既収載品目の改正

アマチャ	加工の追加	通例、揉捻した葉及び枝先
オンジ	部位の追加	根又は根皮
エンゴサク	加工の追加	塊茎を、通例、湯通ししたもの
ショウキョウ	加工の追加	根茎で、ときに周皮をのぞいたもの
タクシャ（末）	英名・ラテン名の変更	Alisma Tuber　　ALISMATIS TUBER
チョウトウコウ	加工の追加	通例、とげで、ときには湯通し又は蒸したもの
テンモンドウ	加工の追加	コルク化した外層の大部分を除い根を、湯通し又は蒸したもの

キョウニン	基原の追加	Prunus armeniaca Linne
		Prunus armeniaca Linne var. ansu Maximowicz
		Prunus sibirica Linne
コウボク	シノニム並記	Magnolia obovata Thunberg (Magnolia hypoleuca Siebold et Zuccarini)
		Magnolia officinalis Rehder et Wilson
		Magnolia officinalis Rehder et Wilson var. biloba Rehder et Wilson
ゴシュユ	学名変更	Euodia ruticarpa Hooker et Thomson (Evodia rutaecarpa Bentham)
		Euodia officinalis Dode (Evodia officinalis Dode)
		Euodia bodinieri Dode (Evodia bodinieri Dode)
シンイ	学名変更	Magnolia salicifolia Maximowicz
		Magnolia kobus De Candolle
		Magnolia biondii Pampanini
		Magnolia sprengeri Pampanini
		Magnolia heptapeta Dandy (Magnolia denudata Desrousseaux)
ビャクシ	学名変更	Angelica dahurica Bentham et Hooker filius ex Franchet et Savatier
ビャクジュツ	学名変更	Atractylodes japonica Koidzumi ex Kitamura
		Atractylodes macrocephala Koidzumi (Atractylodes ovata De Candolle)
ブクリョウ	学名変更	Wolfiporia cocos Ryvarden et Gilbertson (Poria cocos Wolf)

JP収載生薬のうち，CP，KPおよびVPとの共通性が低い品目

アカメガシワ	キョウカツ	ナンテンジツ
アマチャ	コロンボ	ハトムギ
インチンコウ	コンズランゴ	ヒシノミ
ウワウルシ	センコツ	ボクソク
エンメイソウ	センナジツ	ヨウバイヒ
オウヒ	タラコンピ	ワキョウカツ
ガイヨウ	トウガシ	ワコウホン
カミツレ	ドクカツ	ワニクジュヨウ

JSP2012に新規収載

ケイシ	セイヒ	ホップ
ジンギョウ	センレンシ	ワニクジュヨウ
ジンコウ	トウシンソウ	

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）
研究分担報告書

研究分担課題　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

第10回 Forum for the Harmonization of Herbal Medicines（FHH）国際会議に関する報告

第10回FHH Standing Committee会議がベトナム、ハノイ、Fortuna Hotelで開催された。本会議では各地域における生薬並びに生薬製剤の規制の現状に関する報告並びにNomenclature and Standardization、Quality Assurance and Information及びAdverse Drug Reactionに関する3つのSub-Committeeの活動報告がなされた。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、今回の会議においても一部の比較表の更新に関する報告がなされたが、他の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。従って今後も引き続き各種比較表の更新並びに追加記載を行い、更新された比較表については順次、次回の第11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 Region 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、香港で開催された第7回及び第8回FHH Standing Committee並び

にハノイで開催された第 9 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 10 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 24 年 11 月 27-28 日、ベトナム、ハノイ、Fortuna Hotel 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）及び木内文之（慶應大学薬学部）の 3 名で、諸外国からの確認されている参加者は WHO より Dr. Socorro Escalante、中国より Dr. Lin Ruichao、Mr. Liu Chun、Mr. Le Yang、香港より Mr. Robert Law、韓国より Dr. Shin Jung Kang、Prof. Sang Kook Lee、Dr. Soo-kyung Lee、Dr. Jonghwan Kim、シンガポールより Mr. Pang Tit Keong、Ms. Choo Peck Lin、ベトナムより Dr. Cao Minh Quang、Mr. Nguyen Van Thanh、Prof. Le Van Truyen、Dr. Trinh Van Lau、Dr. Tran Viet Hung、Dr. Nguyen Bich Thu、Pharm. Tu Viet Lan、Dr. Nguyen Van Tuu、Prof. Pham Thanh Ky、Pharm. Cao Mai Phuong、Dr. Le Viet Dung、Dr. Le Viet Dung、Dr. Tran Van On、Dr. Mguyen Hoang Anh、Mr. Nguyen Van Hung、カナダより Dr. Duc Vu の総勢 30 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 10 回 FHH Standing Committee 会議の概要

11 月 27 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. Socorro Escalante 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 Prof. Le Van Truyen、Dr. Duc Vu、Prof. Sang Kook Lee 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、Dr. Socorro Escalante、木内教授及び Mr. Robert Law が座長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）WHO（Dr. Socorro Escalante）

西太平洋地域における 2011 年から 2020 年にかけての伝統薬戦略について説明がなされた。特に西太平洋地域各国における伝統薬の安全性、品質並びに行政システムに関する詳細な説明がなされた。

2）中国（Dr. Lin Ruichao）

中国における 2011 年から 2015 年にかけての化学薬品及び TCM の安全性に関する 5 カ年計画の取り組みについて詳細な報告がなされた。また、SFDA が担当している医薬品の規制システム及び品質管理システム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、昨年度に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。

4）日本（合田幸広生薬部長、国立衛研）

2011 年から 2012 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 月に施行された第 16 改正日本薬局方の英語版が刊行され、2012 年 10 月には第 16 改正日本薬局方第一追補が施行されたとの説明がなされた。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に収載された漢方処方エキス及び TLC による新規確認試験法に関する詳細な報告がなされた。

11 月 27 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）

5）韓国（Dr. Shin-Jung Kang）

韓国より FHH 標準生薬の設定に関する新たな提案がなされた。現在、韓国が主催する Sub-Committee II では、GMP 及び GAP の品質保証並び情報交換のための FHH ウェブサイトの維持管理を担当しているが、今後 10 年間の活動を鑑み新たなミッションを立ち上げる必要性がある旨、説明がなされた。そのため新たに FHH 標準生薬の設定に関する会議を 2013 年に韓国において開催し、各国から意見徴収を行いたいとの要望が提出された。会議の詳細については追って韓国よりアナウンスされるとの説明がなされた。

6）シンガポール（Mr. Pang Tit Keong）

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。特にシンガポールにおける代替医療に関連する製品の薬事監視システムについて詳細な説明がなされるとともに ASEAN 諸国との伝統薬等の調和に関する取り組みについて報告がなされた。

7）ベトナム（Dr. Tran Van On）

ベトナム北部地域に新たに建設を開始した Yen Tu 薬用植物園プロジェクトに関する詳細な説明がなされた。本薬用植物園では 1500-2000 種の薬用植物を維持、保存する予定であり、研究活動及び教育活動に資するために活用する予定であるとの説明がなされた。

8）カナダ（Dr. Duc Vu）

昨年に引き続きカナダにおける 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 の安全性に関して、副作用情報の現状の詳細と副作用情報の内容を向上させるための新たな取り組みについて説明なされた。

11 月 28 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）Comparative Studies on Names of Crude Drugs in JP16 and CP2010 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 Names of Crude Drugs in JP16 and CP2010 に関する説明がなされた。既に刊行されている 2007 年版の比較表では JP15 と CP2005 を比較していたが、今回生薬名に関する比較表のアップデートを行い、JP16 と CP2010 における収載生薬から共通生薬を抽出し、新たな比較表を作成した旨、報告がなされた。

2）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 よりベトナムニンジン（*Panax vietnamenensis* Ha et Grushv.）の形態及び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 を用いたプロファイル分析の現状について説明がなされた。

3）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 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試みる。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. Sang Kook Leeより Sub-committee IIの進捗状況に関する全般的な説明がなされた。

Dr. Tran Viet Hungよりベトナムにおける生薬や生薬関連製品の品質評価に用いる標準品の設定に際し、標準物質の天然資源からの抽出、精製、分離及び各種分析機器を用いた構造解析に関する詳細について報告がなされた。

続いて韓国の Prof. Sang Kook Leeより韓国における生薬の標準化に関する研究の一環としてカシュウの標準化を例にあげて報告がなされた。特に主要成分の分離、同定、HPLC及びTLCを用いた成分分析並びに遺伝子鑑別による種の同定等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）

Dr. Lin Ruichao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。

シンガポールの Ms Choo Peck Lin及び香港の Ms. Robert Lawより昨年に引き続き、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。

Dr. Mguyen Van Hung及び Dr. Nguyen Van Doanよりベトナムにおける伝統薬のアレルギーに関する詳細な報告がなされた。ベトナムでは 1986年以降、伝統薬によるアレルギー症状が散見されるようになり、一部ではかなり重篤化する場合も認められ、薬事監視も観点からも注意が必要である旨、説明がなされた。

続いて Mr. Yang Leより中国における薬事監視の現状について詳細な報告がなされた。近年、中国では ADR 報告が急激に増加しており、対策が必要な旨、説明がなされた。

さらに Dr. Nguyen Hoang Anhよりベトナムにおける伝統薬の薬事監視の現状について具体例を示しながら詳細な報告がなされた。

７．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）次期の Coordinating member partyの検討

事務局より次期（2013-2014 年）Coordinating member partyを検討する必要があるとの提案がなされた。審議の結果、次期 FHH Standing Committeeの Coordinating member partyとしてシンガポールが推薦され、ベトナムの次の Coordinating member partyとして今後２年間、シンガポールが FHHの取りまとめを行うことを承認した。

８．閉会の辞

ベトナムの 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 10回 FHH Standing Committee会議がベトナム、ハノイ、Fortuna Hotelで開催された。本会議では各地域における生薬並びに生薬製剤の規制の現状に関する報告並びに Nomenclature and Standardization、Quality Assurance and Information及び Adverse Drug Reaction に関する３つの Sub-Committee の活動報告がなされた。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、中国葯典 2010等、相次いで各国薬局方が更新されており、今回の会議においても一部の比較表の更新に関する報告がなされたが、他の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。従って今後も引き続き各種比較表の更新並びに追加

記載を行い、更新された比較表については順次、次回の第 11 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：生薬規格の国際標準化と国際調和の動向（ISO/TC249 と FHH）．漢方と最新治療, **22** (1), (2013) in press.

2．学会発表

特になし

G. 知的財産権の出願、登録状況

特になし

Western Pacific Regional
Forum for the Harmonization of Herbal Medicines (FHH)
10th Standing Committee Meeting

PROVISIONAL PROGRAMME

27 November 2012 (Day 1)

Time	Contents
8:00 – 8:30	**Registration**
8:30 – 9:00	**Openning Remark:** Welcome address by Chaiman of FHH for the term 2011-2013, Vice Minister Cao Minh Quang
9:00 9:30	**Introducing Participants** **Adoption of Provisional Programme** **Nomination of Co-chairpersons**
9:30 – 9:45	**Group Photo**
9:45 – 10:00	Coffee/Tea Break
Presention 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 *Dr Socorro Escalante; Technical Officer Pharmaceuticals WHO Country officer for VietNam*
10:30 – 11:00	**China** New Developmental Measures for TCM *Prof. Lin Ruichao, National Institutes for Food and Drug Control, SFDA*
Standing Committee Meeting (Session2)	
11:00 – 11:30	**HongKong, China** The latest regulatory control of herbal medicines *Mr. Robert Law* *Chinese Medicine Division, Department of Health*

11:30 – 12:00	**Japan** Pharmacopoeial topics on herbal medicines in Japan from 2011 to 2012 *Dr. Yukihiro GODA* *National Institute of Health Sciences*
12:00 – 14:00	**Lunch**

	Standing Committee Meeting (Session 3)
14:00 -14:30	**Korea** A proposal – Studies on Establishment of FHH Reference Standards *Dr. Shin-Jung Kang* *National Institute of Food & Drug Safety Evaluation*
14:30-15:00	**Singapore** Country Report – Singapore *Mr. Pang Tit Keong* *Health Sciences Authority*
15:00-15:20	Coffee/Tea Break
	Standing Committee Meeting (Session 4)
15:20 -15:50	**VietNam** Yen Tu Medicinal Plant Garden Project (Yen Tu MPG) *Dr. Tran Van On,* *Hanoi University of Pharmacy*
15:50 – 16:20	**Canada** Update on Regulation Modernisation for Natural Health Products Licensing, Compliance, Enforcement and Safety Monitoring activities in Canada *Dr. Duc Vu* *Health Canada*
16:20 – 17::00	**Disscution**
18:30	Welcome dinner (Fotuna Hotel)

28 November 2012 (Day 2)

Time	Contents
Standing Committee Meeting (Session 5) *Report of Sub-committee I – Nomenclature and Standardization*	
8:30 – 9:00	**Comparative Studies on Names of Crude Drugs in JP16 and CP2010** *Dr Nobuo KAWAHARA - Japan*
9:00 – 9:30	**Panax Vietnammensis Ha et Grushv. Identification concerns** *Dr Le Viet Dung, NIMM*
Standing Committee Meeting (Session 6) *Report of Sub-committee II – Quality Assurance and Information*	
9:30 – 10:00	**Research on extraction, isolation and purification of natural compound to establish reference standards for quality control of materials and herbal medicines in VietNam** *Dr Tran Viet Hung* *National Institute of Drug Quality Control*
10:00 – 10:30	*Standardization of Herbal Medicines Polygonum multiflorum (何首烏)* Prof Sang Kook Lee - Korea
10:30 – 10:45	Coffee/Tea Break
Standing Committee Meeting (Session 7) *Report of Sub-committee III – Adverse Drug Reaction*	
10:45 – 11:15	**Report the Alert System for Adulterated Herbal Medicines** *Ms Choo Peck Lin; Health Sciences Authority, Singapore* *Mr. Robert Law, Hong Kong*
11:15 – 11:45	**Traditional Herbs and Allergy** *Dr. Nguyen Van Hung* *Faculty of Pharmacy Haiphong Medical University* *Dr. Nguyen Van Doan* *Center for Allergic-Clinical Immunology Bach Mai Hospital*
11:45 – 12:15	**ADR Monitoring and administration in China** (2011-2012) *Mr. Yang Le - National Center for ADR Monitoring*

12:15-12:45	**Pharmacovigilance practice of traditional medicine drugs: challenges and perspectives for VietNam** *Dr Nguyen Hoang Anh, Hanoi University of Pharmacy*
	Any other business - Appointment of the next member party for coordinating FHH (from 2013 to 2014) - Appointment of the next FHH Secretariat (from 2013 to 2014) **Closing remarks**
13:00	**Lunch**

14:30 Excursion: Bat Trang Ceramic Village

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

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

27 - 28 November, 2012

Fotuna Hotel, 6B Lang Ha street, Ba Dinh distric, Hanoi, Vietnam

Members
Dr. CAO Minh Quang (Vietnam, The Chairman)
Dr. Socorro ESCALANTE (WHO, Pharmaceuticals WHO Country officer for VietNam)

Prof. LIN Ruichao (China)
Mr. Robert LAW (Hong Kong, China)
Dr. Yukihiro GODA (Japan)
Prof. Fumiyuki KIUCHI (Japan)
Dr. Shin Jung KANG (Korea)
Prof. Sang Kook LEE (Korea)
Mr. PANG Tit Keong (Singapore)
Ms. CHOO Peck Lin (Singapore)
Mr. NGUYEN Van Thanh (Vietnam)
Prof. LE Van Truyen (Vietnam)

Special Member
Dr. Duc VU (Canada)

Observers
Mr. Liu CHUN (China)
Mr. Le YANG (China)
Dr. Nobuo KAWAHARA (Japan)
Dr. Soo-kyung LEE (Korea)
Dr. Jonghwan KIM (Korea)
Prof. TRINH Van Lau
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)
Pharm. CAO Mai Phuong (Vietnam)
Dr. LE Viet Dung (Vietnam)
Dr. TRAN Van On (Vietnam)
Dr. MGUYEN Hoang Anh (Vietnam)
NGUYEN Van Hung (Vietnam)

I. Opening of the Meeting

1. The Chairman, Dr. CAO Minh Quang, Vice Minister, Ministry of Health of the Socialist Republic of Vietnam commenced the meeting by delivering an opening address and extending a warm welcome to all participants. After the opening speech, The Chairman invited participants to introduce themselves.

II. Adoption of Provisional Agenda

2. The updated provisional agenda, which had some minor changes following suggestions from Korea and Japan delegations, was adopted by the Meeting.

III. Nomination of Co-chairpersons

3. The nomination of Co-chairpersons was accepted by acclaim (See ***Annex 1*** for details).

IV. Standing Committee Meeting (Session 1)

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

4. The Co-chairperson, Prof. LE Van Truyen invited Prof. LIN Ruichao to present "New Developmental Measure for TCM".

5. The Co-chairperson, Dr. Duc VU invited Dr. Socorro ESCALANTE to present "Regional strategy for Traditional Medicine in the Western Pacific"

6. Prof. LE Van Truyen ask Prof. LIN Ruichao how some traditional way of processing for example *Glycyrrhizae* processed with child urine, some plants processed with mother milk... could be used in industrialized society. Prof. LIN replied that *Glycyrrhizae* usually used for decoction as crude drug, sometime it is added honey to processing depending on the doctor. He added an example of *Aconitum* which was processed to decrease toxicity and explained that traditional processing for traditional use and sometime people did not know why.

7. Dr. Duc VU asked Dr. Socorro ESCALANTE how many countries in the Western Pacific Region had adverse reaction reporting center and how many of them was connected with WHO Uppsala Center in Sweden. Dr. ESCALANTE replied that in the Western Pacific Region there was around 8 or 9 national ADR monitoring centers which are integrating with Uppsala Monitoring Center including Vietnam, China, Hong Kong, Singapore, Taiwan, Australia, New Zealand, Philippine. But most of pharmacovigilance centers are just dealing with modern medicines, there was only China, Singapore, Korea that had been incorporating herbal medicine into the pharmacovigilance system. WHO proposition is this forum could start sharing information on adverse reaction for traditional medicines and WHO could support this information system in the future.

V. Standing Committee Meeting (Session 2)

9. The Co-chairperson, Prof. LEE Sang-kook invited Mr. Robert LAW to present "The latest regulatory control of herbal medicine"

10. The Co-chairperson, Mr. PANG Tit Keong invited Dr. Yukihiro GODA to present "Pharmacopoeial topics on herbal medicines in Japan from 2011 to 2012"

11. Prof. LEE Sang-kook asked Mr. LAW if the proprietary of Chinese medicine included finish products or it also included mixture of herbal medicine for decoction. Mr. LAW replied that the proprietary of Chinese medicine was only for finish dose form like tablets and capsules. Prof. LEE asked Prof. LIN if the situation was the same in China. Prof. LIN replied that the situation was the same but Hong Kong might have some modifications.

12. Prof. LEE enquired what was the 5 Chinese herbs in Schedule 2 that Mr. Law mentioned in slide number 20. Mr. LAW replied that the 5 Chinese herbs in Schedule 2 had to be under import and export control because they was similar to the toxic one and he would give Prof. LEE more details by email.

13. The question of Dr. Shin Jung KANG related to slide 17 of Mr. LAW's presentation, he would like to know what was the representative of new-medicines that Hong Kong government approved. Mr. LAW replied that there was 2 categories of new-medicines, the first one was herbal medicine which was used for longtime ago but now it had been found to have new indication, an other possibility was plant that had not been used before but now it had been found to have pharmacological activity. Base on the fact that there was no history, no clinical experience to use this herb before so clinical trial was needed before it was marketed in Hong Kong.

14. Dr. KANG's second question was how many items that HKCMMS project had studied. Mr. LAW replied that there was 100 monographs had already published, another 100 will be published the end of this year 2012, Mr. LAW would give more information to Dr. KANG after the meeting.

15. Dr. VU enquired how to ensure the compliance of GMP for pCM manufacturer with voluntary basis and if was there any auditing of these manufacturers to check for compliance. Mr. LAW replied that for GMP certification scheme they had inspection requirement, for new application there was full audit and after the issue of certification inspection scheme was once a year for high risk manufacturer and from 1 to 2 year for lower risk manufacturer.

16. Dr. GODA commented the HKCMMS project was excellent and he wanted to know if the project had finished or continued. Mr. LAW replied that the project will continue with 30 herbs and will be finished in 12 to 18 months. Dr. GODA enquired about the revision of monographs which was already published. Mr. LAW replied that there was discussion in scientific committee to issue a list of monographs to review, he added an example of monograph issued 8 years ago and there was improvement in JP and CP so such monograph had to be reviewed and improved.

17. Dr. TRAN Viet Hung raised a question of intellectual property right of traditional medicine in case of modified formulation. Prof. LIN replied that there was no patent for traditional formulation which was published in documents. Mr. LAW added in Hong Kong there was no intellectual property protect for traditional formulation but there was possible IPR for manufacturing process. Dr. ESCALANTE elucidated more about intellectual property concept which was quite similar in every country member of World Trade Organization. Both medicine or traditional medicine patent was applied in the same principle. One of the basic criteria for IPR was a new chemical entity or it involved inventive step, in case of reformulated products there was no new chemical entity or inventive step and that could not be asked for a patent.

18. Dr. ESCALANTE commented that was very good to hear application of clinical trial for traditional medicines and she wanted to know whether the data of clinical trial of traditional medicines was available to access or not. Mr. LAW replied that when clinical trial had done, the results will be put in paper and once he got the information he will share with FHH members.

VI. Standing Committee Meeting (Session 3)

19. The Co-chairperson, Prof. LIN invited Dr. Shin Jung KANG to present "A proposal – Studies on Establishment of FHH Reference Standards".

20. The Co-chairperson, Dr. ESCALANTE invited Mr. PANG Tit Keong to present "Country Report – Singapore".

21. Dr. GODA asked Mr. PANG what kind of AE report of CPM had been obtained in Singapore and did they investigate causes of these adverse events. Mr. PANG replied that there was several types of adverse event being obtained, it could be hepatotoxicity or very general types like nausea, vomiting, discomfort, rash, etc...For the causes of these toxicities, sometimes they was documented sometimes they was not. There was some common herb which contained some types of antraquinones or asarones that may cause hepatoxicicity, but in general the cause of hepatoxicity had not been studied. Dr. GODA enquired whether these AE report was sent to Uppsala Monitoring Center or not, Mr. Pang replied that they was not.

22. Dr. VU asked Mr. PANG about slide number 28, there was Health Supplements and Complementary Health Products, he wanted to know what was the difference between those categories. Mr. PANG replied that Complementary Health Products may be Traditional medicine or products could not be classified as Health Supplements or Chinese Proprietary Medicines. Dr. VU's second question was did Singapore Health Authority allow to make any claims for Complementary Health

Products. Mr. PANG replied that for Health Supplements they allowed them to make function claims, health claims like boost immune system, for CPM by pre-market approval, they allowed them to make higher claims and for TM they can make certain level of medicinal claims but not to the extend of western medicines.

23. Mr. LAW enquired if the information of technical requirements for safety and quality that Mr. PANG mentioned in slide number 34 could be available to get. Mr. PANG replied that for the requirements which had been adopted they was available in ASEAN website and he could forward the link to Mr. LAW. Mr. LAW enquired if Mr. PANG could give him some information in advance because there would be some significant changes in comparison with the current one in website of HAS of Singapore. Mr. PANG replied that for heavy metals they would remove copper as a toxic heavy metal, for ASEAN would be adopting cadmium, so there was 4 toxic heavy metals: arsenic, mercury, lead and cadmium. For microbiological limits the recommended limits based on the limits of British Pharmacopoeia. Assay for maximum level of vitamins and minerals should not be too low or too high and their limit should be internationally recognized.

24. Dr. GODA asked Dr. KANG if there was a English website for Korean reference standards. Dr. KANG replied that the Korean reference standards was now only for domestic. Dr. GODA commented that easy access to reference standards was important for other countries, so he just suggested Korea and China to create website for this purpose. Dr. KANG added that he just suggested a proposal, Korea accumulated a lot of experiences for making reference standards and it was the time to come together to make international standards for FHH. The project would be discussed next year in Korea.

25. Prof. LEE commented that for the establishment of herbal reference standards sample was very important, as China had a lot of herbal reference standards so China could provide those references and then they could compare with other materials and concluded which was the best. Prof. LIN added in China, there was over 600 reference standards and 3 types of reference standards was used: chemical substance, extract of plant and crude drug and he highly appreciated the use of crude drug as reference standards in identification. Then he asked if JP had used crude drug as reference standards. Prof. KIUCHI replied that only 2 crude drug was used as reference standards in JP, one of those was *Angelica.* Dr. KAWAHARA had the data and TLC profiles of medicinal plant in Japan and he said that it would be able to access in their website in March or April next year with English version.

VII. Standing Committee Meeting (Session 4)

26. The Co-chairperson, Prof. Fumiyuki KIUCHI invited Dr. TRAN Van On to present "Yen Tu Medicinal Plant Garden Project".

27. The Co-chairperson, Mr. Robert LAW invited Dr. Duc VU to present "Update on Regulation Modernisation for Natural Health Products Licensing, Compliance, Enforcement and Safety Monitoring activities in Canada".

28. Dr. GODA asked Dr. VU if there was any standards of disintegration for herbal medicines in Canada. Dr. VU replied that in Canada, for crude drug, with regard to quality control they followed certain key pharmacopoeias such as JP, USP, EP, for finish product they also followed quality control standards from different regulators. Those products needed to meet within 10 % of evaluation of the standards including disintegration, dissolution, etc and those test was needed to establish the shelf-life of product. If the company did not submit information that prove the product was within the 10 % of the standards, it would be rejected from the market or reduced the shelf-life.

29. Prof. LIN asked Dr. TRAN Van On if the Medicinal Plant Garden included only Vietnamese plants or it included plants from other countries. Dr. TRAN Van On replied that beside Vietnamese original plants, they would import medicinal plants from other countries and mostly from China but only plants which could be adapted with tropical climate in Vietnam. Dr. TRAN added that Vietnam had 2 main kinds of herbal medicine, the first one was traditional medicine which was very close to Chinese traditional medicine and the second was people medicine which was used by Vietnamese people including 54 ethnic groups and the project would emphasized the development of the second one. Prof. LIN enquired how many medicinal plants was there in Vietnam. Dr. TRAN Van On replied that until now Vietnam had discovered about 4000 species having medicinal property, among them about 800 plants was commonly used and about more than 200 plants used in pharmaceutical industry. Prof. LIN enquired how many herbal finish product was there in Vietnam. Dr. TRAN Van On replied that there was about 2000 herbal finish products registered in Vietnam.

30. Prof. KIUICHI asked Dr. TRAN Van On if the project had any plan to exchange the plant recourses with other plant garden outside Vietnam. Dr. TRAN replied that they had joined the network of botanical gardens in the world and they had invited international experts to help them in the project, especially they had a very close relation with Singapore Botanic Garden.

31. Mr. LAW asked Dr. VU about slide number 13 in which Dr. VU mentioned the Independent Advertising Preclearance Agencies (APAs), Mr. LAW would like to know if it was a self-financial agency and if was there any relationship with

government. Dr. VU replied that this agency is an independent and self-funded agency out of Health Canada. The agency received money from pharmaceutical companies for their advertisements, they regulated themselves and had their own system to evaluate advertisement documents submitted by manufacturers. But in case where they had some doubts, they had to contact Health Canada to determine if advertisement according to the standards or not.

32. Prof. LE Van Truyen asked Dr. VU what was the criteria needed for the third party inspection and how to handle the compromise phenomenon between manufacturer and the third party. Dr. VU replied that they only used the third party audit for herbal medicine because the product was considered as low risk category. For other pharmaceutical product Health Canada always did inspection in house themselves. With regard to third party, for inspection of herbal medicine companies, any inspection agency which was meeting certain ISO criteria or inspector from any regulator in the world would be accepted, but for pharmaceutical only inspection from reputable agencies in the world like USFDA, TGA, European Medicine Agency would be accepted. For the question of conflict of interest, Dr. VU said that when companies used third party inspection, they have to declare and prove there was no conflict of interest between inspector and company.

VIII. Standing Committee Meeting (Session 5)

33. The Chairman of Sub-committee I, Dr. GODA invited Dr. Nobuo KAWAHARA to presented "Comparative studies on the name of crude drugs in JP 16 and CP 2010".

34. Dr. GODA informed that if anyone had wanted a copy of this study they could contact him or ask secretary.

35. Mr. LAW suggested that Dr. KWAHARA could include Hong Kong Chinese materia medica Standards (HKMMS) into his work, in order to have a total review of this matter for all countries in future. Mr. LAW said he would send a hardcopy of HKMMS in English to Dr. Hawahara for the purpose of the comparison. Dr. GODA appreciated Mr. LAW's suiggestion and promised to continue to work hard in the future.

36. An attendee from Vietnam asked Dr. KAWAHARA if the molecular biotechnology was used for identification in JP. Dr. GODA answered that the molecular biotechnology was not used for naming medicine plants in this study, they only compared the name of plants among pharmacopoeia.

37. Dr. Shin Jung KANG asked if *Corydalis tuber* had any genetic relation to *Corytalis rhizome*? Dr. KAWAHARA replied that the question could be discussed in the break time because it required a very detailed answer.

38. Dr. KANG announced that KP 10 would be published in the following month and copies would be sent to Japan during that time. Also, an English version of KP 10 was coming next year.

39. Dr. Goda reminded to all members of FHH that English copies of each and every countries' pharmacopoeia should be sent to Japan as soon as possible, in order to compose a detail statistic.

40. Dr. GODA invited Dr. LE Viet Dung to present "Panax Vietnammensis Ha et Grushv. Identification concerns".

41. Dr. GODA wanted to know if Vietnam had succeeded in finding their hybrid Panax Vietnamese species. Dr. LE replied that last year, they had examined about 50 species of ginseng samples from markets around Vietnam, still this hybrid ginseng species had yet to be found. Dr. LE promised he would make formal announcement in the future if he had succeeded. Dr. GODA said that he will inform to his friend in Janpan who was interested about Panax Vietnamese.

42. Dr. Goda proposed that FHH should apply ISO standards with the purpose of standardize materia medica, including Koran medicine material, different types of Kampo form Japan and other materia medica of other countries in this area. Dr. GODA said that harmonization will be very important in the future, considering FHH's experience in the last 10 years. He also emphasized that any negative feedback should be dealt with later, in order to save time for the discussion. He believed that real situation every country member of FHH should be discussed base on the dominant idea of FHH itself, not on each countries' own point of view. ISO conference participants should be informed about FHH's point of view and FHH's experience. All participants will bear all expenses. Information about the conference will be emailed to all members and reported in the next meeting. He thought that it was necessary for him to attend the ISO conference in South Africa and would like to know if there were any objection.

43. Mr. LAW enquired if FHH was only an observer in the next ISO conference.

44. Dr GODA asked if anyone would like to attend in the upcoming ISO conference with the current regulation of FHH, and encouraged all member to