pharmacogenetic/Rational Use of Medicine network active in Latin America.

1.3. Fundraising efforts

Raise funds for scholarships and training courses together with IUPHAR.

1.4.Funds in the bank

No funds.

2. Subcommittee members

The following colleagues serve as members of the subcommittee since 2007:

Professor MD and Dean, Grace Gonzaga, Dep. of Clinical Pharmacology, Medical School of the University of Santo Tomo, Manila, The Philippines. E-mail gracegarayblasgonzaga@yahoo.com.

Professor MD, Senior Consultant, Lars L Gustafsson (Chairman), Division of Clinical Pharmacology (C1-65), Department of Laboratory Medicine, Karolinska Institutet at Karolinska University Hospital, SE-141 86 Stockholm Sweden. Email: lars-l.gustafsson@ki.se, phone 46-8-58581066 (58581067 secretary), fax 46-8-58581070

Professor MD R L Jayakody, Chairman, Dep. of Clinical Pharmacology, University of Colombo, Sri Lanka. E-mail: jayakodyrl@hotmail.com.

Professor MD Mahmoud Khayyal, Dep. of Pharmacology, Azhar university, Cairo, Egypt (Joined August 2008, Chairman Clinical Pharmacology Section of Egyptian Society of Pharmacology). Email: khayyal@hotmail.com.

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Professor MD PhD Paul Waako, Chairman Dep.of Pharmacology & Therapeutics, University Health College of Medical Sciences, Makerere University, Kampala Uganda. Mail: pwaako@chs.mak.ac.ug

Professor Andrew Walubo, Dep. of Pharmacology, University of the Free State, Bloemfontein, South Africa. E-mail: waluboa@ufs.ac.za

Professor MD Fan-Dian Zeng, Dept. of Pharmacology, Tongji Medical College of Huazhong, University of Science and Technology, Peoples Republic of China. E-mail: fdzeng@163.com.

At Worldpharma in Copenhagen in 2010 new members joined the group:

MD PhD George O. Adjei, Centre for Tropical Clinical Pharmacology & Therapeutics, University of Ghana Medical School, PO Box KB 4236, Accra Ghana. E-mail: goadjei@chs.edu.gh. goadjei@yahoo.com

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Professor MD Adrian Llerena, Clinical Pharmacology, University of Extremadura, Badjoz, Spain. Email: allerena@unex.es

Four senior colleagues serve as advisors: Professor Chris van Boxtel (cvboxtel@upcmail.nl), Amsterdam, The Netherlands; Professor Folke Sjöqvist (folke.sjoqvist@ki.se), Stockholm, Sweden , Professor Anthony Smith (Anthony.Smith@newcastle.edu.au), Newcastle and professor Joan-Ramon Laporte (jrl@icf.uab.es), Barcelona, Spain.

3. Work plan for the Subcommittee

A work plan for 2007-2012 was developed and has been extended to be valid throughout 2014. The extension was reported to IUPHAR in February 2011. It has been followed but the activities have been reduced due to resource constraints.

4. Summary of Subcommittee activities during 2013

4.1. Communication and lobbying for the IUPHAR document on the discipline

The strategic IUPHAR-document "Clinical pharmacology in health care, teaching and research" was jointly published by WHO, CIOMS (Council of International Organizations of Medical Sciences) and IUPHAR (edited by Orme M, Sjöqvist F and Birkett D) at CIOMS website www.cioms.ch in October 2012. The subcommittee members have continued to inform about the document and present it in their home countries and during travels. Our member Andrew Walubo together with colleagues from South Africa published the article about "Clinical Pharmacology becomes a speciality in South Africa" (reference 1). South Africa has made clinical pharmacology a medical speciality as the first country in Africa. Recently Andrew published the results of a review on clinical pharmacological activities in developing countries. Input for his work was provided by Subcommittee members at our meeting at the 9th World Congress in Clinical Pharmacology in Québec 2008 (Reference 2).

4.2 Design and acceptance of symposium at World Congress in Pharmacology and Clinical Pharmacology in Cape Town, South Africa in July 2014

In 2012 the Subcommittee adviced in a questionnaire from the Congress organizers to arrange a total of four symposias and/or themes:

- 1. INITIATIVES FOR RATIONAL USE OF MEDICINES IN AFRICA
- 2. OPEN, GLOBAL DRUG DISCOVERY AND CLINICAL DRUG DEVELOPMENT-a panacea to improve therapy of neglected diseases
- 3. PROS AND CONS AND IMPACT OF CLINICAL DECISION SUPPORTS IN DRUG THERAPY
- 4. INFORMATION TECHNOLOGY IS TRANSFORMING THE PHARMACOLOGICAL SCIENCES

Finally one symposium suggested by the Subcommittee was accepted by the program committee. The symposium is on "Managed introduction of new medicines" with presentations by Drs Nghiem Tran Dung (Vietnam), Ilse Truter (South Africa), Betahnia de Araájo Almedia (Brazil), Angela Timoney (Scotland) and Brian Godman (UK/Sweden) and co-chaired by Truter and Gustafsson (Sweden).

Wednesday 16 July 2014 10:30 – 12:00

Track 5 - Managed introduction of new medicines

Chair: Lars Gustafsson

Challenges and developments in Vietnam Nghiem Tran Dung

Developments and challenges in South Africa - focus on non-communicable diseases, HIV and cancer lise Truter

Developments and challenges in Brazil including neglected diseases Bethânia de Araújo Almeida

The national Scottish partnership model of rapid HTA of new medicines: 10 years experience Angela Timoney

Suggested models to introduce new medicines - building on experience with new oral anticoagulants in Australia and Europe Brian Godman

The symposium will explore different approaches to solve the growing medical and economic challenges of safe use and financing of new expensive medicines and drug combinations in clinical practice. The symposium will highlight how healthcare institutions in rich as well as resource strained countries can ensure affordable access to new therapeutic breakthroughs across continents.

4.3 Follow-up activities after the "Workshop on "Interface Management of Pharmacotherapy" in Stockholm September".

As planned the subcommittee published a report about the course on "Interface management of pharmacotherapy" initiated by WHO and organized by Karolinska Institutet and Stockholm Healthcare Region in collaboration with the Subcommittee in September 2012 and with global participation (Reference 3). IUPHAR provided financial support that made it possible to host participants from Belarus, Mocambique, Uganda and Vietnam. One of the participants in the course, professor Jasper Ogwal-Okeng from Makerere and Gulu Universities in Uganda has been one of the leaders to establish Uganda Pharmacological Society in 2013 (www.uphars.org/index.php). The South-African colleagues have been instrumental to assist our Ugandan colleagues. This society has a major focus on clinical pharmacological research and services. The Subcommittee predict that the strategic document on clinical pharmacology can be of major help when the Ugandan Society implements its program. In addition, another participant in the course in 2013, Dr Nghiem Tran Dung from Ministry of Health in Hanoi was instrumental in organizing a number of international work-shops on Rational Use of Medicines and the selection of essential medicines in Vietnam in October 2013. Drs Lars L Gustafsson, Brian Godman (both Karolinska Institutet) and Soc Escalante (pharmaceutical advisor at WHO Country Office in Vietnam) and Klara Tisocki (Pharmaceutical Officer at WHO Regional Office in Manila, the Philippines) participated. The Vietnamese government is strengthening the model for selection of essential medicines in the country and is aiming to train representatives in Drug and Therapeutics Committees in critical drug evaluation and in the principles of Rational Use of Medicines.

4.4. Participation in the EU-project e-infrastructures for Africa (eI4Africa)

IT-connectivity between academic, governmental and healthcare institutions increase rapidly in all continents including Africa, Asia and Africa allowing easy access to knowledge, literature and databases. Clinical pharmacology is represented (through chairman Lars L Gustafsson) in an EU-project since 2012 to lobby for open access to IT-solutions for academia and public institutions in Africa (http://ei4africa.eu/). During 2013 an outline of needed type of connectivity and information resources for basic and clinical researchers in pharmacology and biomedical scientists in Africa has been defined and a prototype for maintain a virtual room for connectivity, conferencing and sharing data including e-learning tools is to be developed during 2014 (cf below). The responsible partners in Africa are chaired by MD PhD Collen Masimirembwa (director at Ai, African Institute of Biomedical Sciences and Technology, www.aibst.com) and professor Collet Dandara (University of Cape Town, South Africa). The virtual application is called African Pharmacology Science Gateway. Information is available at www.ei4africa.eu/demonstrators/from-africa/.

4.5 Regional networking in pharmacogenetics and Rational Use of Medicine in Latin America

Members of the group have participated and been active in the organization of the 20th !Congreso Latinoamericano de Farmacologica y Terapeéutica" in Havana in October 21th to 25th, 2013. The Iberoamerican Network of pharmacogenetics has gained major support from Dr Adrian Llerena, Badajoz Spain, in the subcommittee. The successful activities of this network has included research (13 research groups, 9 publications in 2013), teaching (10 fellowships) and with scientific meetings (5 during 2013). This regional activity is inspiring for other regional activities.

5. Activities and exploration of options for funding 2014-2015

5.1. The promotion of the clinical pharmacology strategic document will continue by involvement of all and our networks.

5.2. The subcommittee members will meet in South-Africa at minimum one working session to plan for activities for the next 4 years. As preparation a telephone meeting will be organized in April 2014 for those that can attend. The aim is to ensure that members are involved in the activities and strengthen the work of the subcommittee and therefore a second co-chairman is to be elected as well as a secretary of the subcommittee.

5.3. Other planned activities include:

- Application to IUPHAR to support 4 to 6 short term (4 weeks) clinical pharmacological training visits for young residents/researchers focusing on Rational Use of Medicine and critical drug evaluation principles (4000 USD each)
- -Recruitment of members/colleagues to the design and preparation of African Pharmacological Science Gateway
- -Recruit colleagues and institutions willing to start on-line courses on Rational Use of Medicines utilizing recent interests from various online initiatives including The People's Open Access Educational Initiative, the Peoples-uni (http://www.peoples-uni.org/ content/who-are-we and also the massive online courses as provided from an alliance of respected universities, https://www.edx.org/
- -Strengthened collaboration and exchange of visits with pharmacogenetic/Rational Use of Medicine network active in Latin America.
- -Fund-raising with the support of IUPHAR

6, Publications

- 1. Walubo A, Barnes KI, Kwizera E, Greeff O, Rosenkranz B, Maartens G. Clinical pharmacology becomes a specialty in South Africa. S Afr Med J 2013;103:150-1.
- 2. Walubo A. The current status and trend of clinical pharmacology in developing countries. BMC Pharmacol Toxicol 2013;14:49. doi: 10.1186/2050-6511-14-49.
- 3. Björkhem-Bergman L, Andersén-Karlsson E, Laing R, Diogene E, Melien O, Jirlow M, Malmström RE, Vogler S, Godman B, Gustafsson LL. Interface management of pharmacotherapy. Joint hospital and primary care drug recommendations. Eur J Clin Pharmacol. 2013 May;69 Suppl 1:73-8. doi: 10.1007/s00228-013-1497-5.

On behalf of the subcommittee

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