Dr. **Park** replied that sulfur dioxide is a contaminant comes from drying process, it can be controlled, its content in crude drug was not so high. Prof. **Lin** commented it could be a subject to harmonize and suggested a discussion on this issue with Korea after the meeting.

28. Prof. **Lin** asked which was the difference of KP and KHP? Dr. **Park** replied that more common used herbal materials were in KP and less common used herbal materials were in KHP but in term of legislation they were the same. There was a plan to unite in one.
29. Dr. **Goda** asked: what was the category of top twenty item in Korea (2009 – 2010)?. They are OTC, supplements or prescription drugs?. Dr. Park replied that it was the total market share.

IX. Standing Committee Meeting (Session 4)

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

30. The Co-chairperson Prof. **Kim** Yeongshik (Korea) invited Mr. **Pang** Tit Keong from Singapore to present the Update on Herbal Medicines in Singapore – Post-market activities. The speaker introduced the Update on Herbal Medicines in Singapore – Post-market activities.
31. The Co-chairperson Mr. Robet **Law** invited Ms. Belinda **Tan** from Singapore to present the New Initiative – Common Vigilance & Singvigi System. The speaker introduced the New Initiative – Common Vigilance & Singvigi System.
32. Dr. Duc **Vu** asked if Singvigi system was voluntary or mandatory reporting system ? Ms. Tan replied that this was an environmental scanning database, it was not a spontaneous reporting system. Dr. **Vu** asked if the system is coded. Ms. **Tan** replied that there are reference numbers for tracking.
33. Dr. **Chan** (Hong Kong) asked if imported products had to be under the post-market surveillance? For how long a drug had to be put in post-market surveillance? Mr. **Pang** replied that both locally manufactured products and imported products were undergoing post-market surveillance. For post-market surveillance program, they will do annual review of products, for new manufacturers or new importers (2010, 2011), they are put to next year post-market surveillance, for high risk product, for example slimming products, hair-lost product or sexual function, they were definitely put in more intensive post-market surveillance.
34. Mr. **Law** asked: will the information mentioned in slides (resource for documents and templates) be shared to other members? Ms. **Tan** replied that currently they came up with SOPs, so different product group will be using the same template. Since they were drafting, they intended to share this information but they had not finalized yet.
35. The Co-chairperson Prof. **Kim** Yeongshik (Korea) invited Ms. **Tu** Viet Lan to present the Regulation of Herbal Medicine in Vietnam. The speaker introduced the Regulation of Herbal Medicine in Vietnam.
36. Prof. **Zhao** asked about the GAP and the supply of medicinal plants, how many percent was cultivated and how many percent was wildly collected? Ms. **Tu** replied that Ministry of Health issued GACP regulation in 2009 but it was not mandatory, currently only one plant had the certificate of GACP, this was

Crinum latifolium. Prof. Zhao asked: How about the situation of *Cinnamomum cassia* bark? Ms. Tu replied that the next day there will be a presentation of Thien Duoc Company and they will introduce the implementing of GACP.

37. Prof. Zhao commented that 4 years later, Vietnam aims to achieve a target that herbal products will count 30% of domestic product, the current situation was 10%, so it was a big challenge.
38. Dr. Goda asked about the project 886/BYT-KH developing 40 potential medicinal plants, he wanted to know what did potential medicinal plants mean? Ms. Tu replied that they were preparing the list of 40 plants and there were some indicators for choosing herbs in the list. Prof. Le Van Truyen added: 40 potential medicinal plants were selected based on different criteria, for example the possibility for development, the economic value. These 40 plants could cover the list of traditional medicines in national essential drug list but not totally.
39. Prof. Kim asked: what kind of medicinal plant had been cultivated economically in Vietnam? Dr. Ta Ngoc Dung (Secretary of Materia Medica Association) answered this question and also clarified the question of 40 potential medicinal plants: in Vietnam market, more than 300 medicinal plants were being used, but government wanted to concentrate the effort to some medicinal plants and called them most potential medicinal plants. Potential means both economically and medically. The criteria for selecting 40 plants had been setting up, the list including modern medicinal plants and plants with traditional use. Now the database and strategy for developing these 40 plants had been established. A planning to develop 40 potential medicinal plants will be setting up from now to 2015.
40. Prof. Kim asked some example of potential medicinal plants. Dr. Ta replied that *Artemisia annua* is a goods example, because Vietnam is 2nd provider of artemisinin and it contribute a lot to antimalarial campaign.
41. The Co-chairperson Mr. Robet Law invited Dr. Duc Vu to present the Overview of Post- Market Surveillance of Natural Health Products in Canada. The speaker introduced the Overview of Post- Market Surveillance of Natural Health Products in Canada.
42. Prof. Lin asked how to distinguish ADR (Adverse Reaction) and ADE (Adverse Event). Dr. Duc Vu replied that adverse event meant that when there was an observation of an effect and this might be due to certain health product. There was a doubt of association here. For adverse reaction, the linkage between observation and the product would be found through analysis and assessments. These terms could be used interchangeably. In case of contamination and adulteration, we should call adverse event more than adverse reaction
43. Dr. Tran Hung asked: What was the reaction of Health Canada if they had received a report of an adverse event of an herbal medicine, the adverse event was not caused by the herb itself but by contamination or misuse or misidentification. So what was the reaction, withdraw the drug or improve quality control? Because in some cases, withdrawal is the sample way and no use the plant any more even it was a good medicinal plant, for example the case of *Stephania Tetandra*. Dr. Vu replied that withdrawal was not only based on

adverse reactions that were reported. Regulators looked at the benefit and risk profile, if they found the risk is higher than benefit, they would propose certain corrective action, the corrective action did not necessarily mean the product had to be withdrawn. It could be reformulation, change of labeling instruction, add into precautionary statement to highlight certain risks so that healthcare providers and public were aware of the situation. Withdrawal was the last action to apply. In the situation of *Stephania Tetandra* and some herb that containing aristolochic acid, the reason that most of western regulators requested to have product remove is aristolochic acid was known as carcinogenic and mutagenic and they were not sure about the benefit of the product in their society.

44. Ms. Belinda Tan asked: How did you follow up consumer reports? Did you follow up serious adverse reaction reports or you follow up all consumer report? Dr. Duc Vu replied that they did not follow up all ADR reports. They followed up certain serious adverse reaction reports only. For these cases, they needed to identify the risk factor, rule out all concomitances and followed up to the reporter. There was no distinction if reports were public report or healthcare provider report as long as the case was serious. If there were reactions from several people or the same reaction from the same type of product, they will do more follow up on that situation.

XI. Standing Committee Meeting (Session 5)

Report of Sub-committee I - Nomenclature and Standardization

45. The Chairman of Sub-committee I, Dr. Goda invited Dr. Le Viet Dung (Vietnam) to present the Authentication of medicinal plant in Vietnam. Dr. LE Viet Dung introduced some methods applied to identify medicinal plants, he highlighted the TLC fingerprint database, recommendations and solutions.

46. Dr. Yukihiro Goda said that sometimes he had trouble with hybrid species when using the new DNA technique and he wanted to know if Vietnam had encountered the same problem. Dr. Le Viet Dung answered that Vietnam sometimes had trouble with other method like morphological approach with microscopic analysis and chemical analysis so that why they had developed a new and modern technique called DNA fingerprint to identify the difference between two similar species. Vietnam also came up with the problem with hybrid species. He thought that with that new technique, identification between hybrid species could be made. But it was just an initial step and they had to invest more and focus to improve the capability to identify species. And also, it was necessary to build a DNA fingerprint database to improve this new method especially for difficult identification of hybrid species.

47. Dr. Goda asked: by regulation, if a specie was found, to be hybrid one, its name had to be changed in the pharmacopeia, so he wanted to know now how often was the VP changed? Dr. Le replied that the information was updated every year or every two years for VP and it was a good question because sometimes they had had problem with that too.

48. Prof. Zhao said that Acanthopanax was hard to find specie in the market, at least in China. He wanted to know what was the situation in Vietnam? Was it cultivated or was it wild specie? Dr. Le answered that Acanthopanax was a wild

species and it was in Vietnam's cultivation plan. Prof. **Zhao** added that the use of Acanthopanax had led to a near extinct situation. This had caused a shortage in the market, and since the cultivation was just starting, the requirement couldn't be met. Prof. **Zhao** also commented that there was still different in nomenclature between China, Japan and Vietnam. In Vietnamese Pharmacopoeia, *Fallopia multiflorum* has been mentioned, but in Japan and China *Polygonum* was used. He hoped that this would come to a harmonized in the future. Finally, he said that the day before when Vietnam presented about the potential species, he had noticed the specie *Phyllanthus amarus Euphobiaceae.* This specie had not been included in the Chinese Pharmacopeia but it had a monograph in VP, a very interesting thing. It was used to cure Hypotatius. And he thought this might be potential specie.

49. Dr. Yukihiro **Goda** invited the Dr. Nobuo **Kawahara** to present his report. The speaker presented Comparative studies on Pharmacopoeial definitions, requirements and information for crude drug among member countries.

50. Prof. **Zhao** Zhong-zhen said that Dr. **Kawahara**'s work was great and very significant, and the information from report was useful. He also said that in the future if Dr. Kawahara could bring Hong Kong's standard into his work. He also said that the handbook was very useful, even for teaching and studying, because it would help the student to understand the real situation in the world. He thought the next step would be about the relation between EP, USP, BP and Indian Pharmacopeia. Their contents were all related to herbal medicines. He also said that this book had to be compared with EP because some their testing measures for heavy metal and pesticides were different from that of ASIAN countries. Dr. **Kawahara** replied that he would try to combine the Hong Kong standard in that book and also EP, BP and USP, although it was a very hard work. Dr. **Goda** reminded that if any FHH member wanted the book, please contact him by email and he would send them the book.

51. Dr. Yukihiro **Goda** invited Dr. **Tran** Viet Hung (Vietnam) to present his report. The speaker introduced the Review of some issues in quality situation of herbal materials and traditional medicines currently circulating in Vietnam market.

52. Ms. **Chen** Yixin (China) had some comments about herbal material price in the market. She said that there were some reasons that cause price to increase, including the lack of resources, advertisement and the increasing of counter medicine samples. She thought the problem was not so serious in major part of the market of china. After that, she invited Dr. **Lin** to give more information about the quality of herbal medicine.

53. Dr. **Lin** Ruichao (China) said that that was the first time he had ever heard of Vietnam's herbal medicines problem, if the problem was mentioned earlier, he could give a better answer. Dr. **Lin** also said that in Chinese market, the quality of herbal medicine was mixed: some were bad and some were good. Because of that a quality control center was established and he needed to know what and how many plants had problems and where was the problem. He said perhaps in next meeting he would come back with answer. He thought that the current

method of trading between China and Vietnam is a cargo for a cargo, so it would be very hard to control the real quality of material medica. He will give information to Vietnam. He also wanted to know how many kinds of plants imported in Vietnam.

54. Ms. Tu Viet Lan (Vietnam) answered that there were two souces of materia medica: Domestic and imported, especially from China. Every year, 60% – 70 % of materia mediac was imported from China. Ms. Tu said that Vietnam would have methods to increase the quality of crude drug imported from China by requesting the importing company to have a registration with the ministry of health and also by increasing sampling in order to improve the quality control of crude drug.

55. Dr. Le Van Truyen worried those imported crude drug passed through Vietnam border by smuggling channel, so that the quality control was very difficult.

56. Dr. Lin Ruichao shared that China had the same problem. He said that China had imported herbal medicines from Pakistan, India... and they couldn't control the drug quality too. He wanted an idea of how to stop this problem.

57. Dr. Yukihiro Goda said that the sharing of info was very important and he hope Vietnam would share their information just like Canada, Hong Kong, Japan, and Singapore.

XII. Standing Committee Meeting (Session 6)

Report of Sub-committee II- Quality Assurance and information

58. Prof. Yeong Shik Kim, the chairman of Sub – committee II presented his report about Standardization of Rhei Rizoma.

59. Prof. Zhao Zhong-Zhen wanted to know if the drug researched was prepared or not prepared and he would like to see the comparison between the processed drug and raw material.

60. Prof. Kim invited Ms. Nguyen Nhu Trang (Vietnam) from Thien Duoc Company to present the report of a new medicinal herb from Vietnam, *Crinum latifolium.*

61. Prof. Lin Ruichao wanted to know how many plants in Vietnam complied with GACP requirements.

62. Ms. Tu Viet Lan replied that Ministry of Health GACP issued requirements in 2009, now Crinum herbal of Thien Duoc Company has complied with GACP and its finished product meet WHO GMP requirement. GACP requirement was not obligated in Vietnam and her didn't know whether the products imported circulating in the market complied with GACP requirements or not. Prof. Lin Ruichao said that in Singapore or in Japan, they had made good progress in agriculture progress because they had followed WHO's GAP. But he had also stated that it wasn't easy to ensure quantity and quality at the same time.

63. Ms. Tu Viet Lan asked Prof. Lin Ruichao that how many plants there were which followed the GACP in China. Prof. Lin Ruichao answered that there were

about 60 plants which followed GACP, each plant had a certification, and the number of those plants was rising every year.

64. Dr. Nobuo Kawahara (Japan) said that in Japan they also had 63 plants which followed GACP and Guideline for cultivation.

65. The Chairman, Prof. Yeong Shik Kim invited Dr. Duc Vu (Canada) to present his report. The speaker introduced the. Clinical trials regulation and risk-based approach site licensing for natural health products.

66. Mr. Robert Law asked for more information about the allowed level of PCDDs in fish oil. Dr. Duc Vu replied that they used USP standard for PCDDs' contamination level.

67. Mr. Robert Law asked that the allowed lead level which is 0.29 but it was reduced to 0.14, more and more material medicine were found to have the lead level of 0.29 and he would like to know how to reduce the lead level to 0.14? Dr. Duc Vu answered that the reduction of lead level was to ensure the safety of material medica in Canada and he said that the information above was applicable and they expected the possibility that companies had ability to remove the contamination.

68. Dr. Chan Kwok Hung asked under what condition Canada would stop a clinical trial. And who could decide to stop the trial? Dr. Duc Vu replied that if there was some change of the clinical ..., or there was a clear violation of clinical trial protocol, or if the authority saw a high increase of reaction cases of the current testing drug, the company that was testing the drug would be advised to stop the test. And the Canada's health department could use the fail safe mechanism to stop the test too.

69. Prof. Kim wanted to know the different between herbal medicine and dietary supplement in Canada. Dr. Duc Vu replied that in Canada they didn't have the category of supplement product. But in the USA, they had the natural health product which included some products that could cause so false claims. But that's not the same situation in Canada.

XIII. Standing Committee Meeting (Session 6)

Report of Sub-committee III – Adverse Drug Reaction

70. The Chairman Sub-committee III, Dr. Chen Yixin invited Dr. Ren Jingtian to present the Development of China Pharmacovigilance. The speaker introduced the report of development of pharmacovililance in China.

71. Dr. Goda would like to know after the information of ADR report was released, what the government would do. Ms. Chen answered that the government would have many ways to release the information to the public, especially the consumer. Dr. Goda wanted to know what action the government would take when ADR happened. Dr. Lin replied that the government would see if a kind of medicine had ADR. And then they would release the top 12 medicines that had ADR to the public. The medicine then would continue to be observed. If necessary, the product could be stopped from circulating and recalled.

72. The Chairman, Dr. Chen invited the Ms. Choo peck Lin (Singapore) and Mr. Robert Law (Hong Kong) to present the report on the Alert system for adulterated Herbal Medicines.

73. Dr. Duc Vu shared that the FHH system works really well especially for Canada. They had received informations quite regularly from the network and they used that for inspections of similar products in Canada and they also provided that information to people so when they go abroad they wouldn't use those product.

74. Dr. Goda mentioned that a product contain sildenafil had been dissolved in acid to produce metaprosildernafil. Dr. Tran Viet Hung added information that in the past 10 years Vietnam had detected many product contained sildenafil, about more than 20 cases were detected.

75. Dr. Chen said that most of the products that had been presented weren't real medicine. So she thought sharing information about this problem was very important.

XIV. Any Other Business

76. Mr. Robert Law reported the invitation of IRCH's fifth annual meeting to FHH members. The meeting would be held on 30 November to 2 December 2011. He asked Mr. Nguyen Van Thanh if Vietnam would send representative to attend the meeting. Mr. Nguyen Van Thanh replied he would report the invitation to vice-ministry of Health of Vietnam, Dr. CAO Minh Quang who would decide and announce latter.

XV. Closing Remarks

77. The Co-chairman of FHH meeting, Dr. Le Van Truyen highlighted the development of FHH and information exchanged between countries during the meeting. He had also remarked that there were developed countries and developing ones in FHH. He hoped that developed countries would give more support in both technical and financial to developing countries. He also hoped that tradition medicines would develop more and more.

78. On behalf of The Chairman, Mr. Nguyen Van Thanh delivered a closing remark to thank the members for the commitment and contribution to make the meeting a fruitful one. He invited everybody to attend the FHH meeting next year.

Other opinions

79. Dr. Lin Ruichao proposed to organize the next meeting in Ho Chi Minh city.

80. All representatives of member countries expressed their thanks to Vietnam for organizing the meeting.

81. They're being no other opinions, the meeting was closed at 13:00 on 18 November 2011.

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
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 a 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
Doui, M. 他	Temporal change in quality of a Kampo decoction packed by a decocting machine (1) —on Daiokanzoto—	Jpn. J. Pharamacog.	65(2)	103-107	2011
Hosoe, J. 他	Validation studies of qNMR for chemical reagents used as reference standards for quantitative analyses of crude drugs in the Japanese Pharmacopoeia	Pharmaceutical and Medical Device Regulatory Science	43(2)	182-193	2012
Tahara, M. 他	Determination of the purities of commercial reagent products using qNMR for the ensuring the reliability of quantitative analysis	Journal of Environmental Chemistry	22(1)	33-41	2012
Anjiki, N. 他	Quality evaluation of essential oils by a taste-sensing system	Jpn. J. Food Chem. Safety	19(1)	32-37	2012

総説等

発表者氏名	論文タイトル名	発表誌名	巻、号	ページ	出版年
袴塚高志	漢方処方エキスの日本薬局方収載と一般用漢方製剤承認基準の見直し	ファルマシア	48(5)	413-418	2011
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
Goda, Y. 他	Focus of the section on crude drugs in JP16	The Journal of Practical Pharmacy	62(6)	120-126	2011
合田幸広	漢方製剤と生薬製剤の違いを知る	調剤と情報	17(13)	1723-1726	2011

袴塚高志	一般用漢方製剤の「承認基準」	調剤と情報	17(13)	1739-1743	2011
川原信夫	漢方薬に使用される生薬・薬用植物の現状	社団法人東京生薬協会会報	452 (1)	4-8	2012
Sato, M.	Organophosphorus pesticide residue in crude drugs and migration of pesticides to decoctions	J. Trad. Med.	29 (1)	25-29	2012

その他　単行本等

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
木内文之 他	第十六改正日本薬局方医薬品各条生薬等の確認試験及び純度試験に規定されている薄層クロマトグラフィーの試験条件及びRf値	財団法人日本公定書協会	第十六改正日本薬局方	じほう	東京	2011	資料 pp11-16
Goda, Y. 他	Chapter 11: Herbal Medicines	Toko,K.	Biochemical Sensors: Mimicking Olfactory and Gustatory Senses	Pan Stanford Publishing	Singapore	2012	in press