37. Prof. **Zhao** Zhong-zhen enquired on the popularity of the newly added monographs including Ganodema and Herba Andrograpii. Ms. **Nguyen** stated that the these herbs were very popular in Vietnam.

38. Prof. **Lin** Ruichao asked if there was difference in the use of herbs between Northern part and Southern part of Vietnam. Ms. **Nguyen** answered that the herbs from both areas were the same.

39. The Co-chairperson, Dr. Yukihiro **Goda** (Japan) invited Dr. Duc **Vu** from Canada to present the update on the Regulation of the Natural Health Products in Canada.

40. Ms. **Lee** Puey Ngee asked about the details of Natural Health Product (unprocess product license application) regulation programme (UPLAR) Dr. **Vu** explained that all products sold in Canada should either have the Drug Identification Number (DIN) for drugs or the Natural Product Number (NPN) for natural health products (NHPs). Exemption number would also be given to NHPs that awaiting for final product licensing decision but those products must be of low risk type of products. With such exemption number, they could be sold in the market legally.

41. Dr. Yukihiro **Goda** enquired on the pharmacovigilance system of natural health products in Canada. Dr. **Vu** replied that there was a comprehensive framework of pharmacovigilance in Canada. There was a national system to collect the ADR reports. The manufacturers had legal responsibility to report any ADR that they received. There was also a spontaneous ADR reporting system for the healthcare providers. The number of reports on NHPs was small when compared to the number of reports on conventional medicine.

42. Prof. **Zhao** Zhong-zhen enquired about the type of reference that had been accepted and used in Canada. Dr. **Vu** stated that they were using USP and sometimes BP as references for drugs. For NHPs, recognized reference were being used, e.g. those reputable sources of pharmacopoeia.

43. The Co-chairperson, Ms. **Burnett** invited Dr. Narantuya **Samdan** from WHO to present the new developments and the recent

publications in herbal medicines to FHH members.

44. The Chairman, Dr. **Lam** Ping-yan suggested the members could convey the comment on the strategic development of herbal medicine in the Pacific region in the AOB session. Dr. **Samdan** responded that working groups were set up to look at the development on the strategy document on safety and efficacy of the traditional medicine especially on herbal medicines. Dr. **Samdan** welcomed the comments from the members of FHH on the main direction and main challenges of the traditional medicine. All members agreed.

45. Dr. **Kang** Shinjung raised concern on the safety and quality of herbal medicine such as limits for heavy metals in herbal medicines. Dr. **Samdan** responded that the WHO would provide various guideline for proper using of herbal medicine. The member country might take reference to various WHO guideline and devise their own policy accordingly.

46. Ms. **Tan** Mui Mui, Belinda raised concern on the new coding system for herbal medicines for the reporting of adverse event. Dr. **Samdan** responded that there was a project on the international classification in traditional medicines which aimed to harmonize the terminology used in traditional medicines. The project was just commenced and further working group meeting would be held in Japan and Manila.

47. Mr. **Yee** Shen Kuan appreciated Dr. **Samdan**'s sharing on the WHO regional strategy for traditional medicine as FHH mainly consisted of regulator and academia. Dr. **Samdan** also appreciated that she could have a clear understanding on the regional concern of herbal medicines in this meeting.

48. Prof. **Zhao** Zhong-zhen raised concerned on the time-table of drafting the good processing guideline on herbal medicine. Dr. **Samdan** replied that this project was still going on and she welcomed Prof. **Zhao** to contact the headquarter for any input.

49. Ms. **Lee** Puey Ngee questioned on the main difference of focus and strategic direction of WHO for this decade and the next decade. Dr.

Samdan reaffirmed that she was not able to comment as they were still working on certain global survey, but the strategy should be evidence-based and should focus on the safety of traditional medicine.

50. The Chairman thanked all speakers for providing informative presentations and announced to close the Day-1 meeting.

VIII. Standing Committee Meeting (Session 5)

Report of Sub-committee I - Nomenclature and Standardization

51. The Chairman, Dr. **Lam** Ping-yan invited Dr. Yukihiro **Goda**, Chairman of Sub-committee I, to report the progress of work. On behalf of Sub-committee I, Prof. Fumiyuki **Kiuchi** from Japan presented the re-investigation of Crude Drug Identification Tests by TLC to FHH members.

52. Dr. **Goda** supplemented that in JP, the development length of TLC was recommended to be 10cm. In some cases, the development length of TLC for individual monograph could be changed to 7cm if necessary.

53. For VP, the recommended development length of TLC was 12cm. For CP, Prof. **Lin** Ruichao responded that the recommended development length of TLC should depend on individual compound. For Hong Kong, Mr. Robert **Law** responded that 10cm was recommended for the HKCMMS Project. Prof. **Chang** Il-moo expressed that the price of analysis was an important issue for consideration. Dr. **Goda** also indicated that the running time required was another important factor to consider.

54. The Chairman of Sub-committee I, Dr. **Goda** invited Dr. **Kim** Jiyeon from Korea to present the progress on the adoption of green chemistry analysis in Korea. Dr. **Kim** highlighted the activity done on clean analysis in Korea such as avoided using of harmful solvent for TLC Identification Test of herbal medicine.

55. Dr. **Goda** asked if the publication in Korean Journal was in English or Korean and he suggested sending the useful information to all

other members. Prof. **Chang** Il-moo replied that the information was in Korean but they could translate it into English and upload it on the FHH website.

56. Prof. **Zhao** Zhong-zhen questioned on the details of Korean Herbal Pharmacopoeia (KHP). Dr. **Kang** shinjung clarified that some of the popular herbs might be included in KP instead of KHP for example the Korean Ginseng which included both White and Red Ginseng, was covered in KP but not in KHP. Prof. **Chang** supplemented that the English version of KHP was available and would send a copy to members for reference.

57. Prof. **Kiuchi** commented on the solvent system of Bupleurum root and suggested that to harmonize the analytical method among Korea , China and Japan.

58. Dr. **Goda** invited the second speaker, Dr. **Ma** King-wah from Hong Kong, to present the progress on the adoption of green chemistry analysis in HKCMMS. Dr. **Ma** King-wah presented green chemistry approach in the development of HKCMMS.

59. For the request of HKCMMS copies from Ms. **Luc** Thi Thu Hang, Dr. **Ma** indicated that both hardcopies and softcopies in CD could be provided. The HKCMMS could also be downloaded from DH website.

IX. Standing Committee Meeting (Session 6)

Report of Sub-committee II - Quality Assurance and Information

60. The Chairman, Dr. **Lam** Ping-yan invited Prof. **Chang** Il-Moo, Chairman of Sub-committee II, to report the progress of work. On behalf of Sub-committee II, Prof. **Kim** Yeongshik reported the systematic strategy for standardization of herbal medicine in Korea.

61. Prof. **Zhao** Zhong-zhen stated that it was very important to confirm the source of the plant material before the study of herbal medicine could be done. Prof. **Zhao** also appreciated that the well development of the herbal cosmetics industry in Korea and would like to know more about its regulations. Prof. **Kim** explained that the herbal

cosmetic was classified as medicinal cosmetics in Korea and the regulation would be relative relax when compared with medicines.

62. The Chairman of Sub-committee II, Prof. **Chang** invited Dr. Duc **Vu** to present the NHP Program in Canada. The speaker highlighted the details of Health Products and Food Branch Inspectorate.

63. Before the end of session, Prof. **Chang** demonstrated how to operate the FHH website which facilitated the exchange of information among FHH members.

64. The Chairman, Dr. **Lam** thanked Prof. **Chang** for the substantial effort on the development of FHH website and the continuous support of FHH.

X. Standing Committee Meeting (Session 7)

Report of Sub-committee III - Adverse Drug Reactions

65. The Chairman, Dr. **Lam** Ping-yan reported that Prof. **Jin** Shao Hong, the Chairman of Sub-committee III retired from SFDA. Therefore, Dr. **Zhou** Jie Ming was nominated as the new Chairman for Sub-committee III. All members agreed on the nomination. Dr. Zhou then reported the sub-committee III activity and introduced the ADR monitoring system in China to FHH members.

66. The Chairman of Sub-committee III, Dr. **Zhou** invited Prof. **Zhao** Zhong-zhen to present a working report on Chinese medicinal processing which was a unique issue in the standardization of Chinese Materia Medica.

67. Dr. **Zhou** then invited Ms. **Puah** Swee Lin from Singapore and Dr. Sally **Wei** from Hong Kong to report the alert system for adulterated herbal medicines.

68. Dr. Yukihiro **Goda** supported that the trial run of alert system for the past one year was successful and proposed to continue as permanent reporting system in FHH. FHH members supported the proposal.

XI. Any Other Business

Comment on Traditional Medicines Strategy of WHO

69. The Chairman, Dr. **Lam** Ping-yan invited the members to comment on the traditional medicines strategy of WHO.

70. Dr. Narantuya **Samdan** suggested the members could emphasize on the important issues on traditional herbal medicines, identify the main challenges facing in the region, and actions to be taken for the challenges so that she could reflect the comment to the expert meeting in Nov.

71. Mr. **Yee** Shen Kuan stated that WHO already came out with detail direction, challenges and good approach on the strategy on herbal medicines, and he raised out the following points for consideration:-

- Whether the country level indicator served as a guideline which the country could devised their own indicator, or it was a mandatory requirement for all countries to follow;

- WHO could co-ordinate and align the different international platforms, e.g., IRCH and FHH so as the effort would not be duplicated;

- WHO work plan might consider to keep as separate track

72. Dr. Narantuya **Samdan** replied that the strategy document should be a guideline and individual country could devise their own strategic plan according to their situation.

73. To end the discussion, the Chairman, Dr. **Lam** recommended the members sending their further comment or suggestion to Dr. **Samdan** for consolidation.

74. Dr. **Samdan** also invited the members to provide contributions and expert ideas and sharing of knowledge in order to provide safe and efficacious herbal medicines.

Establishment of linkage with International Regulatory Cooperation for Herbal Medicines (IRCH)

75. The Chairman, Dr. **Lam** Ping-yan recapped the members that there was a discussion on whether it was appropriate for FHH to join IRCH as a member in last meeting and should keep in view on this issue.

76. Prof. **Chang** Il-moo responded that many regulatory agents of the FHH members' countries/regions were already members of IRCH and linkage with IRCH had already been established. The resources might overlap if FHH joined as a member of IRCH.

77. Prof. **Lin** Ruichao agreed that FHH could collaborate with IRCH by being an observer rather than a member. Dr. Yukihiro **Goda** echoed to Prof. **Lin**'s suggestion.

78. Mr. **Yee** Shen Kuan stated that Singapore being the members of both parties, he agreed that it was important to maintain the linkage between FHH and IRCH in order to know the current issues of other parties and he was opened in this issue. He opined that further information might be sought before making the decision.

79. Ms. **Luc** Thi Thu Hang and Ms. Jennifer **Burnett** shared the same with Mr. **Yee** Shen Kuan.

80. To make a conclusion, the Chairman, Dr. **Lam** clarified that FHH was a forum for different countries/regions to share the experience and information of harmonized practices in herbal medicines. It was not a legal entity for FHH to be enrolled as a member of IRCH. Nevertheless, as agreed by all members, it was important to strengthen the linkage and enhance the cooperation between FHH and IRCH. FHH should attend the IRCH meeting in the capacity of observer.

Appointment of the next member party for coordinating FHH and FHH Secretariat

81. The Chairman, Dr. **Lam** Ping-yan stated that a rotating coordinating member system was being used for holding the Standing Committee Meeting and its operations for a term of two years. According to the past records, members of China, Japan, Korea and Hong Kong took up the role of coordinating party for the past 8 years. As Singapore had already agreed to take up the role for the period of 2012-2014, Dr Lam therefore invited Australia or Vietnam to be the coordinating member party of 2011-2012.

82. Ms. Jennifer **Burnett** thanked for the invitation from Chairman. She explained that the budget of TGA for 2011 had already been set and submitted. It was difficult for Australia to commit for being the next coordinating party.

83. Ms. **Luc** Thi Thu Hang replied that she would seek approval from the government of Vietnam. (post-meeting notes: Ms. **Luc** Thi Thu Hang informed FHH secretary that the government of Vietnam agreed to take up the coordinating role for the coming two year)

84. Prof. **Lin** Ruichao thanks the contribution of Department of Health, Hong Kong as FHH secretary for the past few years. He also recommended Hong Kong continuing to be the Secretariat of FHH. Prof. **Chang** Il-moo concurred with the recommendation.

85. The Chairman responded that they should further discuss whether Hong Kong would take up the role of FHH Secretariat on permanent or ad-hoc basis.

Other related issues

86. Dr. Yukihiro **Goda** stated that the work of Sub-committee I was financially funded by the Ministry of Japan and all related data and information was uploaded on FHH website. In this regards, Dr. **Goda** would like to seek the permission to share those information in their website. All members agreed on this issue.

87. Prof. **Chang** Il-moo said he was retiring and therefore nominated Dr. **Kang** Shinjung to take up the role of Chairman for Sub-committee II. All members agreed.

88. Dr. Narantuya **Samdan** suggested that FHH should further strengthen the linkage with other countries in WPRO and exchange the information of herbal medicine to other countries such as Malaysia and Laos.

XII. Closing Remarks

90. The Chairman, Dr. **Lam** Ping-yan delivered a closing remark to thank the members for the commitment and contribution to make the meeting a fruitful one.

91. There being no other business, the meeting was closed at 13:00 on 29 October 2010.

**** END OF MEETING ****

The 4th FHH International Symposium

Regulation and Research of Herbs and Herbal Products

Chairman of Standing Committee : Dr. P.Y. Lam (pylam@dh.gov.hk)
Secretariat : Mr. Robert Law and Mr. Peter J See Molina (fhh_secretariat@dh.gov.hk)

Provisional Programme
for the 4th FHH International Symposium (with Poster Session)

Date: 30 October 2010 (Saturday)

Venue: Harbour Grand Hong Kong Hotel
MTR Fortress Hill Station, Exit A
23 Oil Street
North Point, Hong Kong

- 4th FHH International Symposium (08:30 – 17:30 hours)
  Grand Ballroom 2, 1/F
- Poster Presentation (09:00 – 17:00 hours)
  Grand Ballroom 1, 1/F

Language: English

Organizer: Department of Health, Hong Kong, China

Provisional Programme

Date	Time	Contents
	08:30 – 09:00	**Registration**
	09:00 – 09:05	**Opening Ceremony** • Welcome address by Chairman of FHH *(Dr. Ping-yan **Lam**, Director, Department of Health, Hong Kong, China)* • Opening address by WHO Representative *(Dr. Narantuya **Samdan**, Regional Adviser in Traditional Medicine, WHO Regional Office for the Western Pacific)*
	09:05 – 09:15	**Group Photo**
	09:15 – 09:30	Touring of **Poster Display**
	09:30 – 09:45	**Coffee Break**

Date	Time	Contents
	Session 1: Keynote Speech	
	09:45 – 10:15	• WHO Position and New Trends in Traditional Herbal Medicines *(Dr. Narantuya **Samdan**, WHO)*
	Session 2: Quality Assurance of Herbal Medicines	
	10:15 – 10:45	• Introduction of New Chinese Pharmacopeia *(Prof. Ruichao **Lin**, China)*
	10:45 – 11:15	• Scientific Study on Standardization of Herbal Medicine *(Prof. Yeongshik **Kim** , Korea)*
30 October 2010	**Session 3: Pharmacovigilance**	
	11:15 – 11:45	• MHPD Post-Market Surveillance: Natural Health Products *(Dr. Duc **Vu**, Canada)*
	11:45 – 12:15	• Risk Detection in Health Products Regulation *(Ms. Belinda **Tan**, Singapore)*
	12:15 – 13:45	**Lunch Break**
	Session 4: Regulation and Research	
	13:45 – 14:15	• Perspectives on the Current Regulation and Research on Herbs/Botanicals in the USA *(Prof. Harry **Fong**, IAB Member)*
	14:15 – 14:45	• Regulation and Research of Herbal Medicine *(Prof. Kelvin **Chan**, IAB Member)*
	14:45 – 15:15	• Regulation and Research of Herbal Medicines: Challenges and Opportunities *(Prof. David **Briggs**, IAB Member)*

Date	Time	Contents
	Session 5: Efficacy of Herbal Medicines	
	15:15 – 15:45	• Quality issues in the regulation of herbal mediciens in Australia *(Ms Jennifer **Burnett**, Australia)*
	15:45 – 16:15	• Chinese Medicinal Processing: A Unique Issue in the Standardization of Chinese Materia Medica *(Prof. Zhongzhen **Zhao**, Hong Kong, China)*
	16:15 – 16:30	**Coffee Break**
30 October 2010	**Session 6: New Technology for Research and Quality Control**	
	16:30 – 17:00	• Evaluation of Taste of Kampo Formulae and Crude Drugs by a Taste-Sensing System *(Prof. Nobuo **Kawahara**, Japan)*
	17:00 – 17:30	• Determination aristolochic acid A in some medicinal plants belonging to family (Aristolochiaceae) *(Dr. Minh Ngoc **Tran**, Vietnam)*
	17:30 – 17:45	**Closing**

研究成果の刊行に関する一覧表

原著論文

発表者氏名	論文タイトル名	発表誌名	巻、号	ページ	出版年
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Hosoe, J. 他	Trial study to determine absolute purities of chemical reagents used as reference standards in Japanese Pharmacopoeia by using quantitative NMR (qNMR)	Pharmaceutical and Medical Device Regulatory Science	41(12)	960-970	2010
Amakura, Y. 他	TLC-based identification test for the crude drug "Salviae miltriorrhizae Radix" and "Codonopsitis Radix"	Jpn. J. Pharmacog.	65(1)	18-24	2011
Kiuchi, F. 他	Crude drug identification tests with TLC in the Japanese Pharmacopoeia (1), On the TLC tests with 1-butanol/water/acetic acid solvent system	Jpn. J. Pharmacog.	65(1)	25-32	2011
Anjiki, N. 他	Evaluation of the taste of crude drug and Kampo formula by a taste-sinsing system (4) : taste of Processed Aconite Root	J. Nat. Med.	65(2)	293-300	2011
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Kawahara, N.	Recent Progress of International Harmonization of Crude Drugs and Medicinal Plants-Activity of FHH (The Western Pacific Regional Forum for the Harmonization of Herbal Medicines)	Yakugaku Zasshi	131(3)	383-393	2011
袴塚高志	漢方処方エキスの局方収載と一般用漢方処方承認基準の見直し	ファルマシア	48(5)	413-418	2011

単行本

著者氏名	タイトル名	編集者名	書籍名	出版社名	出版地	出版年	ページ
合田幸広・袴塚高志		日本漢方生薬製剤協会	改訂一般用漢方処方の手引き 平成22年4月1日通知（加減方追加）対応追補版	じほう	東京	2010	1-71