Members :

Dr. **Lam** Ping-yan (Hong Kong, China) **(The Chairman)**
Dr. Narantuya **Samdan** (WHO Regional Office for the Western Pacific)
Mr. Michael **Smith** (Australia)
Dr. Michael **Dodson** (Australia)
Dr. **Yang** Sheng (China)
Prof. **Lin** Rui Chao (China)
Dr. **Ting** Tai-lun (Hong Kong, China)
Dr. Yukihiro **Goda** (Japan)
Prof. Fumiyuki **Kiuchi** (Japan)
Prof. **Chang** Il-Moo (Korea)
Dr. **Chang** Seungyeup (Korea)
Mr. **Yee** Shen Kuan (Singapore)
Ms. **Lee** Puey Ngee (Singapore)
Dr. **Nguyen** Van Tuu (Vietnam)
Mr. **Nguyen** Tuan Anh (Vietnam)

Special Member

Dr. Duc **Vu** (Canada)

Observers

Prof. **Jin** Shao Hong (China)
Dr. **Chen** Yi Xin (China)
Dr. Gloria **Tam** (Hong Kong, China)
Dr. **Chiu** Pui-yin, Amy (Hong Kong, China)
Dr. **Chui** Kuk-ying (Hong Kong, China)
Mr. **Chan** Ling-fung (Hong Kong, China)
Dr. Nobuo **Kawahara** (Japan)
Dr. Lida **Teng** (Japan)
Dr. **Park** Juyoung (Korea)
Dr. **Kang** Shinjung (Korea)
Dr. **Lee** Hyomin (Korea)
Dr. **Kim** Jinsook (Korea)
Mr. **Choi** Bangseob (Korea)
Ms. **Puah** Swee Lin (Singapore)

I. Opening of the Meeting

The Chairman commenced the meeting by extending a warm welcome to all participants and then invited Dr. Narantuya **Samdan** to deliver an opening address. After that, the Chairman invited the participants to introduce themselves.

II. Adoption of Provisional Programme

2. The revised provisional programme distributed to the participants in the meeting was adopted.

III. Nomination of Co-chairpersons and Rapporteurs

3. The nomination of Co-chairpersons and Rapporterurs was accepted by acclaim. For details please refer to Annex 1.

IV. Standing Committee Meeting (Session 1) Presentations on the latest progress on regulation of herbal medicines

4. The Co-chairperson, Dr. Duc **Vu** (Canada) invited Mr. Michael **Smith** from Australia to present the Regulation of Herbal Medicines in Australia. The speaker highlighted the Australian regulatory framework for Chinese medicines.

5. Dr. Yukihiro **Goda** asked Mr. **Smith** about the details of life cycle approach and risk assessment of herbal medicine. Mr. **Smith** replied that Australia had a risk-based system. Less stringent pre-markerting control would be given to products of lower risk. On the other hand, there was a stringent pre-marketing and post-marketing control to those products of high risk.

6. Ms. **Lee** Puey Ngee asked about the approach to deal with the combination product in Australia. Mr. **Smith** replied that the combination product might fall into the complementary medicine, non-prescription medicine and prescription only medicine with different regulatory requirements. He also highlighted that a new regulatory framework for homeopathic medicine was under establishment.

7. Dr. Gloria **Tam** asked about the evidences of registration of Chinese medicines with respect to efficacy. Mr. **Smith** responded that the sponsor should provide evidence such as conducting clinical trial to support medicinal claims of the product.

8. The Co-chairperson, Dr. **Vu** (Canada) invited Dr. **Yang** Sheng, China to present the recent progress in Regulation of Traditional Chinese Medicines (TCMs) in China. The speaker highlighted the progress of drug registration of TCMs as well as the introduction of Chinese Pharmacopoeia 2010.

9. Dr. **Goda** asked what type of crude drug would be subjected to the DNA molecule identification. Prof. **Lin** Rui Chao shared that this technique was currently applied on toxic animal drug. Dr. **Goda** agreed this technique was useful to identify the crude herbs but the testing cost was relatively high. Prof. **Lin** concurred with the opinions of Dr. **Goda**.

10. Dr. **Park** Juyoung asked what kind of the safety test items would be included in the new edition of CP 2010. Prof. **Lin** replied that pesticides residues, aflatoxin and heavy metal were included. In addition, he indicated that the study of heavy metal in crude herbs had been completed. Such information would be included in CP 2010 which would be published next year.

11. The Co-chairperson, Mr. **Yee** Shen Kuan (Singapore) invited Dr. **Chiu** Pui-yin, Amy from Hong Kong to present the update on the regulatory control of Chinese medicines in Hong Kong. The speaker highlighted the licensing of Chinese medicine traders, registration of proprietary Chinese medicines and the progress of Hong Kong Chinese Materia Medica Standards project.

12. Ms. **Lee** asked about the details and arrangement of transitional registration. Dr. **Chiu** replied that those proprietary Chinese medicines (pCm) under the transitional registration arrangement should be subjected to its safety evaluation in order to safeguard public health. Eventually, the quality and efficacy of pCm would be assessed before obtaining the full registration status.

13. Prof. **Chang** Il- Moo questioned whether the products registered in China could be sold in Hong Kong without going through the registration process requested by the regulatory authority of Hong Kong. Dr. **Chiu** responded that any pCm imported to or sold in Hong Kong should be registered in accordance with the Chinese Medicine Ordinance. Prof. **Lin** supplemented that any pCm imported from Hong Kong to China for sale should be registered in SFDA without exemption.

14. The Co-chairperson, Mr. **Yee** (Singapore) invited Dr. **Goda** from Japan to present Pharmacopoeial topics on herbal medicines in Japan from 2008 to 2009. The speaker highlighted the updated topics of Japan pharmacopeia (JP) to FHH members.

15. Prof. **Jin** Shao Hong asked what kind of analytical techniques would be found in JP. Dr. **Goda** replied that the HPLC and GC techniques applied on the assay of the active ingredient in crude drug would be found in JP. In addition, some advanced techniques like LC-MS might also be useful for testing of crude drugs. However, the cost of testing was relatively high comparing with conventional techniques like HPLC.

16. Dr. **Goda** also highlighted that the purity and identification of chemical markers could be checked by various methods such as Nuclear Magnetic Resonance (NMR).

17. Prof. **Chang** asked about the progress of clinical study of herbal medicine in Japan. Dr. **Goda** replied that randomized double blind clinical trial had been conducted on six extracts found in JP. Furthermore, he indicated that the cost of trial study was relatively high.

V. Standing Committee Meeting (Session 2)
Presentations on the latest progress on regulation of herbal medicines

18. The Co-chairperson, Prof. **Jin** Shao Hong (China) invited Dr. **Kang** Shinjung and Dr. **LEE** Hyomin from Korea to present the Recent Progress on Regulation of Herbal Medicine in Korea and Risk Assessment to Suggest the New Limits for Cadmium in Herbs respectively. The speakers highlighted the system on Regulation of Herbal Medicine and the principle to set Cadmium limit of herbal

materials in details.

19. Prof. **Lin** Rui Chao raised the concern on setting limit for cadmium as it might be naturally occurred in some herbal materials. In view that cadmium content varies in different parts of a plant, Dr. Yukihiro **Goda** indicated that proper sampling method with adequate sample size was essential to reflect the actual contaminant level of crude drug without bias. On the other hand, the variation of the heavy metal level within the extractive was relatively small (due to the homogeneity of the sample).

20. Prof. **Lin** also shared his experience on various testing techniques of heavy metals like Inductively coupled plasma mass spectroscopy (ICP-MS) and Atomic Absorption (AA). He opined that the limit of cadmium for herbal materials should be subjected to regular review and revision when necessary.

21. The meeting also agreed that cross-checking of heavy metal in herbal materials might be considered on a need basis within the member parties.

22. The Co-chairperson, Prof. **Jin** (China) invited Mr. **Yee** Shen Kuan from Singapore to present the update on the regulation of Complementary Health Products in Singapore (November 2008 to November 2009). Mr. **Yee** highlighted the regulatory framework of herbal medicine to FHH members.

23. Dr. **Goda** asked about the details of post-marketing control of herbal medicine in Singapore. Mr. **Yee** replied that inspectors from HSA were going round to take samples and sending for testing base on risk-based approach. Currently, HSA focused on those products with greater impact on consumers. In addition, some products were required to be tested before marketing in Singapore.

24. Dr. Michael **Smith** asked about the timeline for the ASEAN framework to be implemented. Mr. **Yee** indicated that they were moving towards this goal step by step at this moment.

25. The Co-chairperson, Dr. **Ting** Tai-lun (Hong Kong) invited Mr. **Nguyen** Tuan Anh from Vietnam to present Status of Herbal medicines and Crude drugs in Vietnamese and Study of isolation and purification of

ten chemical standards for Herbal Product Quality Control and then invited Dr. Duc **Vu** from Canada to present the overview of the Natural Health Products Regulations in Canada.

26. The Co-chairperson thanked the speakers for providing informative presentations and called the morning session to the end.

VI. Standing Committee Meeting (Session 3) Presentations on the issue related to adulteration of "western drug" in herbal medicines

27. The Co-chairperson, Prof. **Chang** Il-Moo (Korea) invited Dr. Michael **Dodson** from Australia to present the Adulteration of Herbal Medicine: an Australian Perspective.

28. Prof. **Jin** Shao Hong asked how many samples were tested in Australia. Dr. **Dodson** replied that 600 samples were tested per year.

29. Prof. **Lin** Rui Chao asked how ADR was differentiated from ADE. Dr. **Dodson** recapped that the topic was discussed in the Dalian meeting in Sept, 2009 and further discussion would be conducted in future.

30. The Co-chairperson, Prof. **Chang** (Korea) invited Prof. **Lin** from China to present the issues on the adulteration of western drug in Chinese herbal medicines.

31. Dr. Duc **Vu** asked what type of testing methods would be deployed to identify the drug analogue in adulterated product. Prof. **Lin** replied that HPLC and LC-MS would be used to deal with drug analogue analysis.

32. Dr. **Kang** Shinjung indicated that TLC and HPLC methods were common tools for testing of herbal medicines. Prof. **Lin** agreed on his opinion. He also added that Near Infra-red (NIR) was good for screening because it was a convenient testing method and it only required small amount of samples. Prof. **Jin** remarked that NIR was a fast and non-destructive analytical technique to screen the contamination in herbal medicines.

33. The Co-chairperson, Prof. **Chang** (Korea) invited Mr. **Chan**

Ling-fung from Hong Kong to present the adulteration of undeclared substances in herbal products.

34. Prof. **Jin** questioned about how many samples were tested every year. Mr. **Chan** replied that 2500 samples were tested every year. Prof. **Jin** further asked the criteria and principle of sampling from Hong Kong market. Mr. **Chan** replied that those testing samples were drawn from the retailer, wholesaler and manufacturer of pCm in accordance with the risk-based principle. Dr. **Lam** Ping-yan added that the current focus was on the sale of male enhancement and slimming products.

35. Mr. **Chan** also indicated that inspectors from the Department of Health would inspect the high risk products after receiving the information from other health regulatory authorities. Also, the suspected undeclared substances would be tested in accordance with the claims of herbal products.

36. Dr. **Lam** pointed out that gibenclamide was found with sildenafil in some adulterated herbal products and invited members' views on this finding. Dr. **Vu** considered that most patients with diabetes generally had impotency problems and therefore anti-diabetic drug, namely glibenclamides, was added.

37. Prof. **Chang** opined that the information shared among member countries/region was essential to tackle the adulteration of western drug in herbal medicines. He proposed that members could exchange information via FHH website. The Chairman, Dr. **Lam** indicated that issues related to information exchange on adulteration with western medicines would be discussed in a later session.

38. The Co-chairperson, Prof. **Chang** (Korea) invited Dr. Yukihiro **Goda** from Japan to present the survey analysis of illegal compounds in dietary supplementary intended for sexual enhancements or diet and herbal products implying psychotropic effects by NIHS in Japan.

39. Prof. **Chang** questioned whether the pharmaceutical law was applied to the adulterated food or health supplement. Dr. **Goda** indicated that chemical compound detected in food or health supplement intended to have drug effect would fall under the regulatory control of

pharmaceutical law in Japan.

40. Prof. **Jin** observed that tadalafil detected in the shell of product was very much less than the effective dosage. Dr. **Goda** agreed on his observation and supplemented that it was still considered as illegal product even though small amount was detected.

41. Prof. **Jin** also highlighted that the drug regulatory authorities were now facing the problem of testing of drug analogue.

42. Dr. **Kang** observed that the level of contamination within the same batch of products varied significantly. Dr. **Goda** replied that it might be due to the poor manufacturing process such as improper mixing.

VII. Standing Committee Meeting (Session 4) Presentations on the issue related to adulteration of "western drug" in herbal medicines

43. The Co-chairperson, Dr. Yukihiro **Goda** from Japan invited Dr. **Park** Juyoung from Korea to present the Regulations against Adulteration in Korea. The speaker highlighted the regulatory system and types of adulteration in Korea.

44. Prof. **Jin** Shao Hong observed that various functional food were being examined under Korea's surveillance program. Dr. **Park** elaborated that body weight control and sexual enhancement products were also being examined under the surveillance program.

45. In response to Dr. **Goda**'s question, Dr. **Park** confirmed that the data were obtained from the food section.

46. Prof. **Jin** observed that one of the herbal tea products was adulterated with sennosides which was used for body weight control. He questioned that whether the sennosides came from senna leaves or a synthetic chemical compound intentionally added into the products. Dr. **Park** replied that Senna leaves were being added into products without declaring on the label.

47. The Co-chairperson, Dr. **Goda** (Japan) invited Mr. **Yee** Shen Kuan from Singapore to present the Adulteration of Herbal Medicines in Singapore (November 2008 to November 2009). The speaker highlighted adulteration in Singapore and adulteration of herbal medicines with the database for illegal health products on HSA website.

48. Dr. **Lam** Ping-yan observed that adulterants might be embedded into capsule shells, and commented that those contaminated capsule shells could be harmful to the consumers.

49. The Co-chairperson, Mr. Michael **Smith** (Australia) invited Mr. **Nguyen** Tuan Anh from Vietnam to present the Determination of Rhodamine B in Fructus Gardeniae by HPLC. The speaker highlighted the analytical method developed for determination of Rhodamine B in Fructus Gardeniae.

50. Prof. **Jin** asked whether there was any regulation control to restrict the farmers from soaking Rhodamine B in Fructus Gardeniae. Mr. **Nguyen** replied that there was currently no regulatory control on this matter.

51. The Co-chairperson, Mr. **Smith** (Australia) invited Dr. Duc **Vu** from Canada to present the Life Cycle approach in health products safety surveillance in Canada: Issue with adulteration of Natural Health Products. The speaker highlighted the post-market surveillance of health products and the life cycle approach in Canada with the issues of adulterations with pharmaceutical products in non-licensed NHPs.

52. Prof. **Jin** asked the details of adulterated products in Canada. Dr. **Vu** replied that adulterated products found contained sildenafil, glibenclamide, anabolic steroids, etc.

Discussion of Paper "Adulteration of Herbal Medicines"

53. The Chairman, Dr. **Lam** Ping-yan invited Mr. Robert **Law** from Hong Kong and Ms. **Puah** Swee Lin from Singapore to present the Paper of "Adulteration of Herbal Medicines". The speakers highlighted the definition of adulteration of herbal medicine, the possible factors contributing to increase adulteration cases and the proposed measures to

mitigate adulteration problem.

54. Three proposed measures were raised for discussion. They included (a) drug regulatory authority as the coordinator of product adulteration issues, (b) information exchange and (c) screening and laboratory testing.

55. The members supported the proposal of (a) and (c). Further discussion was focused on the aspect of information exchange.

56. Dr. Yukihiro **Goda** expressed the views as follows:

"Japan would fundamentally agree to exchange information on adulterated herbal medicines with western drugs, if the following conditions were accepted.

i. The definition and regulatory system of illegal drugs and herbal medicines differed within each country/region. Therefore, the information of the adulteration problem in herbal medicines to be shared was restricted to the cases that the drug regulatory authorities in each country/region had judged illegal and already disclosed to the public.

ii. Further discussion would be needed to agree the practical way of the information exchange. If the information exchange was performed by using the proposed form in Annex 2, it was difficult to fill up all the blanks."

57. Dr. **Goda** mentioned that the contact division in Japan was Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, Japan.

58. In response to **Dr Goda**'s concern, Mr. **Yee** Shen Kuan remarked that the information provided in the form "Alert for Adulterated Herbal Medicines" was not mandatory requirement. The members were encouraged to fill in the information when such information was available. Mr. **Yee** also proposed to trial the form and refine it way on.

59. Prof. **Chang** Il-Moo proposed that the members might use the ADR system to cover the reporting of adulterated cases. Dr. Duc **Vu** suggested that a separate system to report the adulteration issues might be used.

60. After discussion, the members agreed to have separated system from ADR to report the adulteration cases. In regard to the details of the reported form, it would need to be further discussed before finalization.

61. Prof. **Jin** Shao Hong highlighted that for the issue related to adulteration of "western drug" in herbal medicines, such problem might also be found in food or health food supplements.

62. The Chairman, Dr. **Lam** announced to close the afternoon session and recommended to resume the discussion after the Progress Report of Sub-committee III.

VIII. Standing Committee Meeting (Session 5)
Progress report of Sub-committee I (Nomenclature and Standardization)

63. 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, Dr. Nobuo **Kawahara** presented comparative studies on the developing solvent for TLC in pharmacopoeia, considering clean analysis among FHH member countries in 2009. Dr. **Ma** King Wah also shared the green chemistry approach in the development of Hong Kong Chinese Materia Medica Standards.

64. Dr. Narantuya **Samdan** asked about the type of TLC plate used for testing in JP.

65. Dr. **Kawahara** replied that Silica Gel F254 plate was used in the testing.

66. Dr. **Goda** expressed his appreciation on the green chemistry approach of development of Hong Kong Chinese Materia Medica Standards. The Chairman, Dr. **Lam** remarked that using non-toxic solvent for chemical analysis should be promoted to chemical analysis laboratory.

IX. Standing Committee Meeting (Session 6)
Progress report of Sub-committee II (Quality Assurance and Information)

67. The Chairman, Dr. **Lam** Ping-yan invited Prof. **Chang** Il-Moo, Chairman of Sub-committee II, to report the progress of work. Prof. **Chang** reported the publication of the FHH's Official Archives for Five-years' Activities (2002-2007) in 2008 and also introduced the video conferencing through the website of FHH. He invited members to use this new facility to facilitate the communication among the member states.

68. Dr. Yukihiro **Goda** expressed the concern on the security issue. Prof. **Chang** reassured that the current system would install a robust firewall against the hacker.

69. Dr. **Goda** asked if the system was compatible with Macintosh system. Prof. **Chang** replied that he had tried on Microsoft Vista & XP and would check on the compatibility with Macintosh.

70. Prof. Chang suggested creating hyperlink between FHH homepage and the member states' Health Authority official homepage. The members, in principle, agreed on this arrangement and the secretariat of FHH would follow up on this issue.

X. Standing Committee Meeting (Session 7)
Progress report of Sub-committee III (Adverse Drug Reactions)

71. The Chairman, Dr. **Lam** Ping-yan invited Prof. **Jin** Shao Hong, Chairman of Sub-committee III, to report the progress of work. Prof. **Jin** highlighted the achievement of FHH Sub-committee III Workshop in Dalian particularly related to factors affecting safety of herbal medicines and adulteration of western drug in herbal medicines.

72. Prof. **Chang** Il-Moo requested Prof. **Jin** to upload those presentations on FHH website. Prof. **Jin** consented to upload the powerpoints to the website upon obtaining the agreement from the presenters.

73. Dr. Duc **Vu** suggested the members of FHH to send the ADR reports to Uppsala ADR centre.

Discussion on the paper of "Adulteration of Herbal Medicines"

74. The Chairman, Dr. **Lam** Ping-yan invited members to continue the discussion on the paper of "Adulteration of Herbal Medicines".

75. Mr. **Yee** Shen Kuan suggested that considerations be given to exchange information of adulteration cases amongst FHH platform through FHH website and emphasized that the information should be restricted to member states.

76. Dr. Duc **Vu** echoed to the suggestion of Mr. **Yee** on the proposal that when individual member posted the adulteration information on their own Health Authority website, such information would be sent to FHH website correspondingly. Prof. **Chang** Il-Moo agreed to give assistance on this issue.

77. Prof. **Jin** Shao Hong recommended to handle the adulteration information with care and emphasized that such information should be circulate to FHH members in a restricted manner.

78. The members agreed on this issue and recommended that those adulteration information should be forwarded to the secretariat of FHH and then redirected the information to the member states in restricted manner.

79. After deliberations, the members agreed to participate in the reporting of the adulteration of herbal medicines on a trial basis and reviewed the issue next year. The trial run study would be under the purview of Sub-committee III.

XI. Any Other Business

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

80. The Chairman, Dr. **Lam** Ping-yan invited Dr. **Chiu** Pui-yin, Amy from Hong Kong to present a proposal of establishment of focal point in FHH to enhance the communication with IRCH.

81. Mr. Michael **Smith** agreed to enhance the communication between FHH and IRCH by establishing a formal linkage with IRCH first and

consider whether to join as a member in the next Standing Committee meeting. Prof. **Chang** Il- Moo concurred with Mr Smith's comments. After discussion, the member agreed to appoint the secretariat of FHH as the focal point with IRCH.

Selection of Co-ordinating member party of 2011-2012

82. The Chairman, Dr. **Lam** Ping-yan invited the members to show their interest of being the co-ordinating member party of 2011-2012.

83. Mr. **Yee** Shen Kuan said that those countries which had not hosted the meetings previously including Singapore could consider this issue and feedback to the secretariat of FHH later on.

84. Dr. Yukihiro **Goda** suggested that members should forward updated information of focal person to the secretariat of FHH after the meeting.

XII. Closing Remarks

85. Dr. Narantuya **Samdan** expressed the gratitude for attending the FHH meeting. She shared the future planning of WPRO on the safety and development of herbal medicines to FHH members. She mentioned that one of the work plan of WRPO was to evaluate the situation of traditional medicines in the member states of Western Pacific Region and also promote the further development on traditional medicines. In addition, she invited the FHH members enhancing the communication among FHH, WPRO and member states of Western Pacific Region regarding the ADR and adulterated drugs. She also invited the FHH members to provide professional inputs for the following guidelines namely Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines (1993), Guidelines for clinical research in acupuncture (1995) and Guidelines for the Appropriate use of Herbal Medicines (1998). She highlighted that FHH members could share more experience on the substitution of toxic solvents to non-toxic one for chemical analysis to the member states of Western Pacific Region and promote the green chemistry analysis joint hand in hand. Finally, Dr. **Samdan** encouraged the member states to support the work of WHO with their expert knowledge on regulation of herbal medicines.

86. 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.

END OF MEETING

87. The Chairman, Dr. **Lam** Ping-yan thanked the members again for their support and contribution to the meeting. There being no other business, the meeting was closed at 12:00 noon on 27 November 2009.

Participation List

Chairman

Dr. **LAM** Ping-yan, Director of Health, Department of Health, Hong Kong, China

World Health Organization

Dr. Narantuya **Samdan**, Regional Adviser in Traditional Medicine, WHO Regional Office for the Western Pacific

Members

Australia

Mr. Michael **Smith**, Head, Office of Complementary Medicines, Therapeutic Goods Administration

Dr. Michael **Dodson**, Medical Officer, Office of Complementary Medicines, Therapeutic Goods Administration

China

Dr. **Yang** Sheng, Assistant Consultant, Division of TCMs, Department of Drug Registration, State Food and Drug Administration

Prof. **Lin** Rui Chao, Director, Division of Chinese Materia Medica and Natural Products, National Institute for the Control of Pharmaceutical and Biological Products, State Food and Drug Administration

Hong Kong, China

Dr. **Ting** Tai-lun, Government Chemist, Government Laboratory

Japan

Dr. Yukihiro **Goda**, Head, Division of Pharmacognosy, Phytochemistry and Narcotics, National Institute of Health Sciences

Prof. Fumiyuki **Kiuchi**, Professor, Keio University, Division of Natural Medicines, Faculty of Pharmacy

Participation List

Korea

Dr. **Chang** Seungyeup, Director General, Biopharmaceuticals and Herbal Medicine Evaluation Department, Korea Food and Drug Administration

Prof. **Chang** Il-Moo, University Chairprofessor, College of Oriental Medicine, Kyung Hee University, and Emeritus Professor, Seoul National University

Singapore

Mr. **Yee** Shen Kuan, Division Director (Complementary Health Products Division), Division Director (Enforcement Division), Health Products Regulation Group, Health Sciences Authority

Ms. **Lee** Puey Ngee, Deputy Director (Medical Advertisement Unit), Pharmacovigilance & Compliance Division, Health Products Regulation Group, Health Sciences Authority

Vietnam

Dr. **Nguyen** Van Tuu, Deputy Director, National Institute of Drug Quality Control (NIDQC), Chairman, Vietnamese Pharmacopoeia Commission

Mr. **Nguyen** Tuan Anh, Deputy Director, Laboratory of Herbal Medicines – Materials, National Institute of Drug Quality Control (NIDQC)

Special Member

Canada

Dr. Duc **Vu**, Director, Marketed Biologics, Biotechnology and Natural Health Products, Health Canada

Observers

China

Prof. **Jin** Shao Hong, Director, Center for Drug Reevaluation, State Food and Drug Administration, National Center for ADR Monitoring

Dr. **Chen** Yi Xin, Director, Division of ADR Monitoring, Center for Drug Reevaluation, State Food and Drug Administration, National Center for ADR Monitoring

Participation List

Hong Kong, China

Dr. Gloria **Tam**, Deputy Director of Health, Department of Health

Dr. **Chiu** Pui-yin, Amy, Assistant Director (Traditional Chinese Medicine), Department of Health

Dr. **Chui** Kuk-ying, Senior Chemist, Government Laboratory

Mr. **Chan** Ling-fung, Senior Pharmacist (Traditional Chinese Medicine), Department of Health

Japan

Dr. Nobuo **Kawahara**, Director, Research Center for Medicinal Plant Resources, National Institute of Biomedical Innovation

Dr. Lida **Teng**, Former Research Assistant, Centre of Pharmacognosy and Phytotherapy, The School of Pharmacy, University of London

Korea

Dr. **Park** Juyoung, Senior Scientific Officer, Herbal Medicine Research Division, National Institute of Food and Drug Safety Evaluation

Dr. **Kang** Shinjung, Manager, Herbal Medicinal Products Division, Korea Food and Drug Administration

Dr. **Lee** Hyomin, Manager, Risk Analysis & Research Division, National Institute of Food and Drug Safety Evaluation

Dr. **Kim** Jinsook, Division Head, Division of Traditional Korean Medicine Integrated Research, Korea Institute of Oriental Medicine

Mr. **Choi** Bangseob, Deputy President, Association of Korean Oriental Medicines

Mr. **Roh** Donghyun, Manager, Pharmaceutical Affairs Team, Association of Korean Oriental Medicines

Participation List

Singapore

Ms. **Puah** Swee Lin, Senior Regulatory Specialist (Chinese Proprietary Medicines), Complementary Health Products Division, Health Products Regulation Group, Health Sciences Authority

厚生労働科学研究費補助金（医薬品・医療機器レギュラトリーサイエンス総合研究事業）
分担研究報告書

分担研究課題
生薬の品質確保と国際調和に関する研究

研究分担者　川原　信夫　独立行政法人医薬基盤研究所薬用植物資源研究センター長

西太平洋地区４カ国（日本、中国、韓国、ベトナム）の薬局方収載生薬の各種試験法並びに規格値の比較に関する研究
—クリーンアナリシスと国際調和を指向したサイコのTLC条件検討—

クリーンアナリシスを指向した国際調和の観点から，日本，中国，韓国，ベトナム４カ国の薬局方に収載される共通生薬について，TLCを用いた確認試験法で使用される各種有害試薬の比較表を作成し，比較試験を行った．今年度は第十五改正日本薬局方第一追補以前の日本薬局方（JP）において展開溶媒にクロロホルムを用いているサイコに関して詳細な検討を行った．この結果，中華人民共和国薬典及びベトナム薬局方の有害試薬を用いない試験条件でも指標成分が検出可能であることが確認された．本結果を基にJPの確認試験における試験条件の変更を行い，第十五改正日本薬局方第二追補において有害試薬を使用しない試験法が収載された．

A．研究目的

近年，伝統医療としての漢方薬あるいは生薬への関心が高まる中で，名称の類似，同名異物等の問題が表面化してきている．生薬の安全性を確保し，有効利用を考える上で，生薬の正しい認識と理解が必須であり，各国で使用されている生薬に関する情報を収集，整理し，共通認識を得ることは生薬，薬用植物の国際調和の観点からも非常に重要と考えられる．このような背景から2002年３月に北京において「生薬・薬用植物に関する国際調和のための西太平洋地区討論会」（FHH：Western Pacific Region Forum for the Harmonization of Herbal Medicines）設立のための国際会議が開催された．本フォーラムでは，西太平洋地区の６カ国７地域（日本，中国，韓国，ベトナム，シンガポール，オーストラリア，香港）の生薬・薬用植物の規制に関する関係者が一堂に会し，生薬・薬用植物の安全性，有効性及び品質に関する技術的な記録とコンセンサスを提供することが目的に掲げられた．日本はその下部組織である Nomenclature and Standardization に関する Sub-Committee 会議を主催することを受諾し，2002年５月，FHH東京会議が開催された．本会議において以下の５つの専門部会（Expert working group，EWG）が設立された．

1) Nomenclature
2) Testing Method in Monographs
3) List of Chemical Reference Standards (CRS) and Reference of Medicinal Plant Materials (RMPM)
4) List of Analytically Validated Method
5) Information on General Test

これらの専門部会では，将来的な国際調和を踏まえ，各国の薬局方収載生薬について共通点と相違点を認識すること目的として，それぞれの分野における各国薬局方の比較表を作成することが課