Table 2　X線粉末回折の比較データ

鉱物名	(和名)	化学式	比較データ
Calcite	(カルサイト)	$CaCO_3$	JSPDS 47-1743
Dolomite	(ドロマイト)	$CaMg(CO_3)_2$	JSPDS 36-0426
Gibbsite	(ギブサイト)	$Al(OH)_3$	ICDD 33-0018
Halloysite	(ハロイサイト.10 Å)	$Al_2Si_2O_5(OH)_4 \cdot 2H_2O$	JSPDS 29-1489
Metahalloysite	(メタハロイサイト.7 Å)	$Al_2Si_2O_5(OH)_4$	JSPDS 29-1487
Illite	(イライト)	$(K,H_3O)Al_2Si_3AlO_{10}(OH)_2$	JSPDS 26-0911
Microcline	(カリ長石)	$KAlSi_3O_8$	JSPDS 19-932
Quartz	(石英)	SiO_2	JSPDS 46-1045
Talc	(タルク)	$Mg_3Si_4O_{10}(OH)_2$	JSPDS 13-0558

Table 3 各滑石水抽出液の味認識用脂質膜センサ出力値

番号	TMPW No.	X線粉末回折後のタイプ分け	センサの応答出力 (mV)			
			AAEセンサ		AC0センサ	
			測定液 a	測定液 b	測定液 a	測定液 b
滑石1	25283		-0.48	-0.40	-0.87	-0.65
滑石2	25292	A	-0.84	-0.71	-1.22	-1.07
滑石3	25867		-0.55	-0.02	-0.42	-0.30
滑石4	27171		-1.00	-0.78	-1.27	-0.94
滑石5	27175	B	-0.63	-0.76	-1.52	-1.34
滑石6	27176		-2.26	-1.98	-4.50	-3.84
滑石7	11844		-1.21	-0.94	-1.46	-1.02
滑石8	13925	C	0.40	0.58	0.00	0.00
滑石9	25279		-1.98	-0.98	-1.75	-1.54
滑石10	26071		-5.76	-5.21	-10.05	-8.96
滑石11	26077	D	-6.92	-6.31	-11.67	-10.78
滑石12	26080		-19.92	-18.46	5.51	4.98
滑石13	25322		-20.63	-15.73	37.81	2.46
滑石14	25323	E	-18.82	-12.93	39.41	-1.88
滑石15	25326		-19.75	-14.42	26.09	0.89
滑石16	27172		-3.20	-2.59	-5.10	-3.62
滑石17	27173	F	-2.73	-1.85	-3.91	-2.98
滑石18	27174		-5.05	-3.97	-6.37	-6.14

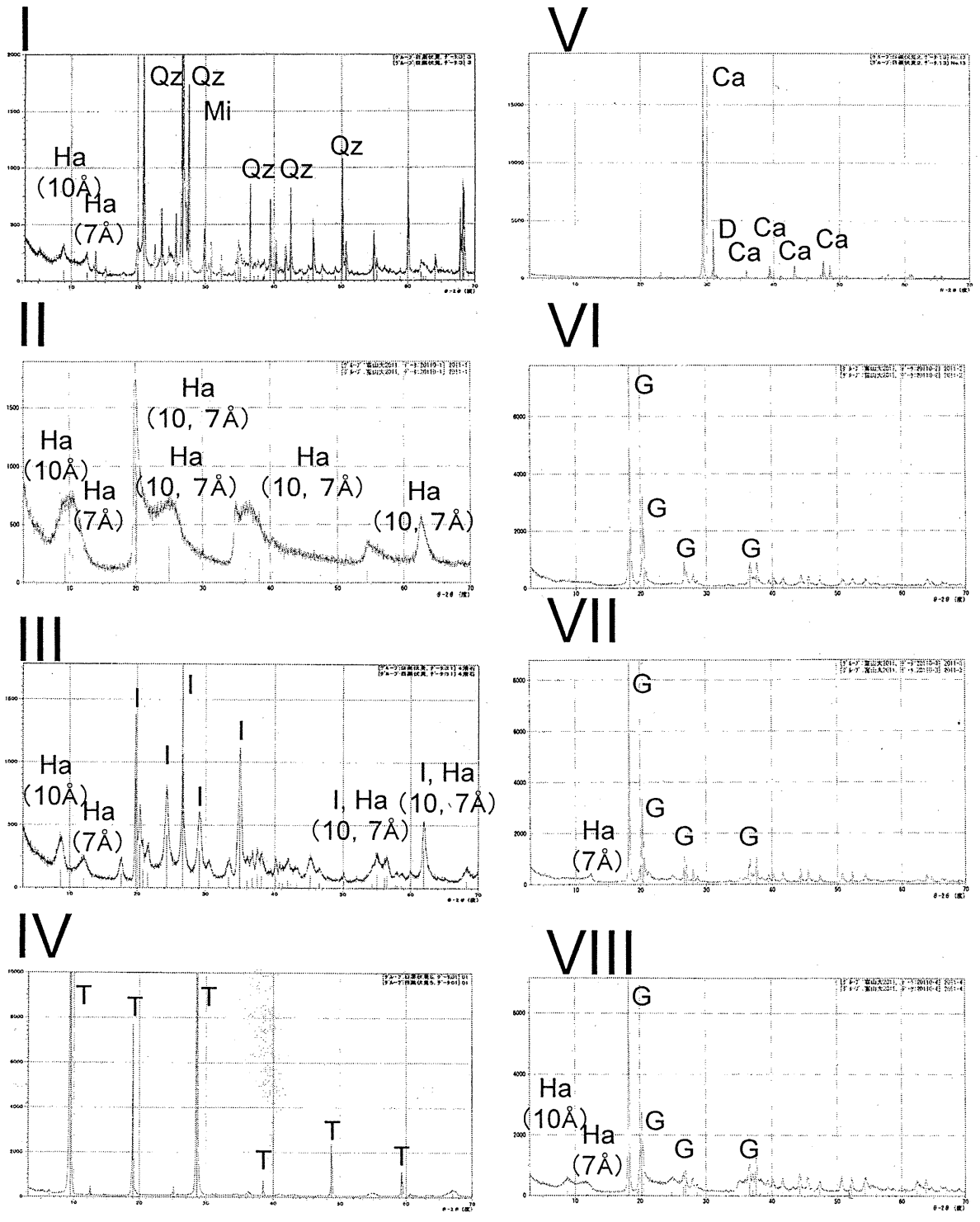

Fig. 1 各タイプの生薬「滑石」のX線粉末回折データと含有される鉱物種

I: タイプ A (滑石1), II: タイプ B (滑石4), III: タイプ C (滑石7), IV: タイプ D (滑石10), V: タイプ E (滑石13), VI: タイプ F (滑石16), VII: タイプ F (滑石17), VIII: タイプ F (滑石18). Ca: カルサイト, D: ドロマイト, G: ギブサイト, Ha (10Å): ハロイサイト (10Å) , Ha (7Å): メタハロイサイト (7Å), I: イライト, Mi: カリ長石, Qz: 石英, T: タルク.

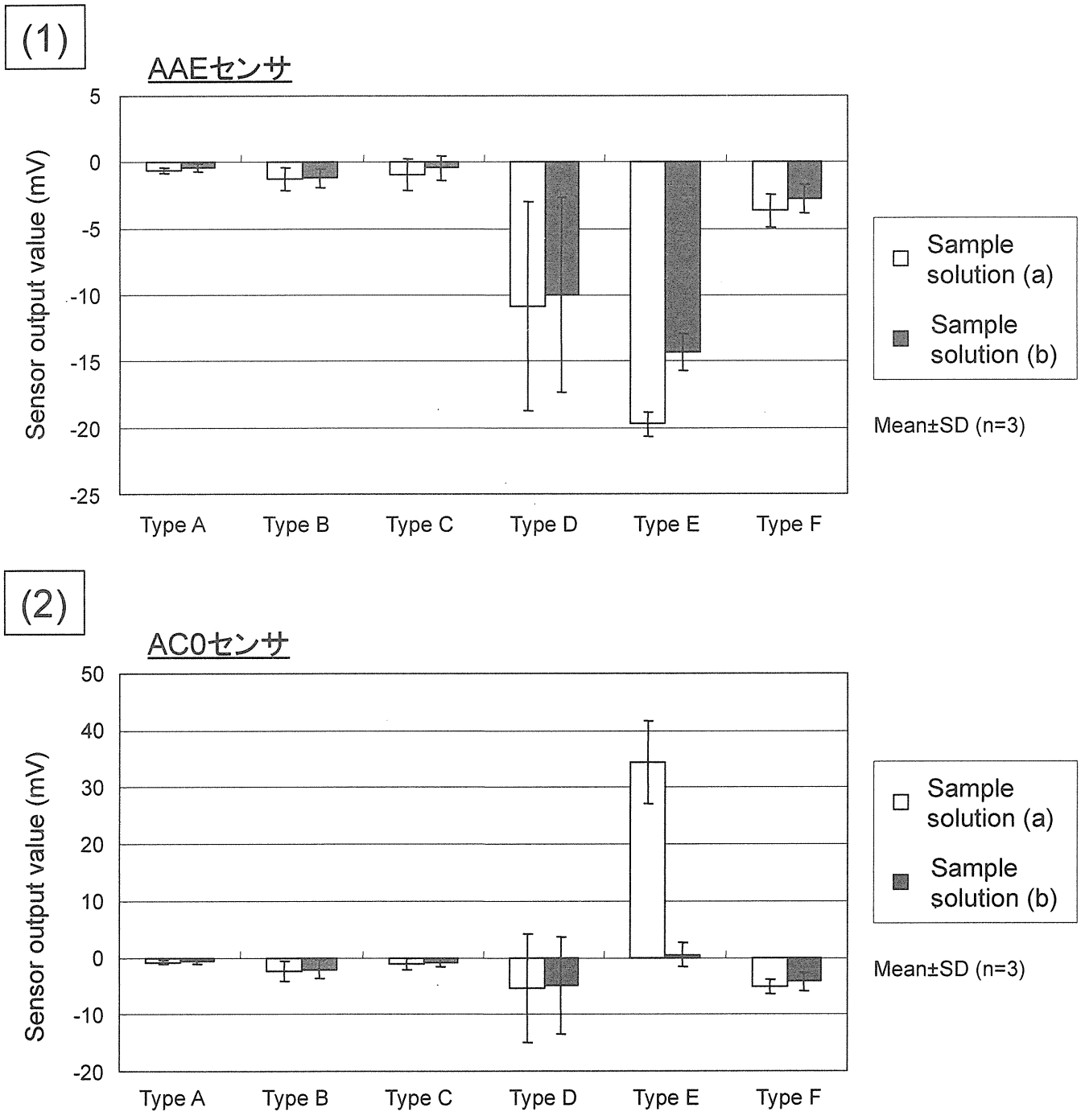

Fig. 2 味認識用脂質膜 AAEセンサ (1) 及び AC0センサ (2) の滑石水抽出液に対する出力（平均値±標準偏差）

Table 3 に記載したA～Fの各タイプ滑石3検体のセンサ出力平均値を示す.

厚生労働科学研究費補助金（医薬品・医療機器等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

分担研究者　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

第9回 Western Pacific Regional Forum for the Harmonization of Herbal Medicines（FHH）国際会議に関する報告

第9回 FHH Standing Committee 会議がベトナム、ハノイ、メリアホテルで開催された。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。特に、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。しかし近年、第16改正日本薬局方、中国薬典2010等、相次いで各国薬局方が更新されており、比較表に関しても最新版の内容にリニューアルする必要性が認められた。そこで今後は各種比較表の更新並びに追加記載を行い、次回の第10回 FHH Standing Committee 会議において報告することとなった。

A．研究目的

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 Regional Forum for the Harmonization of Herbal Medicines）設立のための国際会議が開催され、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、東京で、Sub-Committee I 会議が開催され、本会議において以下の5つの専門部会（Expert working group）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、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題事項として議決された。

これらの課題事項の進捗状況に関しては 2003 年 11 月に中国・昆明で開催された第1回 FHH Standing Committee、2004 年9月に中国・上海で開催された第2回 FHH Standing Committee、2005 年 6 月に東京で開催された第3回 FHH Standing Committee、2006 年 11 月に東京で開催された第4回 FHH Standing Committee、2007 年 10 月及び 2008 年 11 月に韓国、ソウルで開催された第5回及び第6回 FHH Standing Committee 並びに香港で開催された第7回及び第8回 FHH Standing Committee おいて報告がなされ、比較表の完成に向けて継続的な活動を行うことが了承された。さらに主任研究者並びに本分担研究者は、本 Sub-Committee I の実質的な運営者であり、本報告書では、ベトナ

ム、ハノイで行われた第 9 回 FHH Standing Committee 会議の内容を中心に報告する。

B．研究方法

本会議は平成 23 年 11 月 17-18 日、ベトナム、ハノイ、メリアホテルで開催された。日本側の参加者は合田幸広（国立医薬食品衛生研究所）、川原信夫（医薬基盤研薬用植物資源研究センター筑波研究部）、木内文之（慶應大学薬学部）及び Lida Teng（東京大学）の 4 名で、諸外国からの参加者は WHO より Dr. Lam Nguyen-Tuan、中国より Dr. Lin Ruichao、Ms. Chen Yixin、Dr. Ren Jingtian、香港より Dr. Chan Kwok Hung、Mr. Robert Law、Prof. Zhao Zhong-zhen、韓国より Dr. Lee Jeongseok、Prof. Kim Yeongshik、Dr. Park Juyoung、Dr. Kim Jiyeon、Dr. Seo Jaeuk、Ms. Kim Minkyung、シンガポールより Mr. Pang Tit Keong、Ms. Choo Peck Lin、Ms. Tan Mui Mui, Belinda、ベトナムより Dr. Cao Minh Quang、Mr. Nguyen Van Thanh、Dr. Le Van Truyen、Dr. Trinh Van Quy、Dr. Tran Viet Hung, Dr. Nguyen Bich Thu, Pharm. Tu Viet Lan, Dr. Nguyen Van Tuu, Prof. Pham Thanh Ky, Dr. Le Viet Dung, Dr. Ta Ngoc Dung, Pharm. Cao Mai Phuong、オーストラリアより Ms. Jennifer Burnett、カナダより Dr. Duc Vu の総勢 34 名のメンバーで行われた。今回の会議のスケジュール、英文要約を別紙に示す。

C．研究結果、考察

第 9 回 FHH Standing Committee 会議の概要

11 月 17 日午前

1．オープニングセレモニー

開催国ベトナムを代表して Dr. Cao Minh Quang より開催の祝辞が述べられた。引き続き WHO の Dr. Nguyen Tuan Lam より、挨拶が述べられた。全体写真の撮影後、座長の Mr. Nguyen Van Thanh より本会議の暫定的なプログラムの説明がなされ、本プログラムに沿って審議を行うことが了承された。午前中の会議（セッション 1 及び 2）では合田部長、Dr. Trinh Van Quy、Dr. Duc Vu 及び Mr. Pang Tit Keong が座長を務めることが了承され、午後の会議（セッション 3 及び 4）では、Dr. Lin Ruichao、Prof. Kim Yeongshik、Ms. Jennifer Burnett 及び Mr. Robert Law が座長を務めることが了承された。また、ベトナムが今後 2 年間秘書業務を務めることが了承された。

2．各国における生薬の規制に関する最近の話題について Part 1（セッション 1 及び 2）

1）オーストラリア（Ms. Jennifer Burnett）

オーストラリアにおける伝統薬の規制システムの枠組みについて説明がなされた。また、昨年に引き続きオーストラリアにおける補完医療に関する現状についても説明がなされた。

2）中国（Dr. Lin Ruichao）

中国薬典 2015 の作成及び編集に関するプロジェクトの進捗状況について詳細な報告がなされた。また、伝統薬の標準化に関する話題について報告がなされた。

3）香港（Mr. Robert Law）

香港特別行政区における伝統薬の規制の現状に関して説明がなされた。また、引き続き伝統薬の専売ライセンス及び専売伝統薬の登録並びに香港標準生薬プロジェクトの進捗状況について報告がなされた。

11 月 17 日午後

3．各国における生薬の規制に関する最近の話題について Part 2（セッション 3 及び 4）

4）日本（合田幸広生薬部長、国立衛研）

2010 年から 2011 年における日本の生薬行政関連のトピックについて報告がなされた。2011 年 4 月に第 16 改正日本薬局方が施行され、2012 年 10 月には第 16 改正日本薬局方第一追補が施行予定であるとの説明がなされ、引き続き第 16 改正日本薬局方第二追補に向けた検討が行われている旨、報告がなされた。特に第 16 改正日本薬局方第一追補の内容に関する詳細な報告がなされた。

5）韓国（Dr. Park Juyoung）

韓国における生薬の規制の現状に関する報告がなされた。特に韓国薬局方（KP）並びにKorean Herbal Pharmacopoeia (KHP) の最近の変更点等にについて詳細な説明がなされたまた、重金属、農薬及び残留二酸化硫黄等の基準値の設定に関しても説明がなされた。

6）シンガポール（Mr. Pang Tit Keong, Ms. Tan Mui Mui, Belinda）

シンガポールにおける生薬及び生薬製剤の規制に関する動向について説明がなされた。さらにシンガポールにおける新しい薬事監視システム（SVS: Sing Vigi System）の概要について説明がなされた。

7）ベトナム（Ms. Tu Viet Lan）

ベトナムの伝統薬及び生薬類に関する生薬行政関連のトピックについて報告がなされた。また第4改正ベトナム薬局方（VP 4）の進捗状況についても詳細な報告がなされた。

8）カナダ（Dr. Duc Vu）

カナダにおける natural health products (NHPs) の承認販売後の安全性監視に関する現状について報告がなされた。また、カナダ国内におけるNHPsの副作用情報の現状の詳細について説明がなされ、それら副作用情報の内容を向上させていく必要性があるとの説明なされた。

11月18日午前

4．Sub-committee I (Nomenclature and Standardization) に関する報告（セッション5）

合田幸広生薬部長より Sub-committee I の進捗状況に関する全般的な説明がなされた。

1）ベトナムにおける薬用植物の栽培並びに品質評価について

Dr. Le Viet Dung よりベトナムにおける薬用植物の栽培並びに品質評価に関する検討結果について詳細な報告がなされた。特にTLC、HPLC及びGCを用いた新規確認試験法及び定量法の確立を目指した取り組みについて説明がなされた。

2）Comparative Studies on Pharmacopoeial Definitions, Requirements and Information for Crude Drugs among FHH Member Countries in 2007 (Reorganized edition with explanatory notes of tables) に関する報告

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の川原信夫センター長より Comparative Studies on Pharmacopoeial Definitions, Requirements and Information for Crude Drugs among FHH Member Countries in 2007 (Reorganized edition with explanatory notes of tables) に関する説明がなされた。既に刊行された2007年版と比較表の各種内容は変わらないが、各比較表についての詳細な説明文を加筆し、よりわかりやすい内容に更新した旨、報告がなされた。

3）ベトナムにおける生薬製剤及び伝統薬の品質に関する現状について

Dr. Tran Viet Hung よりベトナム市場における生薬製剤及び伝統薬の品質の現状について説明がなされた。特に近年、シルデナフィル類似化合物の混入が問題となっており、今後の対応が必要であるとの説明がなされた。

4）Sub-committee I の今後の方針

JP16が刊行され、またCP 2010の英語版も刊行され、さらに近日中にはVP 4の英語版が刊行される予定であるので、入手次第更新を行う。また、EWG3に関しては引き続きCPのCRS及びRMPMのデータを入手し、比較表の作成並びに更新を行う。EWG4に関しては、関連情報がある場合、引き続き情報を提供する。以上各EWGで作成した比較表等は順次 FHH のウエブサイトに収載する。さらに引き続きクリーンアナリシスを念頭に国際調和を推進する観点から、各国局方のTLCによる生薬の確認試験において、有害溶媒を用いる展開溶媒条件と有害溶媒を用いない展開溶媒条件がある場合、有害溶媒を用いる条件を既定している国は、自国の生薬で有害溶媒を用いない他国の条件を検討する。さらに試験において良好な結果が得られた場合、有害溶媒を用いない

TLC 条件について国際調和を図る様、自国で検討する。

５．Sub-committee II (Quality Assurance and Information)に関する報告（セッション６）

Prof. Kim Yeongshik より Sub-committee II における Quality Assurance の現状に関してダイオウを例として説明がなされた。ダイオウは基原種が多岐にわたっているが、HPLC による各種主要化合物の定量並びに成分比を多変量解析することにより、種の分類が可能である旨、詳細な説明がなされた。

続いてベトナムの Dr. Nguyen Thi Ngoc Tram よりベトナムの薬用植物から新しい生薬製剤の開発研究に関する詳細な報告がなされた。

さらにカナダの Dr. Duc Vu よりカナダにおける NHPs の臨床治験について、その安全性並びに有効性に関する規制の現状について詳細な説明がなされた。

６．Sub-committee III (Adverse Drug Reaction (ADR))に関する報告（セッション７）

Ms. Chen Yixin より Sub-committee III の進捗状況に関する全般的な説明がなされた。

続いて Dr. Ren Jingtian より中国における薬事監視の現状について詳細な説明がなされた。

さらにシンガポールの Ms. Choo Peck Lin 及び香港の Mr. Robert Law より生薬製剤に混入される異物の報告並びに警告システムについて詳細な説明がなされた。

７．International Regulatory Cooperation for Herbal Medicines (IRCH)に関して(その他の事項)

香港の Mr. Robert Law より第４回 IRCH が 2011 年 11 月 30 日から 12 月 2 日に開催予定であるとの説明がなされ、FHH からも多くのメンバーに参加していただきたいとの依頼がなされた。

８．今後の Standing Committee 及び Sub-committee の運営における確認事項について

１）来年度の開催地について

事務局より来年度も引き続きベトナムで第 10 回 FHH Standing Committee が開催予定であり、開催時期は 2012 年 11 月頃を予定しているが、開催地に関してはハノイの他、ホーチミンシティ等も検討している旨、説明がなされた。

９．閉会の辞

ベトナムの Dr. Le Van Truyen より今回の会議に関する総括意見が述べられ、その後、座長の Mr. Nguyen Van Thanh 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。

D. 結論

第９回 FHH Standing Committee 会議がベトナム、ハノイ、メリアホテルで開催された。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。特に、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。しかし近年、第 16 改正日本薬局方、中国薬典 2010 等、相次いで各国薬局方が更新されており、比較表に関しても最新版の内容にリニューアルする必要性が認められた。そこで今後は各種比較表の更新並びに追加記載を行い、次回の第 10 回 FHH Standing Committee 会議において報告することとなった。

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

1) 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).

２．学会発表

1)　川原信夫：生薬・薬用植物情報の集積と発信．日本生薬学会第 58 回年会（2011. 9. 25, 東京）

G. 知的所有権の取得状況

特になし

Western Pacific Regional
Forum for the Harmonization of Herbal Medicines (FHH)
9th Standing Committee Meeting
PROVISIONAL PROGRAMME

17 November 2011 (Day 1)

Time	Contents
08 : 00 – 08 : 30	**Registration**
08 : 30 – 09 : 00	**Handover ceremony** for the Coordinating Member Party cum FHH Secretariat (2011-2013) from Hong Kong to Vietnam, signing of a certification in recognition of the Coordinating Member Party cum FHH Secretariat (2011-2013).
	Nomination of Chaiman of FHH for the term 2011 - 2013
	Opening Remark: Welcome address by Ministry of Health Representative
09 : 00 – 09 : 30	**Introducing Participants**
	Adoption of provisional agenda
	Nomination of Co-chairpersons
09 : 30 – 09 : 45	**Group Photo**
09 : 45 – 10 : 00	**Coffee/Tea Break**
	Presentation of country/region report related to the latest development on herbal medicines
	Standing Committee Meeting (Session 1)
10 :00 – 10 : 30	**WHO** Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020): A brief introduction *(Dr. NGUYEN Tuan Lam)*
10 : 30 – 11 : 00	**Australia** Regulation of Herbal Medicines in Australia *(Ms. Jennifer Burnett)*
	Standing Committee Meeting (Session 2)
11 : 00 – 11 : 30	**China** Compilation Project of Chinese Pharmacopoeia, Volume 1, Edition 2015

	(Prof. Lin Ruichao)
11 : 30 – 12 : 00	**Hongkong, China** The latest regulatory control of herbal medicine *(Mr. Robert Law)*
12 : 00 – 14 : 00	**Lunch**
	Standing Committee Meeting (Session 3)
14 : 00 – 14 : 30	**Japan** Pharmacopoeial topics on herbal medicines in Japan from 2010 to 2011 (*Dr. Yukihiro GODA*)
14 : 30 – 15 : 00	**Korea** Recent Progress on the Regulation of Herbal Medicine in Korea (*Dr. PARK Juyoung*)
15 : 00 – 15 : 15	**Coffee/Tea Break**
	Standing Committee Meeting (Session 4)
15 : 15 – 15 : 45	**Singapore** Country report - Singapore *(Mr. PANG Tit Keong and Ms. Belinda TAN)*
15 : 45 – 16 : 15	**Vietnam** Regulation of Herbal Medicine in Vietnam (*Ms. TU Viet Lan*)
16 : 15 – 16 : 45	**Canada** Overview of Post-Market Surveillance of Natural Health Products in Canada *(Dr. Duc VU)*
18h30	**Welcome dinner** Sum Villa Restaurant, 10 Dang Thai Mai street, Tay Ho district, Hanoi

18 November 2011 (Day 2)

Time	Contents
	Standing Committee Meeting (Session 5) ***Report of Sub-committee I – Nomenclature and Standardization***
08 : 30 – 09 : 30	Authentication of medicinal plants in Viet Nam (*Dr. LE Viet Dung*)
	Comparative Studies on Pharmacopoeial Definitions, Requirements and Information for Crude Drugs among FHH Member Countries in 2007 (Reorganized edition with explanatory notes of tables) (*Dr. Nobuo KAWAHARA*)
	Review of some issiues in quality situation of herbal materials and traditional medicines currently circulating in Vietnam market (*Dr. TRAN Viet Hung*)
	Standing Committee Meeting (Session 6) ***Report of Sub-committee II – Quality Assurance and Information***
09 : 30 – 10 : 30	Standardization of Rhei Rizoma (大黄) (*Prof. Yeong Shik KIM*)
	The reseach and development of new medicinal herbal products from Vietnamese herbs (*Representative of Thien duoc Limited Company)*
	Clinical Trials Regulations; and Risk-Based Approach Site Licensing for Natural Health Products (*Dr. Duc VU, Canada*)
10 : 30 - 10 : 45	**Coffee/ Tea Break**
	Standing Committee Meeting (Session 7) ***Report of Sub-committee III - Adverse Drug Reaction***
10 : 45 – 11: 45	Development of China Pharmacovigilance (*Dr. REN Jingtian*)
	Report the Alert System for Adulterated Herbal Medicines (*Ms. Choo Peck Lin, Singapore and Mr. Robert Law, Hong Kong*)
11 : 45 – 12 : 15	**Any other business** Invite FHH members to participate as observer in the upcoming Fifth annual meeting of IRCH to be held on 30 November to 2 December 2011

12 : 15 – 12 : 30	**Closing remarks**
12 : 30 – 13 : 30	**Lunch**
13 : 45 – 14 : 00	**Excursion** – Performance of puppetry art *57B Dinh Tien Hoang Street, Hanoi* – Visit old quarter in Hanoi

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

Notes on the Ninth Standing Committee Meeting of the Western Pacific Regional Forum for the Harmonization of Herbal Medicines

17 - 18 November, 2011
Ballroom section 3, 1st level
Melia Hanoi Hotel, 44B Ly Thuong Kiet street, Hanoi, Vietnam

Members :
Dr. **Cao** Minh Quang (Vietnam, The Chairman)
Dr. Nguyen Tuan Lam (WHO, National Professional Officer Vietnam)
Ms. Jennifer **Burnett** (Australia)
Prof. **Lin** Ruichao (China)
Dr. **Chen** Yixin (China)
Dr. **Chan** Kwok Hung (Hong Kong, China)
Mr. Robert **Law** (Hong Kong, China)
Dr. Yukihiro **Goda** (Japan)
Prof. Fumiyuki **Kiuchi** (Japan)
Dr. **Lee** Jeongseok (Korea)
Prof. **Kim** Yeongshik (Korea)
Mr. **Pang** Tit Keong (Singapore)
Ms. **Tan** Mui Mui, Belinda (Singapore)
Mr. **Nguyen** Van Thanh (Vietnam)
Prof. **Le** Van Truyen (Vietnam)
Prof. **Trinh** Van Quy (Vietnam)

Special Member
Dr. Duc **Vu** (Canada)

Observers
Dr. **Ren** Jingtian (China)
Prof. **Zhao** Zhong-zhen (Hong Kong, China)
Dr. Nobuo **Kawahara** (Japan)
Dr. Lida **Teng** (Japan)
Dr. **Park** Juyoung (Korea)
Ms. Kim Minkyung (Korea)
Dr. Seo Jaeuk (Korea)
Dr. **Kim** Jiyeon (Korea)
Ms. **Choo** Peck Lin (Singapore)
Dr. **Tran** Viet Hung (Vietnam)
Dr. **Nguyen** Bich Thu (Vietnam)
Pharm. **Tu** Viet Lan (Vietnam)
Dr. **Nguyen** Van Tuu (Vietnam)
Prof. **Pham** Thanh Ky (Vietnam)
Dr. **Le** Viet Dung (Vietnam)
Dr. **Ta** Ngoc Dung (Vietnam)
Pharm. **Cao** Mai Phuong (Vietnam)

I. Handover Ceremony

Representatives of Australia, WHO, China, Japan, Hong Kong, Korea, Singapore, Canada, Vietnam signed the Certificate Recognizing Socialist Republic of Vietnam as the Coordinating Member Party cum FHH Secretariat (2011-2013) of the Standing Committee, the Western Pacific Regional Forum for the Harmonization of Herbal Medicines.

II. Nomination of Chairman of FHH for the term 2011 – 2013

Dr. CAO Minh Quang, Vice Minister, Ministry of Health of Socialist Republic of Vietnam was nominated as Chairman of the Western Pacific Regional Forum for the Harmonization of Herbal Medicines for the term 2011 – 2013.

III. Opening Remark:

Dr. CAO Minh Quang, new Chairman of the Forum delivered an opening address in which he was extending a warm welcome to all participants and expressed special thanks to old members who have contributed for the Forum since its foundation.

After opening speech, Dr. CAO transferred the chairman role of the Meeting to Mr. NGUYEN Van Thanh, Deputy General-Director of Drug Administration of Vietnam and the co-chair, Prof. LE Van Truyen, former vice minister of Health.

IV. Introducing participants

All members, observers participating in the Standing committee meeting introduced themselves

V. Adoption of provisional agenda

The updated provisional programme distributed to the participants in the meeting was adopted

VI. Nomination of Co-chairpersons and Rapportteurs

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

VII. Standing Committee Meeting (Session 1)

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

1. The Co-chairperson, Prof. **Trinh** Van Quy (Viet Nam) invited Dr. **Nguyen** Tuan Lam from WHO representative office in Viet Nam to present the Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020): A brief introduction. The speaker introduced the Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020).
2. Dr. **Lee** Jeongseok (Korea) had a comment on slide 11 in which Korea had not been listed among the countries implementing GMP on HM, actually Korea had been implementing GMP for all pharmaceutical finishes products since 1991 and they had plan for implementing GMP on HM from next year. Dr. **Nguyen** replied that he was going to note this information and would communicate with Dr. Samdan. The data in this presentation may not be fully updated and they would revise and update it.
3. Dr. Goda added that it was a good chance to correct information of each country.
4. The Co-chairperson Dr. Yukihiro **Goda** invited Ms. Jennifer **Burnett** from

Australia to present the Regulation of Herbal Medicines in Australia. The speaker introduced the regulation of herbal medicines in Australia.

5. Mr. Robert Law asked Ms. Burnett if the Ingredients in listed medicines (slide 5) was available on the website of TGA. Ms. Burnett replied that the list that currently appear in their website had the last update from 2005 and she strongly recommended people do not use it as definitive source. TGA was going to put the new list in the website and then it would be able to everybody.
6. Dr. Duc Vu asked Ms. Burnett about the exclusivity of the market for some products, in the situation where the manufacturers submitted clinical trial for herbal medicines in a new approve, would they qualify for market exclusivity? Ms. Burnett replied that usually in the cases where sponsor had conducted clinical trial they would try for the registration of herbal medicines, which provided market exclusivity rather than just proved ingredient. So that was difficulty, they had to discuss with sponsor which was the most appropriate part of their product. Normally when people applied for new list of substance there were ingredient supply rather than sponsor of finished product. So they actually wanted to sell their ingredient to other manufacturers. But if someone had gone to the trouble with expense over clinical trial, they would normally put in application for new registered medicines.
7. 2nd question of Dr. Vu related to GMP requirement: Did TGA applies the GMP for all of the market authorisation holders and how did TGA ensure the complying? Ms. Burnett replied that with the listed medicines, they automatically entered into a TGA electronic application. Part of the application aims identify all the manufacturers associated with manufacture. Each manufacturer needed to exist in database with current approval from TGA or a license. So that how GMP compliance was ensure. One aspect difficult to cover was the manufacturing of the intermediates, some ingredients gone degraded process before supplying raw material to the manufacturers of the finished products. They were looking to modify their system to make it available so they could identify these manufacturers as well. This may include some herbal extract manufacturers.
8. Dr. Chen Yixin (China) asked Ms. Burnett to explain what does ingredient in "ingredient-based" searching mean? Does it mean to AAN, AHS or chemical? Ms. Burnett replied that they relied on ADR database, put the identification of the causative medicines. They asked to include AUSTR or AUSTL No. of the medicine into the entry. They used that then to cross check with their register which includes the formulation of herbal medicines. Every month or every quarter they included ADR events to their database. They had looked for listed medicines and then they entered those medicines identification No. into another database which was then associated them with the formulation. They could search that database based on the ingredient. So if someone wanted to go back and look at ingredient X, it would show with the formulation, which was associated with the reporting ADR …
9. Dr. Le Van Truyen (Vietnam) asked if there were in Australia traditional medicine practioner? If yes, how to control the herbal medicines produced by these practitioners? Ms. Burnett replied that TGA regulated practitioners. In the

past, there had been a number of different registration processes available for different practitioner within each state within Australia, when they were moving toward to a national registration system that would consolidate the individual state system so it now allowed easier of identification of practitioner and their training education and on-going education and awareness, all integrate in the system. If the practitioners used commercially supplying medicines, these medicines were regulated by TGA but if they were using the raw herbs to formulate their own, these products could not be evaluated by registration board.

10. Prof. Kim Yeongshik asked: What was the market share of herbal medicine, interest of people about using herbal medicines in Australia? Herbal medicines were regarded as drug or dietary supplements? Ms. Burnett replied that it was estimated that about 70% of Australian use complementary medicines which included vitamins and minerals, medicines which in some other countries could be considered as dietary supplements but in Australia it was consider as medicines. So it was very large uses of these medicines within Australia and that did not include the practitioners' supplying medicines.
11. The question of Prof. Fumiyuki Kiuchi and the answer of Ms. Burnett:

Standing Committee Meeting (Session 2)

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

12. The Co-chairperson, Dr. Duc Vu invited Prof. Lin Ruichao to present the Compilation Project of Chinese Pharmacopoeia Volume 1, edition 2015. The speaker introduced the Compilation Project of Chinese Pharmacopoeia Volume 1, edition 2015.
13. Dr. Goda asked whether the supplement that Prof. Lin mentioned was supplement of monographs or technical information? Prof. Lin replied that the supplement could have 2 parts, one was about products and other was technical. Dr. Goda added if it would be translated in English? Prof. Lin replied that they will try. Dr. Goda's second question was about the limited of sulphur dioxide. Prof. Lin replied that sulphur dioxide was added into wine as stabilizer. The determination of this substance was not a problem but the limitation was subject to discuss, it was just a suggestion.
14. Dr. Trinh Van Quy (Vietnam) commented that the Chinese Pharmacopoeia was very good, it was a very good reference to establish monographs of Vietnamese Pharmacopoeia, the volume 1 of CP had more than 2400 monograph, it was really big one. Then Dr. Trinh had 2 questions, the 1rst one was how to control complicated preparations, for example the very famous preparation from China "Angong Nuihuang Wan". Prof. Lin replied in 2 languages English and Chinese, Mr. Law translated Prof. Lin's opinion as follow: for the quality of drug GMP concept was essential. All good drugs had good quality control during manufacturing process. In the final stage testing was done to ensure the quality. That's means good manufacturing practice was essential and critical to produce reliable, safety and good quality drugs. Dr. Zhongzhen Zhao added some information to the second part of Prof. Lin's answer: the drug that Dr. Trinh mentioned was really good product made from China and it was precious one. It

was very popular in Asian countries and produced by some very famous manufacturers with internal standards, its formula was a secret.

15. The 2nd question of Dr. **Trinh** was about the price of "Angong Nuihuang Wan", there was different prices in different cities or provinces in China. Prof. **Lin** replied that he only knew about the quality and could not answer this question.
16. Prof. **Kim** asked: In Korea, they were taking similar steps to standardize herbal medicine, this project was supported by KFDA. Now they were reporting new edition of Chinese Pharmacopoeia but for all cases they found that their results were different from results shown in this new edition. He suggested if they have chance to show results to each other so they could harmonize. Prof. **Lin** replied that he agreed with Prof. Kim, FHH was for this purpose, all ideas and suggestions were welcome. Then Prof. Lin gave some examples of harmonization of FHH.
17. The Co-chairperson, Mr. **Pang** Tit Keong (Singapore) invited Mr. Robert **Law** from Hong Kong to present the latest regulatory control of herbal medicine. The speaker introduced the latest regulatory control of herbal medicine.
18. Dr. **Le** Van Truyen (Vietnam) asked if Hong Kong medical authority recognized the combination of chemical API and herbal medicine in a same formulation? Mr. **Law** replied that they were not in this organisation. Hong Kong was a special administration region. For international activities Hong Kong was usually attached with China to joint the function and share experiences. They are not independent authority.
19. Ms. **Burnett** asked Mr. Law about slide 17, stability test was required for proprietary Chinese medicines. Did all 108 of registered pCm have stability data supplied? Mr. **Law** replied that for 108 registered pCm manufacturers had to provide stability test results with 2 requirements, the first one is acceleration test for 3 months to give the estimation of expired date, for real time stability test manufacturers had to provide 3 years data.
20. Dr. **Nguyen** Bich Thu (Vietnam) asked Mr. Law his experiences in establishing of standards of medicinal plants. How to identify different species in one monograph, how to use marker compound. Mr. **Law** then introduced the procedure to establish their standards, in collection sample stage, SFDA and SATCM helped them to collect sample from production site in China to ensure that they have correct specie, this was fundamental step. Then analytical procedure to look for active markers or major ingredients in the herb. For identification they used TLC, HPLC fingerprint approach was also used, for the quality aspect they will do the assay part to find out how many active ingredient inside and then step for statistic treatment of all data. There was International advisory board scientist committee who will look after technical issues and reviewed all statistic data end endorsed results. The most important was method used, it will pass to government laboratory to ensure that this method will be reproduced or can be used in third laboratory. For the question of multispecies problem, they would try to put one specie in one monograph but it will take time. For the moment, they tried to distinguish different species in one monograph by microscopic method, TLC or HPLC fingerprint method or other chemical analysis.

21. Other question of Dr. Nguyen about stability of standard plants and its time of storage. Mr. Law replied that there were 2 aspects that affect the quality of materia medica during storage: the environment (humidity, temperature) and the nature of materia medica. For material containing oil, the active ingredient dropped a lot during storage, so for materia medica like that, they tried to find a marker which was fairly stable for quality control. Concerning Dr. Nguyen's further question about slide preparation (processed drug), Mr. Law answered that at the moment they focused on crude drug, they had not studied slide preparation yet. They intended to cover slide preparation in the future but it will be more difficult to set up the limit because different area had different processing method so active ingredient will change accordingly. But it was the direction they work on it.

VIII. Standing Committee Meeting (Session 3)

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

22. The Co-chairperson, Prof. Lin Ruichao invited Dr. Yukihiro Goda to present the Pharmacopoeial topics on herbal medicines in Japan from 2010 to 2011. The speaker introduced the Pharmacopoeial topics on herbal medicines in Japan from 2010 to 2011.
23. Dr. Tran Hung (Vietnam) asked if there was any rule or regulation in JP for number of markers for quality control of complex extract? Dr. Goda replied that for preparation that contained at least 5 herbs, they tried to apply 3 markers for HPLC quantification test. For some kampo extract contained more than 10 herbs, they tried to make 4 or more marker compound regulation. The 2nd question of Dr. Tran was about the change of the length of TLC development, was this applied to one monograph or all monographs? Dr. Goda answerd they tried to apply for all monographs but now the work was undergoing.
24. Prof. Kim (Korea) asked: Regarding to Rehmannia, if there was any other TLC or HPLC marker for identification of processed Rehmannia? Prof. Kiuchi answer they don't find any……compound in this study, he would like Prof. Kim give them information and Prof. Kim agreed. Prof. Kim asked why choose HPLC for identification? Dr. Goda answered if they found a good marker, TLC identification would be fine. If they did not find good marker, HPLC identification will be used. But sometimes when HPLC was used for quantification, it was also used for identification.
25. Dr. Nguyen Bich Thu asked, for defining marker compounds of Tokishakuyakusan, Japanese Angelica root and Cnidum Rhizome had 2 common marker compounds, how to distinguish these 2 plants? Dr. Goda replied they could not distinguish 2 plants in final mixture but during manufacturing process.
26. The Co-chairperson, Ms. Jennifer Burnett invited Dr. Park Ju Young to present the Recent Progress on Regulation of Herbal Medicine in Korea. The speaker introduced the Recent Progress on Regulation of Herbal Medicine in Korea.
27. Prof. Zhao asked if the limitation of sulfur dioxide (30 ppm) was too strict in comparison with that indicated in Chinese Pharmacopeia (150 and 400 ppm). How many percent of crude drug in the market passed through this limitation?