

Final

GLOBAL COOPERATION GROUP MEETING REPORT

TUESDAY NOVEMBER 16, 2004

ROYAL PARK HOTEL, YOKOHAMA

Participants:

Dr. Yves Juillet (Co-chair)	EFPIA
Mr. Mike Ward (Co-chair)	Canada
Mr. Kazuhiko Chikazawa	MHLW
Mr. Kazutaka Ichikawa	JPMA
Dr. Justina Molzon	FDA
Dr. Alice Till (<i>replacing Dr. C. Loew</i>)	PhRMA
Dr. Peter Arlett (<i>replacing Dr. P. Brunet</i>)	EU
Dr. Lembit Rägo	WHO
Dr. Odette Morin	IFPMA
Dr. Hong Ki Min	APEC
Dr. Yuppadee Javroongrit (Observer)	ASEAN
Dr. Ibrahim A. Al-Showaier	GCC
Dr. Davi Rumel	PANDRH
Dr. Nditonda Chukilizo	SADC

Also present:

Mr. Akira Kawahara	MHLW
Dr. Yoshiaki Uyama	PMDA
Dr. Spiros Vamvakas	EMEA
Mr. Stéphane Callewaert	EFPIA
Dr. Joan Blair	FDA
Ms. Sema Hashemi	FDA
Dr. Michelle Limoli	FDA
Dr. Peter Honig	PhRMA
Dr. Michael Garvin	PhRMA
Dr. Ryoko Krause	IFPMA
Ms. Daniela Renggli	IFPMA
Dr. Petra Doerr	EFTA
Dr. Sabine Kopp	WHO

The co-chairs, Dr. Yves Juillet and Mr. Mike Ward, opened the 2nd meeting of the new GCG. Representatives from all regional harmonisation activities were present in the meeting.

The agenda was adopted without changes.

Dr. Morin announced the specific site dedicated to GCG in the ICH web site and mentioned the possibility to ask questions to the GCG via the web site (no questions were posted so far via the new site). Further, she updated the group on recent ICH activities including MedDRA. Small companies with less than 100 adverse reports as well as non-for profit research organisations can now use MedDRA free of charge via the EMEA EudraVigilance site.

Dr. Juillet stressed that *Step 2* guidelines are open for comments also from non-ICH regions and invited the GCG participants to provide comments on the upcoming *Step 2* guidelines.

Mr. Ward presented a draft on standardised response for questions to GCG regarding endorsement of training services. The group agreed with the proposal.

Regional harmonisation update

GCC: Dr. Al-Showaier from the Saudi Food and Drug Authority, representing the Gulf Co-operating Council (GCC), gave an overview of the GCC structure and activities including numbers of evaluated and authorised products by GCC. Further issues discussed were production of guidelines, performing inspections.

APEC: Dr. Javroongrit gave an update, on behalf of Dr. Pothisiri (official APEC representative), of the second Life Sciences Innovation Forum (LSIF) meeting held in September 2004 in Malaysia, with participation of representatives from 13 APEC countries. The focus was to review the draft Strategic Plan (with a scope to define specific areas around research, development, manufacturing and marketing of medicinal products to be finalised by November 2004), to discuss Best Practice and to identify Collective Actions.

ASEAN: Dr. Javroongrit gave an update of the last Pharmaceutical Product Working Group (PPWG) in July 2004 in Bangkok, which attracted 300 participants from 9 countries. ASEAN concluded in the last PPWG meeting that their participation to the GCG should be as an observer, who will give his/her individual opinion, not representing ASEAN (not as a permanent representative). In this context, Dr. Javroongrit mentioned that generally ASEAN benefits from the ICH guidelines, which are adopted as such in particular for safety and efficacy topics. In the last PPWG meeting, final drafts of the ASEAN Guidelines on Stability and Bioavailability / Bioequivalence were adopted. Issues resulting from differences between the ASEAN and the existing ICH and WHO stability guidelines were discussed. WHO will address issues regarding implementation of the new ASEAN stability guideline in their upcoming general meeting on stability in Geneva in December 2004. ASEAN further mentioned that full implementation of the ASEAN CTD (ACTD) was agreed to take place by 31 December 2008. The next PPWG meeting will be in February in Philippines.

PANDRH: Dr. Rumel presented an overview of the structure and activities of PANDRH, including issues around the registration process in the different countries, bioequivalence and differences in classification of OTC/prescription drugs in the different PANDRH countries. The upcoming conference in March 2005 will focus on three PANDRH documents on, GMP, bioequivalence and GCP. Dr. Molzon mentioned that although the principles remain the same, the ICH guidelines were modified to fit the situation in the PANDRH regions. Reasons for deviations from international standards and the possible consequences were discussed in view of the current importance of participation of all regions in the global development.

SADC: Dr. Chukilizo (alternate to the SADC permanent representative) presented an overview of the structure and activities of the SADC. Recently approved documents included guidelines on General information on registration of medicinal products, Application form for registration of medicinal products, Stability and WHO's manufacturing practices. Guidelines under preparation include among others one on HIV vaccine trials in human participants. Dr. Chukilizo announced an upcoming meeting on technical guidelines in January 2005, to which he invited a representative of ICH.

Mission, Activities and Operations of the GCG

Dr. Juillet presented an overview of the GCG rules and procedures. Based on a presentation by Mr. Ward the group aimed to define a mission statement that will guide future activities in a focussed way. Objectives to be included in the mission of the group (suggested by Mr. Ward) could include ICH guidelines, harmonisation and regulation across the regions including technical guidelines beyond the scope of ICH as well as training and capacity building.

Brainstorming Session

During the brainstorming, several specific topics were proposed. Some interest was expressed in organising exchanges and interactions with other regulatory authorities regarding training on and contribution to the review of new products. Several ongoing activities were mentioned and all present regulators expressed their willingness to contribute, preferably on the level of regional initiatives across nations to improve efficiency (compared to activities on a national level). WHO proposed to identify certain topics that deserve more attention in terms of their role across regions and provide training and implementation help.

Dr. Juillet wrapped-up the brainstorm discussion and summarised the main topics of interest identified:

- Technical topics of interest:
 - Implementation of the CTD and the e-submission;
 - GCP implementation, and general considerations on clinical trials;
 - Implementation of the E5 guideline "Ethnic Factors in Clinical Trials";
 - Pharmacovigilance topics: including in particular E2B and MedDRA.
- Need for Assistance and Training:
 - Review process / Assessment of data;
 - Joint inspections (e.g. on GCP);
 - Good Harmonisation Practices.

Two regional representatives indicated topics among the ones mentioned above which would be central in their upcoming regional meetings (see above regional reports), pharmacovigilance for the next ASEAN meeting, CTD implementation for the next SADC meeting (to be confirmed within one month).

It was proposed that the other representatives would consult their regions to identify critical topics to them.

It was also proposed that the regional representatives should identify specific issues of interest to them to present in depth in the next meeting of the GCG.

Furthermore, the representatives were invited to provide comments on the upcoming *Step 2* guidelines and provide input into the currently ongoing ICH brainstorming to identify future pharmacovigilance topics.

In addition to these specific technical areas, the GCG should focus on the development of a model to enable harmonisation of important issues across regions beyond ICH regions.

GCG Mission Statement

In the concluding discussion the following draft mission statement was proposed for the new GCG:

“To promote a mutual understanding of regional harmonisation initiatives in order to facilitate harmonisation processes related to ICH guidelines regionally and globally, and to strengthen the capacity of drug regulatory authorities and industry to implement them”