択のガイドライン作成に対する情報提供のため、CP、JP、KP 及び HKCMMS において標準試料として用いられている化合物の比較表を Sub-committee I でとりまとめ、WHO に提供したい旨提案がなされた。

これに対し中国より、CP の最新版の情報を反映させるため、過去に作成した比較表の提供の要望があり、Sub-committee I で作成した各国薬局方の TLC 条件の比較表の電子ファイルを中国に対し提供した。

次回は 2015 年に中国が座長国となり、13th FHH Standing Committee 会議を開催することが決定され、FHH 事務局（シンガポール）より、日程が確定したら連絡するように要望が出された。

また、日本は 2017 年及び 18 年の開催予定国とされた。

最後に、合田薬品部長、木内慶応大教授より挨拶があり、合田薬品部長からは、国際調和のためには各国の相互理解と、自国の伝統薬の歴史をよく認識することが重要である、とのメッセージが伝えられた。

10. 閉会の辞

シンガポール HSA の Assoc. Prof. Cheng Leng Chan より閉会の辞が述べられた。FHH の今後のさらなる発展を祈念して会議を終了した。

11 月 27 日（終日）

11. 5th FHH International Symposium

本年は 12th FHH Standing Committee 会議に合わせ、5th FHH International Symposium が HSA において開催され、各国参加者より、16 題の講演が行われた（別紙 3 にシンポジウムのプログラムを添付する）。わが国からは、国立医薬品食品衛生研究所生薬部の政田さやか主任研究官が「Evaluation of the Botanical Origin of *Cimicifuga* Products in the Japanese Market」と題し、我が国に流通するブラックコホシュ等のショウマ類を含む製品の現状について発表を行った。本発表の質疑では、我が国における食品と医薬品の区別の現状について会場から質問があり、合田薬品部長より食薬区分について解説がなされた。

D. 結論

第 12 回 FHH Standing Committee 会議がシンガポール、Peninsula Excelsior Hotel で開催された。本会議では各地域における生薬並びに生薬製剤の規制の現状に関する報告並びに Nomenclature and Standardization 、 Quality Assurance and Information 及び Adverse Drug Reaction に関する 3 つの Sub-committee の活動報告がなされた。

FHH のメンバー国各国においては、生薬並びに生薬製剤の安全性を高めるため、監視・審査制度を強化する動きを活発化させており、これらの安全性確保に対する各国の強い意思が感じられた。また、韓国が主導する FHH RMPM の規格化においては、日本、中国、ベトナムの各国の試料提供により比較研究が進展したことや、ベトナム薬局方の改訂においては、日本、中国、韓国の薬局方情報が参考にされたなど、FHH の目標とする国際協調の成果も多く報告された。

日本が主催する Sub-committee I (Nomenclature and Standardization) では、各国薬局方の比較検討を以前より遂行しており、その成果として各国薬局方における生薬関連試験法の比較表を作成し、これらの内容に関する冊子を順次刊行してきた。

本年は FHH 事務局より提供を受けた香港特別行政区の香港中薬材標準と日本薬局方（及び局外生規）との共通収載生薬について定量試験法の比較表を作成し、本会議において報告した。本比較表は、生薬の安全かつ効果的な利用に関する国際調和を推進する上で、香港と日本の両国のみならず、他の FHH 参加国にとっても有益な情報となるものと考えられる。

E. 健康危険情報

本研究において健康に危険を及ぼすような情報はない。

F. 研究発表

1．論文発表

なし

2．学会発表

なし

G. 知的財産権の出願、登録状況

特になし

（別紙 1）

Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH)

Report of the Twelfth Standing Committee Meeting of the Western Pacific Regional Forum for the Harmonization of Herbal Medicines

25 - 26 November, 2014

Peninsula.Excelsior Hotel, Singapore

Members

1.	A/Prof CHAN Cheng Leng	Singapore, Chairperson of FHH (Term 2013-2014)
2.	Mr WANG Kuiran	China
3.	Mr LIU Chun	China
4.	Ms Polly CHAN	Hong Kong, China
5.	Dr Alice WONG	Hong Kong, China
6.	Dr Yukihiro GODA	Japan
7.	Prof Fumiyuki KIUCHI	Japan
8.	Dr Rackseon SEONG	Korea
9.	Prof So-Young PARK	Korea
10.	Mr YEE Shen Kuan	Singapore
11.	Ms HUI Foong Mei	Singapore
12.	Mrs THUY Nguyen Thi Thu	Vietnam
13.	Mrs THU Nguyen Bich	Vietnam

Special Member

1.	Dr Duc VU	Canada

Observers

1.	Ms HUANG Yasha	China
2.	Mr YU Jiandong	China
3.	Mr YU Jiangyong	China
4.	Dr Nobuo KAWAHARA	Japan
5.	Dr Noriaki KAWANO	Japan
6.	Dr Takashi HAKAMATSUKA	Japan
7.	Dr Sayaka MASADA	Japan
8.	Dr KIM Jonghwan	Korea
9.	Ms PARK Joohee	Korea
10.	Dr AHN Young Sup	Korea
11.	Mr KIM Dong Hyun	Korea
12.	Mr PANG Tit Keong	Singapore
13.	Dr GE Xiaowei	Singapore
14.	Ms Patricia NG	Singapore
15.	Ms CHUA Siew Wei	Singapore
16.	Mrs NGUYEN Thi Phuong Mai	Vietnam
17.	Mrs PHUONG Nguyen Thi Lan	Vietnam
18.	Mr Van Hai PHAM	Vietnam
19.	Dr Eike REICH	CAMAG Laboratory, Switzerland
20.	Mr LIU Jie	United States Pharmacopeia Convention - China

I. Opening of the Meeting

1. The Chairperson, A/Prof Chan Cheng Leng, commenced the Meeting by extending a warm welcome to all participants. After that, the participants were invited to introduce themselves.

II. Adoption of Provisional Agenda

2. The provisional agenda was adopted by the participants with a minor change (please see ***Annex 1*** for the finalized agenda).

III. Nomination of Co-chairpersons

3. The nomination of Co-chairpersons was adopted (please see ***Annex 2*** for the list of Co-chairpersons).

IV. Standing Committee Meeting (Session 1)

Presentations of Regional/Country Reports Related to Latest Developments in Herbal Medicines

4 The Co-chairperson, A/Prof Chan Cheng Leng gave a brief introduction of Ms Trisha Garrett. As Australia had sent their regret that they were unable to participate in face-to-face meetings, a video presentation by Ms Garrett on "Australian Regulation of Complementary Medicines" was given. With no questions raised by the participants, the Meeting proceeded to the next agenda item.

5. Mr Wang Kuiran then invited Dr Duc Vu to share about the "Pharmacovigilance of Natural Health Products and Non-prescription Drugs in Canada". A/Prof Chan asked Dr Vu how Health Canada dealt with claims made on the products for post-market surveillance. Dr Vu explained that the indications and claims required substantiation by manufacturers. For low functional claims, information from literatures sufficed whereas for higher claims like chronic or serious diseases, companies needed to submit information such as clinical trials. Ms Hui Foong Mei sought clarification on the controls that Health Canada had for naturally occurring potent substances. Dr Vu clarified that Health Canada had requirements for Good Laboratory Practice, Good Manufacturing Practice and for potent herbal constitution, they would request information related to the chemical structure or purity of substance to be submitted to the licensing department. Ms Hui further queried if there were any establishment of tolerance limits for the

naturally occurring potent substances. Dr Vu replied that there were several tolerance limits for heavy metals, pesticides, microbial contamination and that Health Canada followed the World Health Organization (WHO) requirements for contaminants. Companies could also choose to follow certain pharmacopoeia standards such as those of the United States Pharmacopoeia or the European Pharmacopoeia.

V. Standing Committee Meeting (Session 2)

Presentations of Regional/Country Reports Related to Latest Developments in Herbal Medicines

6. After Mr Wang Kuiran's presentation on "Progress of TCM Regulation in China and Prospect of FHH", Dr Vu asked if there would be an English edition of the Chinese Pharmacopoeia 2015. Mr Wang clarified that they were working on the translation of the Chinese Pharmacopoeia 2015 and it would be published in late 2015 or early 2016. Dr Yukihiro Goda pointed out that the International Symposium would only be held every other year and not both years as mentioned by Mr Wang during his presentation. Dr Goda also asked if the English edition of the Chinese Pharmacopoeia 2015 could be sent to every member state. Mr Wang replied that they would consider sending a complimentary copy of the English edition to the FHH member states in 2016. Mr Yee Shen Kuan commended China for looking into the tightening of the Traditional Chinese Medicine (TCM) raw herbs control as China was the main exporter of TCM raw herbs. With regard to the Chinese and Western combination preparation as mentioned in the presentation, Mr Yee asked if it could be elaborated in greater detail. Mr Wang clarified that these products were evaluated based on clinical science and China would closely monitor the adverse drug reactions related to them.

7. For the next presentation, Ms Polly Chan shared with the Meeting on the topic "Progress Report on Regulation on Chinese Medicine in Hong Kong". Dr Goda sought clarification on the meaning of listed and registered Chinese Medicine Practitioner (CMP). Ms Chan explained that before the enactment of the Chinese Medicine Ordinance, there were many CMPs who did not receive formal education but had long history of practice. She also shared that there was a clause in the Ordinance stating that the practitioner could be a listed CMP if they had been practicing for more than 15 years. But for the newly trained CMPs, they had to go through the full registration to be a registered CMP. Ms Chan added that there were some Chinese Medicines that listed CMPs could not prescribe. In response to Dr Vu's question on the registration process of the CMPs in Hong Kong, Ms Chan explained that there was a statutory board to oversee the registration. The Chinese Medicine Board and a committee would recognize and assess the standard of the educational institutes and the courses that they offered. Dr Alice Wong further clarified that all the institutes recognized by the registration committee were also recognized by the State Administration of Traditional Chinese Medicine of the People's Republic of China (SATCM). Prof Fumiyuki Kiuchi queried on why the three diseases, namely stroke rehabilitation, acute lower back

pain and palliative care for cancer patient were selected for the integrative Chinese and Western Medicine (ICWM) service for in-patients in public hospitals. Ms Chan replied that this was a new pilot project for evidence-based diseases, and these three diseases were evaluated to be relatively evidence-based according to literature and normally people would apply TCM and Western medicinal theory to treat them. Mr Yee asked if the 8600 proprietary Chinese medicine (pCm) with "Notice of confirmation of transitional registration of pCm" had any certificate of registration. Ms Chan explained that the legal status of such pCm was the same as that with the registration license. They hoped to convert the 8600 transitional registration to fully registered pCm but that would take time and they did not want these pCm to lose the legal status. Mr Yee further queried on the validity period of the certificate of registration. Ms Chan replied that the registration license was valid for 5 years after which they needed to apply for renewal of the license.

8. Dr Goda was then invited to speak on "Pharmacopoeial Topics on Herbal Medicines in Japan from 2013 to 2014". Dr Seong Rack Seon commented that the range of amygdalin in the Tokakujokito extract from 38mg to 152mg was very wide. Dr Goda replied that the amount of amygdalin present depended on the manufacturing process. He added that the Japan Pharmacopeia took into consideration the range of amygdalin amount set by each manufacturer. Although the range set by each manufacturer was narrow, the compilation from all manufacturers resulted in the wide range.

9. After Dr Seong's presentation on "Recent Progress on Regulations of Herbal Medicines in Korea", Dr Goda sought clarification on the need to conduct purification testing for Cynanchi Wilfordii Radix. Dr Seong explained that as there were two species that were morphologically similar, it was necessary to conduct purification testing for identification.

VI. Standing Committee Meeting (Session 3)

Presentations on country / region report related to the latest development on herbal medicines

10. Ms Hui Foong Mei was invited to present on "Regulation of Complementary Health Products in Singapore and ASEAN Traditional Medicines & Health Supplements Harmonization – An Update". Dr Vu sought clarification on how Singapore dealt with false advertising of health products. Ms Hui explained that an advertising permit was required for Chinese Proprietary Medicines in Singapore. For Traditional Medicines and Health Supplements, companies would be requested to substantiate the claims with relevant data, for example, scientific papers. Currently, the type of data required to be submitted was not stipulated but the development of the Association of Southeast Asian Nations (ASEAN) guidelines on claims and claims substantiation for Traditional Medicines and Health Supplements would be used as reference. Dr Wong asked for the basis of setting the limits for the toxic heavy metals and what was the reference used. She also

questioned on whether there was any separate limits for children and adolescents. Ms Hui informed that Singapore was going to adopt the ASEAN harmonized limits for the toxic heavy metals which were referenced to the WHO standards. As for the limits for the pediatric population, Ms Hui explained that setting limits by concentration may not be a robust approach as compared to maximum daily intake limit approach and Singapore was in the process of reviewing these limits. Dr Vu commented that the setting of toxic heavy metal limits could be based on concentration of heavy metals, calculation of the level of intake, the reference dose or the amount of daily intake and the sensitivity in children must be taken into account for setting limits in children.

11. Mrs Nguyen Thi Phuong Mai then presented on 'Update and development of materia medica monographs to prepare for VP V publishing'. In response to Dr Goda's question on how the content of the reference substance was determined, Mrs Nguyen replied that it was by the High Performance Thin Layer Chromatography (HPTLC).

VII. Standing Committee Meeting (Session 4)

Report of Sub-committee I – Nomenclature and Standardization

12. The Chairman of Sub-committee I, Dr Nobuo Kawahara, invited Dr Noriaki Kawano to present on "Comparative studies on Japanese Pharmacopoeia and Hong Kong Chinese Materia Medica Standards". Prof Park So-Young clarified on the marker compounds for Radix et Rhizoma Glycyrrhizae documented in Hong Kong Chinese Materia Medica Standards. Ms Chan replied that as some of the marker compounds were studied many years ago, she would need to check on their accuracy.

VIII. Standing Committee Meeting (Session 5)

Report of Sub-committee II - Quality Assurance and Information

13. The Chairman of Sub-committee II, Dr Seong, invited Dr Kim Jonghwan to present on the "Update on FHH RMPM Establishment Guideline". Ms Chan commented that there might be a need to review if it was necessary to standardize Angelica gigas as this species was only found in Korea.

14. This was followed by Dr Eike Reich's presentation on "Quantitative High Performance TLC of RMPM to be used for Identification and Semi-quantitative Limit Tests".

15. For the next presentation, Prof Park So-Young presented on "Report for FHH Website Revitalization". Mr Yee commended Sub-committee II for revamping the website and also suggested that all member states to use the website for information exchange and updates. He also proposed for the information captured previously by Professor Il-Moo Chang be brought over to the new website and to amend the words "member countries" to "member states", which member states agreed. Prof Park clarified that there was a "2002" tab in the website and the information by Prof Chang from 2002 could be found under that tab. The Meeting also discussed on the number of users for each FHH member state as Prof Park mentioned that too many users might cause problems to the website. The Meeting agreed that a maximum of 5 users for each FHH member state.

IX. Standing Committee Meeting (Session 6)

Report of Sub-committee III - Adverse Drug Reactions

16. The Chairman of Sub-committee III, Mr Yu Jiandong, called upon Mr Liu Chun to present "ADR Monitoring & Technical Requirement for Registration of TCM in China". Prof Kiuchi asked if there was any difference in the document submission for the 9 registration categories. Mr Liu replied that the documents were different and added that from 2012 to 2014, there were about 20 approved combination preparations. Dr Goda queried on how many approved products were there in category 1 "Active ingredient obtained from plant, animal or mineral materials and its preparations that have not been marketed in China". Mr Liu clarified that currently 2 clinical trials were approved for that category. As Chinese medicinal preparations contained multiple ingredients, Ms Hui asked about the challenges that China faced in identifying the exact herb that would cause adverse events. Mr Liu replied that it was a difficult task to assess which ingredient in the preparation caused the adverse event so they would track all the history of drug usage and also revise the package insert contents if required. Ms Hui also asked about the trend observed in the modernization of Chinese medicine in China. Mr Liu explained that they placed equal importance on the TCM products and the modernized ones, and that both traditional and innovative products are encouraged. CFDA had different requirements for registration for TCM but for modernized TCM, the focus was on their modern medicinal theories, for example, additional research on claims and indications. Dr Goda sought clarification on whether China had any evidence to show that Berberine was carcinogenic. Mr Liu replied that they did not have any data on hand but would check with their colleagues again. Dr Vu commented that in theory, Health Canada would not accept any products known to be carcinogenic to animals as such products would be considered carcinogenic to humans. For example, products containing Aristolochic Acid would not be accepted as a precautionary measure, although there was no data to suggest the risk of carcinogenicity to humans. Ms Patricia Ng mentioned that it would be useful if there was available information on the interaction of Western drugs and TCM due to the common use of Western drugs and Chinese medicine in China. Mr Liu replied that they were reviewing the requirements, paying particular attention to the safety, quality, efficacy and the method of evaluation of the Western drugs and TCM herbal combination preparations. He mentioned that

China could share the information with FHH member states when they collected more information and conducted scientific analysis. Ms Ng further requested for the information not to be limited to Western drug and TCM herbal combination preparations but to also include the information on the interactions between Western drug prescriptions and TCM prescriptions. Mr Liu explained that they were currently putting warning and cautionary information, such as possible interactions with Western drugs, on the package insert of TCM preparations, especially for the TCM injections. Ms Ng further queried on whether it was possible to include the Western drug and TCM herbal interactions into the Chinese Pharmacopoeia. Mr Liu clarified that currently there was a series of relevant reference books on the guidance of how to use the herbs or medicine. In these books, they had indicated the contraindications of using a medicine with other herbs. Dr Seong asked Mr Liu what was the percentage of the adverse drug reactions that were caused by herbal medicine. Mr Liu shared that according to the 2013 adverse drug reaction monitoring report, about 17% of reactions were associated with TCM preparations and 83% with chemical drugs.

X. Standing Committee Meeting (Session 7)

Discussion on Achievements to Date and Future Work Plans

17. Secretariat shared on the achievements submitted by Australia, Hong Kong, Japan, Singapore and Vietnam. Ms Huang Yasha presented on China's achievements and proposed work plans. This was followed by discussion on future work plans proposed by China, Japan, Korea and Vietnam.

18. Member states had in principle agreed to the direction of the Meeting and also suggested that there should be a time slot allocated at the next Meeting to revisit the purpose of FHH Meetings and to further discuss and refine the work plans. The finalized work plans proposed by the FHH members for the next few years can be found in ***Annex 3***.

19. For the benefits of new representatives involved in FHH, Mr Yee Shen Kuan briefly described the history and progress of FHH and highlighted the role played by the World Health Organization (WHO) Western Pacific Region Office (WPRO) in establishing FHH. He said that though WHO WPRO was unable to send representatives to this Meeting, they had assured the Secretariat that they would continue to support and collaborate in future activities of FHH. Mr Yee encouraged the Meeting to continue keeping WHO WPRO informed on the progress and the work done by FHH members as FHH could contribute to improving the quality of traditional medicines in the region. With the restructuring of organizations, the change of personnel and environment over the years, Mr Yee urged all member states to relook at the future directions of FHH and make necessary adjustments from time to time in order to stay relevance.

20. Secretariat requested an update for the focal points for each member state and the chairpersons for each respective Sub-committees. The Chairpersons for the Sub-committees and focal points for each member state were confirmed as follows:

Sub-committee I	Chairperson: Dr Nobuo Kawahara
Sub-committee II	Chairperson: Prof So-Young Park
Sub-committee III	Chairperson: Prof Ma Shuangcheng
Australia	Focal Point: TGA International
Canada	Focal Point: Dr Duc Vu
China	Focal Point: Ms Huang Yasha
Hong Kong	Focal Point: Ms Polly Chan
Japan	Focal Point: Dr Takashi Hakamatsuka
Korea	Focal Point: Dr Kim Jonghwan
Singapore	Focal Point: Mr Pang Tit Keong
Vietnam	Focal Point: Mrs Nguyen Thi Phuong Mai

(Post-meeting note as of 19 Dec 2014: Australia has confirmed that the FHH focal point for Australia is Therapeutic Goods Administration (TGA) International.)

XI. Any Other Business

21. Dr Hakamatsuka proposed that the table of comparison of information on marker substances for China Pharmacopoeia, Japan Pharmacopoeia, Korea Pharmacopoeia and Hong Kong Chinese Materia Medica Standards as compiled by Sub-committee I be sent to WHO in view that WHO was developing a guideline for selecting marker substances of herbal origin for quality control for herbal medicines.

22. In response to Dr Hakamatsuka's proposal, China requested for Japan to send the previously compiled table of comparison to China for them to check if the information was in accordance to the new edition of the Chinese Pharmacopoeia.

23. Sub-committee II proposed for the adoption of the second draft of the RMPM guideline. In response to the proposal, Ms Chan asked what would happen after the second draft was adopted and also mentioned that they would like to look at the whole document as they did not

participate in the Sub-committee II Meetings. Sub-committee II explained that the second draft was not the final version and the guideline would be revised based on the opinions of the FHH member states. The Secretariat suggested that the guideline to be sent to the Secretariat for circulation to the focal points of FHH member states.

(Post-meeting note as of 5 Jan 2015: The second draft of the RMPM guideline was sent to all the focal points of the FHH member states and the FHH member states were required to reply Dr Kim Jonghwan directly.)

24. Sub-committee II also proposed another FHH member state to hold the Sub-committee II Meeting in 2015. Vietnam responded that they would check with the Vietnam Ministry of Health on the possibility of hosting the next Sub-committee II Meeting in Vietnam. Sub-committee II was agreeable and requested Vietnam to reply by email as soon as possible.

(Post-meeting note as of 5 Jan 2015: Vietnam had responded that they were unable to host the Sub-committee II Meeting in 2015. As such, Korea had suggested for the Meeting to be held in Rheinfelden, Switzerland. The Secretariat would be sharing information such as the venue and date to the focal points on Sub-committee II's behalf. However, participants would be required to contact the host country directly for travel arrangements and Korea, represented by Dr Kim Jonghwan, would liaise with the host country on logistics issues.)

25. Member states approved the nomination of China to be the co-ordinating member state as well as FHH Secretariat for the years 2015-2016. On behalf of FHH members, Mr Yee thanked China for hosting the Meetings in 2015 and 2016 and also the international symposium in 2016. Mr Yee also thanked Japan for agreeing in principle to host FHH Meeting in 2017-2018 and to Dr Goda and Prof Kiuchi for their past contributions to FHH as they would relinquish their current positions. In addition, the Meeting also looked forward to working with Dr Hakamatsuka, who would take over Dr Goda for future FHH related works.

XIII. Closing Remarks

26. A/Prof Chan Cheng Leng, chairperson of FHH term 2013 to 2014, delivered closing remarks to thank the members and observers for their commitment and contribution to make the Meeting a success.

27. As there was no other business, the Meeting concluded at 1230 hours on 26 Nov 2014.

Annex 1

Finalized Agenda for 12th FHH Standing Committee Meeting
25 November 2014 (Tuesday), PENINSULA.EXCELSIOR HOTEL

Time	Agenda Item
8:30 – 9:00 am	Registration
9:00 – 9:15 am	Welcome Remarks by Chairperson of FHH (Term 2013 – 2014) *Assoc Prof Cheng Leng CHAN;* *Deputy Group Director,* *Health Products Regulation Group,* *Health Sciences Authority, Singapore*
9:15 – 9:30 am	Introduction of Participants Adoption of Provisional Program Nomination of Co-Chairpersons
Standing Committee Meeting (Session 1) – Presentation of Regional/Country Reports Related to Latest Developments in Herbal Medicines Co-chairpersons: Assoc Prof Chan Cheng Leng and Mr Wang Kuiran	
9:30 – 9:50 am	**Australia** Australian Regulation of Complementary Medicines *Ms Trisha GARRETT;* *Head, Office of Complementary Medicines* *Therapeutic Goods Administration, Australia*
9:50 – 10:10 am	**Canada** Pharmacovigilance of Natural Health Products and Non-prescription Drugs in Canada *Dr Duc VU;* *Director, Marketed Biologics,* *Biotechnology and Natural Health Products Bureau,* *Marketed Health Products Directorate, Health Canada*
10:10 – 10:30 am	Photo-Taking
10:30 – 10:50 am	Tea Break
Standing Committee Meeting (Session 2) – Presentation of Regional/Country Reports Related to Latest Developments in Herbal Medicines Co-chairpersons: Dr Duc Vu and Mrs Thu Nguyen Bich	
10:50 – 11:10 am	**China** Progress of TCM Regulation In China and Prospect of FHH *Mr Kuiran WANG;* *Deputy Director-General,* *Department of Planning and Finance,* *China Food and Drug Administration, China*

11:10 – 11:30 am	**Hong Kong Special Administrative Region** Progress Report on Regulation on Chinese Medicine in Hong Kong *Ms Polly CHAN;* *Senior Pharmacist,* *Chinese Medicines Information and Research Section,* *Chinese Medicine Division, Department of Health, Hong Kong SAR*
11:30 – 11:50 am	**Japan** Pharmacopoeial Topics on Herbal Medicines in Japan from 2013 to 2014 *Dr Yukihiro GODA;* *Head, Division of Drugs, National Institute of Health Sciences,* *Ministry of Health, Labour and Welfare, Japan*
11:50 am – 12:10 pm	**Korea** Recent Progress on Regulations of Herbal Medicines in Korea *Dr Rack Seon SEONG;* *Director of Herbal Medicine Research Division,* *National Institute of Food and Drug Safety Evaluation,* *Ministry of Food and Drug Safety, Korea*
12:10 – 1:30 pm	Lunch
Standing Committee Meeting (Session 3) – Presentation of Regional/Country Reports Related to Latest Developments in Herbal Medicines Co-chairpersons: Ms Polly Chan and Dr Seong Rack Seon	
1:30 – 1:50 pm	**Singapore** Regulation of Complementary Health Products in Singapore and ASEAN Traditional Medicines & Health Supplements Harmonization – An Update *Ms Foong Mei HUI; Acting Director,* *Complementary Health Products Branch,* *Health Products Regulation Group,* *Health Sciences Authority, Singapore*
1:50 – 2:10 pm	**Vietnam** Update and Development of Materia Medica Monographs to Prepare for VP V Publishing *Mrs Thi Phuong Mai NGUYEN;* *Deputy Head,* *Pharmacopoeia Division,* *Vietnamese Pharmacopoeia and Formulary Centre,* *National Institute of Drug Quality Control, Vietnam* *Mrs Nguyen Thi Lan PHUONG;* *Deputy Head,* *Lab For Testing of Traditional Medicines and Medicinal Plants,*

	National Institute of Drug Quality Control, Vietnam
Standing Committee Meeting (Session 4) – Report of Sub-Committee I – Nomenclature and Standardization Co-chairperson: Dr Nobuo Kawahara	
2:10 – 2:40 pm	Comparative studies on Japanese Pharmacopoeia and Hong Kong Chinese Materia Medica Standards *Dr Noriaki KAWANO;* *Senior Researcher,* *Research Center for Medicinal Plant resources,* *National Institute of Biomedical Innovation, Japan*
2:40 – 3:00 pm	Tea Break
Standing Committee Meeting (Session 5) – Report of Sub-Committee II – Quality Assurance and Information Co-chairperson: Dr Seong Rack Seon	
3:00 – 3:30 pm	Update on FHH RMPM Establishment Guideline *Dr Jonghwan KIM;* *Deputy Director,* *Herbal Medicine Research Division,* *National Institute of Food and Drug Safety Evaluation*
3:30 – 4:00 pm	Quantitative High Performance TLC of RMPM to be Used for Identification and Semi-quantitative Limit Tests *Dr Eike REICH;* *Head of Laboratory,* *CAMAG Laboratory,Switzerland*
4:00 – 4:30 pm	Report for FHH Website Revitalization *Prof So-Young PARK;* *Professor, College of Pharmacy,* *Dankook University, Korea*
4:30 – 5:00 pm	Discussion
6:30 – 9:00 pm	FHH Dinner

26 November 2014 (Wednesday), PENINSULA.EXCELSIOR HOTEL

Time	Agenda Item
Standing Committee Meeting (Session 6) – Report of Sub-Committee III – Adverse Drug Reaction Chairperson: Mr Yu Jiandong	
9:00 – 10:30 am	ADR Monitoring & Technical Requirement for Registration of TCM in China *Mr Chun LIU;* *Principal Staff Member,* *Department of Drug and Cosmetics Registration,* *China Food and Drug Administration, China*
10:30 – 10:50 am	Tea Break
Standing Committee Meeting (Session 7) – Discussions on Achievements to Date and Future Workplans Chairperson: Mr Yee Shen Kuan	
10:50 – 11:20 am	Discussion – Other Matters Arising (Compilation of Members' Achievements to Date and Future Workplans) *Mr Tit Keong PANG;* *Head of Secretariat* *FHH (Term 2013 – 2014)*
11:20 – 11:50 am	Any Other Business
11:50 am – 12:10 pm	Closing Remarks by Chairperson of FHH (Term 2013 – 2014)
12:10 – 1:30 pm	Lunch

Annex 2

Finalized List of Co-chairpersons for Standing Committee Meeting Sessions

Session	**Co-chairperson(s)**
Session 1 – Presentation of Regional/Country Reports Related to Latest Developments in Herbal Medicines	Assoc Prof Chan Cheng Leng and Mr Wang Kuiran
Session 2 – Presentation of Regional/Country Reports Related to Latest Developments in Herbal Medicines	Dr Duc Vu and Mrs Thu Nguyen Bich
Session 3 – Presentation of Regional/Country Reports Related to Latest Developments in Herbal Medicines	Ms Polly Chan and Dr Seong Rack Seon
Session 4 – Report of Sub-committee I: Nomenclature and Standardization	Dr Nobuo Kawahara
Session 5 – Report of Sub-committee II: Quality Assurance and Information	Dr Seong Rack Seon
Session 6 – Report of Sub-committee III: Adverse Drug Reaction	Mr Yu Jiandong
Session 7 – Discussions on Achievements to Date and Future Workplans	Mr Yee Shen Kuan

Annex 3

Finalized 3-Year Workplan (2014-2016) proposed by FHH member states

	Lead Member State(s)	Sub-committee	Project/Activity/Task	Objectives	Expected Outcomes	Targeted Date of Completion
1)	China	III	Act as the next Chair country	Host the FHH standing committee meetings in 2015 and 2016; host the International Symposium in 2016		Nov-15 Nov-16
2)	China	III	Lead the discussion and adoption of a revised FHH ToR based on the basic operational document of FHH approved in 2002	To discuss and adopt a revised FHH ToR based on the basic operational document of FHH approved in 2002	Adopt revised FHH ToR	Nov-16
3)	China	III	Shift the focus of TCM risk assessment from post-marketing surveillance to pre-marketing surveillance	Continuously improve the marketing authorization and risk surveillance of TCM	Publish 3-5 guidelines	End of 2016
4)	China	II	Collaborate with other FHH members to research on standards of Chinese crude drugs	To jointly formulate 10-20 shared standards of Chinese crude drugs among FHH members	Jointly issue FHH shared standards for 5-10 common Chinese crude drugs	End of 2016
5)	Japan	I	New comparative studies on Pharmacopoeia and HKCMMS	Mutual understanding of Pharmacopoeial descriptions among member countries	Preparation of new "Comparative studies on Pharmacopoeial definitions requirements and information for crude drugs among FHH member countries"	2016
6)	Japan	I	Clean Analysis on TLC	Harmful solvent free	JP, CP, KP, VP and HKCMMS	2016
7)	Korea	II	FHH RMPM Project	To report the revised draft guideline and revitalised FHH website		2014
8)	Korea	II	FHH RMPM Project	To suggest the introduction of decision-making process to obtain practical performances like ISO		2014
9)	Korea	II	FHH RMPM Project	To complete FHH RMPM guideline, distribution protocol and establish the 1st FHH RMPM, Angelica gigas including A.acutiloba, A.sinensis		2015
10)	Korea	II	FHH RMPM Project	To establish other RMPM continuously, NLT 2 items		2016
11)	Vietnam	I	Join the FHH RMPM establishment.	Reach a consensus on technical guideline for establishing FHH RMPM.	Conduct the collaborative study to ensure the reliability of the results of chemical tests (TLC, GC, HPLC).	2014-2017
12)	Vietnam		Inform and share research result or detection of adulteration in crude drugs and the problems in quality control.	Provide information to Subcommittee II to the up load to the FHH website	Official information are public in VN	Every time

（別紙 2）

Western Pacific Regional
Forum for the Harmonization of Herbal Medicines (FHH)
5th International Symposium

PROGRAMME

27 November 2014 (Thursday), HSA OUTRAM AUDITORIUM

Time	Agenda Item
8:30 – 9:00 am	Registration
9:00 – 9:15 am	Welcome Remarks *Asst Prof Raymond CHUA,* *Group Director, Health Products Regulation Group,* *Health Sciences Authority, Singapore*
Session 1: Pharmacovigilance and Challenges of Herbal Medicines ***Facilitator: Mr Yu Jiandong***	
9:15 – 9:30 am	Pharmacovigilance of Natural Health Products in Canada Case Studies: 1) Ibogaine use in Detoxification and 2) Melatonin use in Pediatric Patients *Dr Duc VU,* *Director, Marketed Biologics,* *Biotechnology and Natural Health Products Bureau,* *Marketed Health Products Directorate, Health Canada*
9:30 – 9:45 am	Adulterated Sexual Performance Enhancers with PDE-5 Inhibitors and Their Analogues *A/Prof Hwee-Ling KOH,* *Department of Pharmacy,* *National University of Singapore*
9:45 – 10:00 am	Adulteration and Authentication of Herbal Medicines *Dr Chee Leong KEE,* *Senior Analytical Scientist, Pharmaceutical Laboratory,* *Pharmaceutical Division, Applied Sciences Group,* *Health Sciences Authority, Singapore*
10:00 – 10:30 am	Q&A
10:30 – 10:45 am	Photo-Taking
10:45 – 11:15 am	Tea Break

Session 2: Quality Control of Herbal Medicines and Developments in Regulation ***Facilitator: Dr Seong Rack Seon***	
11:15 – 11:30 am	Research and Development of TCM Quality Control Standard *Mr Jiangyong YU,* *Deputy Division Director* *Chinese Pharmacopoeia Commission,* *China Food and Drug Administration, China*
11:30 – 11:45 am	Hong Kong Chinese Materia Medica Standards (HKCMMS) *Ms Polly CHAN,* *Chinese Medicine Division,* *Department of Health, Hong Kong SAR*
11:45 – 12:00 pm	Regulation of Chinese Medicine in Hong Kong *Dr Alice WONG,* *Chinese Medicine Division,* *Department of Health, Hong Kong SAR*
12:00 – 12:15 pm	Comparison between Chinese and Western Approaches to Medicine *Prof Alex LAW,* *Director of Biomedical Sciences and Chinese Medicine,* *School of Biological Sciences,* *Nanyang Technological University, Singapore*
12:15 – 12:30 pm	Global Herbal Medicines Standard Initiative by United States Pharmacopeia *Mr Jie LIU,* *Standards Acquisition,* *United States Pharmacopoeia, China*
12:30 – 1:00 pm	Q&A
1:00 – 2:00 pm	Lunch
Session 3: Developments in Analysis of Herbal Medicines – Part I ***Facilitator: Ms Polly Chan***	
2:00 – 2:15 pm	Preparation and Testing of TCM Reference Materials *Mr Jiandong YU,* *Chief Pharmacist, Institute for Control of Chinese Traditional Medicine and Ethnic Medicine,* *National Institutes for Food and Drug Control,.* *China Food and Drug Administration, China*