Draft Report
International Pharmaceuticals Regulators Forum
Meeting in Osaka, Japan; 11-12 November 2013

AGENDA 11 November 2013

1	Welcome and introductions	10:00 – 10:15
2	Adoption of the agenda	10:15 – 10:20
3	Report of the previous meeting	10:20 – 10:30
4	IPRF links to other initiatives (IGDRP, ICH GC)	10:30 – 11:00
5	Finalization of Terms of Reference	11:00 – 12:00
6	Discussion of draft working procedures	12:00 – 12:45
7	Logo and website presentation	12:45 – 13.00
	Lunch	13:00 – 14:00
8	Regulatory updates	14:00 – 15:30
	Coffee break	15:30 – 15:45
9	Ongoing activities a) E6 Discussion Group b) Gene Therapy Discussion Group c) Cell Therapy Discussion Group d) Contact list (Safety information; GCP and GMP)	15:45 – 16:45
10	Update on IGDRP	16:45 – 17:00
	End of first day	17:00
	IPRF Dinner (hosted by MHLW/PMDA)	19:30

1 Welcome and introductions

Petra Doerr as IPRF chair welcomed the participants to the meeting.

Naoyuki Yasuda, on behalf of the host country Japan and as co-chair, also expressed a warm welcome and wished everybody a fruitful meeting.

A “Tour de table” was done for introduction of the participants.

2 Adoption of the Agenda

The agenda was adopted with a small change to point 9 d) where a contact list on GMP was included in addition to safety issues and GCP.

3 Report of the previous meeting

The report from the meeting in La Hulpe was adopted without change.

4 IPRF links to other initiatives (IGDRP, ICH GC)

The chair initiated the discussion on links of IPRF to other international initiatives like e.g. IGDRP (International Generic Drug Regulators Pilot) and invited the members to express their point of view. It was pointed out that this would be on open discussion with no intention to make a decision during this meeting of how various initiatives should/could be linked together.

FDA pointed out that IPRF is playing an important role in sharing and exchanging of information and identifying best practices. It is seen as an important place for discussion and coordinating training needs.

The EU Commission DG Sanco stressed the importance of clarifying the different roles of existing international initiatives and how they could work together in the most efficient way. No regulatory authority has time and resources to contribute to every initiative.

MHLW stated that a lot of energy is already put in existing initiatives. Therefore, it is important to pay attention to how the different initiatives work together to avoid duplication of effort.

HC considers the newly established IPRF as strong push for international collaboration and stressed the need to use resources at best value. IPRF as regulatory hub will provide the members with a platform for topics that are much broader and wider in range than the ICH topics.

The MFDS, Korea, is pleased to participate in IPRF and appreciates the formalised status of the previous Regulators Forum. It was pointed out that the Forum is seen to be very helpful for non-ICH member countries helping them to solve problems before being able to implement ICH guidelines.

ANVISA expressed its hope for the IPRF to become an open forum for discussion. The Forum should avoid any overlap with other initiatives and should be effective regarding outcomes for the benefit of all.

The GCC appreciates the move to more transparency and is pleased to see that ICH developed from a rather closed forum to a more open one. There is a need for more regulatory topics to be discussed.

ASEAN sees the optimum benefit of IPRF in its support to implementing best regulatory practice in the different regions.

WHO offered to provide technical support to the IPRF as per WHO mandate. The role that WHO will take within the Forum is not yet fully clear and WHO would be happy to know more about the expectations of the group.

PANDRH raised the question of how IPRF would see the inclusion of regulatory agencies with less capacities and resources and how the Forum could possibly be of benefit for them.

In summary, it can be concluded that the IPRF is seen as important regulatory platform for sharing of information and regulatory best practice as well as networking. The Forum will support the implementation of ICH guidelines and provide the platform for discussion of broader topics not covered by the scope of ICH or other international initiatives.

The Forum should be an open forum, but for regulators only. It should have a simple organisation structure, work in a transparent way, provide for flexibility and have a permanent secretariat to facilitate work.

Duplication with other already existing initiatives should be avoided by all means.

5 Finalisation of Terms of Reference

The document Terms of Reference as circulated with the meeting package was gone through to explain the comments received and to discuss/add potential new remarks/comments.

The term “strategy” was further defined meaning “strategies for collaboration”.

Agreement was reached to use the term “medicinal products for human use” regarding the scope of the IPRF activities.

It was decided that only examples for potential discussion topics are included in the Terms of Reference. The list of potential topics is therefore not exclusive.

Criteria for membership should be flexible enough to allow countries to decide whom they send. The term “Regulatory Authority (RA)” should be used.

Participation is not limited to the members of the existing group. It is an open Forum for all Regulatory Authorities worldwide. Although being open to interested RAs, IPRF would not actively “recruit” and invite new members (no active promotion for the time being). Participants would have to cover their own costs for travel and accommodation. The concept of RHIs to represent certain regions is still encouraged to keep the IPRF management to an operational level. Should the group get too big in future, participation might be limited to one member per RA. The Terms of Reference would then be revisited.

The subsections under section VII Meetings will be deleted.

The amended version was circulated for final comments with the objective of being adopted at the end of the meeting during the conclusion session.

6 Discussion of draft working procedures

The co-chair presented a first draft concept of the working procedures.

The primary goal is to facilitate IPRF’s organisational work.

The working procedures should consider the following four topics/categories:

- Organisation and administration of IPRF meetings
- Project proposal process including potential templates to be used
- Working group organisation and Regulators participation
  - Information sharing (ad hoc and best practices) and networking (contact lists)
  - Definition of reporting process to whole group
  - Brief description of how groups are working
- External communication (if needed)

7 Logo and website presentation

The chair presented three different versions for a potential IPRF logo.

The green version would be the preferred one by Swissmedic. Some participants favoured the logo with the capsules, but in general, the green logo was much appreciated. It was suggested to darken the green so it appears in an appropriate way when used for presentation.

The prototype of the new IPRF website with the green logo and the different features that would be available was shown. The website would have a public section and a user-only section for the IPRF working documents to be shared among the members. The overall design and layout of the website was found to be very useful for the work of IPRF.

8 Regulatory updates

<u>MHLW / PMDA</u>

MHLW informed about an amendment to the Pharmaceutical Affairs Act and that the name of the Act will be changed. There will be a separate chapter for medical devices.

PMDA provided the information that a regional branch has been opened that will deal with pharmaceutical affairs consultations and GMP inspections.

A 4th PMDA training course on Generic Drugs was announced for February 2014.

US FDA

FDA informed that their biggest challenge is the budget constraint at the moment which is impacting on user fees negotiations as the government shut-down was delaying work in this area.

Management is currently focusing on an extensive programme for generic drug review.

Information was provided on the re-organisation of the Office for Pharmaceutical Science.

The FDA strategic plan regarding drug shortages has just been published on FDA website.

EU Commission/DG Sanco and EMA

A new legislative proposal regarding the amount of fees for Pharmacovigilance activities according to the new EU Legislation on Pharmacovigilance is currently being discussed by the EU Council and Parliament. It is hoped that it will be adopted before the elections at EU level in spring 2014. If this is not possible, years of delays are expected.

A proposal for a revised clinical trial regulation is also under discussion and it is hoped that agreement will be reached by the parties concerned by end of 2013.

With regard to the requirements for the importation of APIs manufactured in Third Countries into the EU, it was informed that 4 Third Countries are now listed, two applied for listing and are under assessment (Brazil, Singapore). All other countries are issuing written confirmation according to the requirements.

Following implementation of the new Pharmacovigilance requirements, the symbol of the black triangle is now implemented identifying medicinal products for human use that are under closer monitoring. A video is available on the EMA website for further detail.

EMA informed about the hosting of a workshop on biosimilars end of October 2013 and another workshop on antimicrobial resistance on the 8th of November 2013.

A catalogue of all shortages in the EU has been published on the EMA website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/11/news_detail_001940.jsp&mid=WC0b01ac058004d5c1

A presentation was given on the re-organisation of the EMA and the new structure was shown.

Please refer to the presentation for more details.

Health Canada

HC informed that Parliament Session was (finally) re-opened in October 2013. A 0 % deficit bill was announced that will entail much discussion on budget issues.

Regarding the requirements for API, HC stated that the respective regulation has finally been adopted.

Swissmedic

Swissmedic's service mandate which is valid for a period of four years has been amended to include projects in the area of development cooperation. These projects can either be done in collaboration with the Swiss Agency for Development Cooperation or non-profit organisations.

Russia

There will be a new definition for biosimilars as well as a fast registration scheme.

A "Sunset clause" approach will be implemented.

An active search for safety issues will be available via the Authority's website.
Sanctions for violations will be strengthened and risk minimisation activities will be adapted to the Russian regulatory system.

WHO
The new structure of the Department of Essential Medicines and Health Products was presented.
WHO informed that the 16th ICDRA will take place in Rio de Janeiro, Brazil from 24 to 29 August 2014. The draft programme is available on the 16th ICDRA website.
http://www.anvisa.gov.br/hotsite/icdra/index.html
Please refer to the presentation for more details.

ANVISA
Registration for the 16th ICDRA will be soon open via the ICDRA website (please see the link above).
ANVISA informed that they are about to finalise the restructuring by December 2013.
The Resolution on traceability of medicines is approved while other legislative initiatives are still within the process of consultation.

Korea
MFDS informed that the number of regional Pharmacovigilance centres for collecting of ADRs will be increased to 25 centres (currently 22).
A new organisation will be put in place to deal with the huge amount of ADRs.

Singapore
There are no special amendments to the pharmaceuticals law at the moment.
A new IT platform will be available via the website as of February 2014.

China
CFDA informed about additional staffing for pharmacovigilance tasks.
There are a couple of new ongoing initiatives regarding generic drugs, paediatrics as well as the quality of clinical trial data.

Chinese Taipei
Chinese Taipei informed of a reorganising of their Ministry of Health. However, TFDA is not affected this time.
There are several revised guidelines on DMF, tissue and cell therapy products as well as labelling.
Several international activities have also taken place: there has been a workshop on harmonisation of bridging studies as well as an APEC symposium on orphan drug clinical studies.

PANDRH
PANDRH informed of an upcoming conference in May 2014 in Canberra, Canada. At the meeting, adoption of the new strategic plan is envisaged.

GCC
GCC informed about two trainings on pharmacovigilance that have taken place in September 2013.
There is a new proposal to establish a central FDA for GCC. The new body would look into consolidation of review processes within the region. The proposal will be further discussed.

ASEAN

ASEAN provided information about several workshops that have taken place in the region.
It was stated that the Philippines are within the process of getting PIC/S member.
With regard to the Mutual Recognition Agreement on GMP inspection, it was informed that Singapore has joined the agreement.

APEC
APEC informed about several workshops that have been organised by the Regional Harmonisation Centre.

EAC
EAC provided information about the ongoing process of harmonisation of guidelines on the registration process in the region as well as about capacity building and training programmes.

SADC
SADC informed that the concept for eCTD implementation in the region has been approved.
The established process for training within regions needs revision and will probably have to be changed to meet the various needs.

9 Ongoing activities

a. E6 Discussion Group
Yoshiaki Uyama presented the activities of the E6 Discussion Group.
Please refer to the presentation for further information.

b. Gene Therapy Discussion Group
Joan Blair informed about the proceedings of the group. The group works by telephone conference and provides regular updates to each other. A specific survey on classification of products by each Authority has been carried out and discussed.
The group is looking for the possibility to meet face-to-face in 2014 in conjunction with a professional society/association meeting on the topic.

c. Cell Therapy Discussion Group
Joan Blair informed about the proceedings of the group. The group works by telephone conference and provides regular updates to each other. They have had their first face-to-face meeting in April 2013 in New Zealand. A publication is in preparation.

d. Contact list (Safety information, GCP, GMP)
The contact lists will have to be updated and kept up-to-date on a regular basis. It was agreed that this would be done by the Secretariat. The lists will be available on the "Members-only" section of the IPRF website.

10 Update on IGDRP

Mike Ward provided an update on the activities of IGDRP with special focus on the progress made at the 5th meeting that took place from 28 -30 October 2013 in Geneva, Switzerland.
The next meeting of the IGDRP will be hosted by Chinese Taipei, presumably beginning of the week from 19 of May 2014. A three day meeting is proposed.
Please refer to the presentation for more details.

AGENDA 12 November 2013

11	Future work on IPRF a) Biosimilars b) MedDRA c) Other topics as per participants' proposals[1] (PAHO platform)	09:00 – 10:30
12	Future of ICH	10.30 – 11.30
13	Conclusion of the meeting a) Finalisation of Terms of Reference b) Public statement and action items c) Next meeting	11:30 – 12:00
	End of meeting	12:00

11 Future work on IPRF

Biosimilars

Emer Cooke presented on regulatory challenges and potential topics/areas for harmonisation regarding biosimilars. The creation of a working group was proposed and a call for expression of interests for countries/regions to nominate members was spelled out.

Please refer to the presentation for further details.

Various members expressed their interest in the topic and participating in the working group (EMA, FDA, MHLW/PMDA, MFDS Korea, HC, GCC, ASEAN, HSA, Swissmedic, Chinese Taipei, PANDRH, ANVISA, SAHDC) . Members of IPRF not being able to participate in the working group can still benefit from all documents prepared by the group through the IPRF website (closed-user group).

Korea pointed out that there are a lot of workshops, seminars, symposia around biosimilar products and their registration requirements worldwide. Russia proposed a training programme/minimum professional requirements for reviewers assessing biosimilar marketing authorisation applications.

In summary:

Agreement was reached to establish an IPRF Working Group on Biosimilars.

The Secretariat will prepare a nomination form by end of November 2013. Feedback regarding nomination should be provided to the Secretariat by end of 2013 so the working group could start work by beginning of 2014. The MFDS of Korea agreed to take the chair of the group. Per interested party, it is proposed to have one member and one alternate. Regulatory Authorities from RHIs can also attend as member in their function as competent authority.

MedDRA

Rudolf Stoller, Swissmedic, presented the Swiss pharmacovigilance system and a planned switch to MedDRA regarding coding of ADRs.

Please refer to the presentation for further details.

The Health Sciences Authority, Singapore had converted the coding of adverse drug reaction terms from WHO-ART to MedDRA in 2011. Legacy data which were coded in WHO ART was also

[1] PAHO platform for information sharing (PRAISsec)

converted to their equivalent MedDRA preferred terms. Currently, all ADR reports are coded in the WHO ART which is the Lowest Level Terms equivalent of MedDRA.

The WHO-ART to MedDRA bridge is very helpful. All WHO-ART preferred terms have been mapped to the corresponding terms in MedDRA. This mapping acts as a bridge between the two terminologies – it makes it possible to connect the data coded in WHO-ART to data coded in MedDRA. Using this bridge, our ADR database is then able to map these respective WHO-ART ADR terms to MedDRA's PTs based on the bridge provided by UMC.

ANVISA informed that they are not using MedDRA yet, but intend to do so in future.

HC informed about their electronic reporting of ADRs.

PAHO's regional platform on access and innovation for health technologies (PRAISsec)

Analia Porras and Mike Ward informed about PAHO's regional platform on access and innovation for health technologies. Mike Ward explained the different features of the platform and raised the question whether this platform PRAISsec could be the common platform for all international initiatives in the future. For the time being, international initiatives as IPRF, IGDRP, etc. use different kind of platforms. PRAISsec will be established as a secure platform for the exchange and sharing of confidential information.

A pilot will be run on GMP reports and should be ready to start sometime within the first half of 2014 provided the standards are agreed upon by the Regulatory Authorities concerned.

Questions were raised on the possibility of having access to the platform for non-PANDRH members and regarding sustainable funding for maintenance of the platform in the long-run.

Please refer to the presentation for further details.

Future topics for IPRF

The chair invited all members to notify the Secretariat of any potential future topics that could be taken up by IPRF. A long-term strategy plan for potential topics to be taken up will be developed by the chair and co-chair.

12 Future of ICH

Theresa Mullin informed the members of the discussions ongoing in the ICH Steering Committee on ICH Organisation and Membership.

Please refer to the print-out provided regarding "ICH Organisation and Membership".

A lot of members expressed their interest in the re-organisation of ICH and appreciated that ICH is going to be more open.

The ICH SC will be asked whether and when the document could be made public. The chair confirmed that the group will be updated on any progress made.

Post-Meeting Note

The ICH Steering Committee did not conclude its discussions on the criteria for membership at its meeting in Osaka. Follow-up telephone conferences have been scheduled in the coming weeks in order to advance the discussion. The IPRF members will be updated on the progress made.

13 Conclusion of the meeting

Adoption of the Terms of Reference

A revised version dated 11 November 2013 with the agreed changes from the first day of the meeting and additional comments/changes from HC was distributed to the members.

The Terms of Reference were adopted with the changes made (version 12 November 2013).

Once final, the Terms of Reference will be published on the IPRF website.

Public Statement and Action Items

A public statement was drafted that will be distributed to all members for comments and feedback. The list of action items will also be circulated for comments.

Appendix I – Participants list

Country	Participant
Brazil	Laura Castanheira Patricia Pereira Luciana Shimizu Takara
Canada	Louise Dery Mike Ward
China	Dong Jiangping
Chinese Taipei	Meir-Chyun Tzou Wen-Yi Hung Hsu lih-Jiuan
EU	Emer Cooke Sébastien Goux Lenita Lindstrom Tomas Salmonson Spiros Vamvakas
Japan	Chieko Hirose Yasuko Inokuma Jun Kitahara Nobumasa Nakashima Shiori Okajima Yoshiaki Uyama Naoyuki Yasuda *(co-chair)*
Republic of Korea	Sun Hee Lee Eun Hye Park Hee Young Park
Singapore	Christina Lim Dorothy Toh
Switzerland	Petra Doerr *(chair)* Cordula Landgraf
Russia	Sergey Glagolev
United States	Joan Blair Michelle Limoli Justina Molzon Theresa Mullin
APEC	Jeong Mi Kim
ASEAN	Yuppadee Javroongrit

EAC	Jane Mashingia Fred Siyoi
GCC	Saleh Bawazir
PANDRH	Analia Porras
SADC	Fortunate Fakudze Joseph Mthetwa
WHO	Samvel Azatyan Daisuke Koga Sabine Kopp Lembit Rägo