出國報告(出國類別:考察)

## 參加赴越南中藥草考察團

服務機關:衛生福利部

姓名職稱:黃彥豪 專員

派赴國家:越南

出國期間:108年10月29日至11月01日

報告日期:108年12月31日

### 摘 要

台北市進出口商業同業公會受經濟部國貿局委託,辦理赴越南中藥草考察團。國際貿易局邀集行政院農委會與本部、該公會及若干臺灣廠商代表組成考察團,於今(108)年10月29日至11月2日(11月2日無行程,職11月1日返台),在河內市、安沛省及老街省等地,考察中藥草種植;拜會越南農業暨農村發展部、衛生部及國家藥用材料研究所。評估臺灣向越南購買、栽種藥用植物之貿易發展事宜,提升雙邊貿易,加強雙方國際合作基礎。

於越南當地考察草果及肉桂之中藥材種植、採收及加工,參觀當地廠商林安盛桂林公司之肉桂採收及加工過程;考察越南藥料公司之生產之中藥材產品,了解越南中藥材之產製情形。拜會越南農業暨農村發展部、衛生部及國家藥用材料研究所,溝通臺灣廠商購買越南產製中藥材的國際貿易可能面臨之疑慮,及了解臺越官方所能提供之協助。

老街省有種植川芎、白朮、桔梗、砂仁、草果及三七等中藥材,農業暨農村發展廳將於明(109)年完成檢驗機構硬體設施,日後可提供當地採購中藥材之品質檢驗,控管品質;可出具官方檢驗證明文件,供當地產製中藥材輸臺之用。參觀越南藥料公司,了解其產製芍藥、黃柏、肉桂、鈎藤、黃耆、黃連、續斷及甘草等百餘項中藥材;具有GLP 認證的檢驗室、符合 GSP 認證之儲存地點及 WHO-GMP 認證之食品製造廠,把關品質,生產優質中藥產品。

安沛省大量栽種肉桂,品質佳;當地對肉桂作物之應用及加工已 具規模,如中藥材之桂皮、桂枝、桂蒂、小桂子及桂心等利用;運用 肉桂餘料加工成膠(三)合板之原料。因肉桂栽種成熟時間冗長,且無 配套措施,當地農民對肉桂栽種已不積極投入,甚至希望在肉桂採收 完後就想改種經濟性高的水果,以致已在當地投資之臺商,希望越南 政府能有栽種中藥材之鼓勵措施。

拜會越南中央醫藥材料研究所(NIMM),了解中藥材檢驗及 越南當地藥用植物開發、栽種及應用現況;傳統醫藥管理局 (TMA),表示希望在平等雙贏的原則下進行雙邊中藥貨品貿易,並提供越南中藥材供應商與可提供契作栽種供應之中藥材等名單,及互留雙方聯絡窗口,極度希望促成提升臺越雙邊貿易。

臺灣廠商表示,因為考察時間太短及未安排在中藥材採收時間 參訪,無法參觀更多中藥材栽種採收及與當地廠商對話,希望越南 廠商能來臺灣進行貿易對談會及當地官方能確保貿易貨品品質。

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### 壹、目的

經濟部國貿局執行,行政院鄧政務委員振中乙行訪越駐越南代表處代辦事項,委託臺北市進出口商業同業公會辦理赴越南中藥草考察團。考察團於今(108)年10月29日至11月2日(11月2日無行程,職11月1日返台),於河內市、安沛省及老街省等地考察中藥草種植及拜會越南農業暨農村發展部、衛生部傳統醫藥管理局及國家藥用材料研究所。

考察團此行係由國貿局引領臺灣中藥業者前往考察,越南(北部)種植中藥材情形;評估向越南購買、栽種藥用植物之貿易發展事宜,以提升雙邊貿易往來,加強雙方國際合作基礎。

### 貳、過程

#### 一、 本次出訪越南行程如下:

日期	時間	工作内容
10/29	19:00	團員抵達越南河內之內排國際機場,搭車前往越南北部
(二)		的老街省,旅館 Check-in
	07:30-08:30	拜會老街省農業暨農村發展廳
10/30	08:30-15:30	搭車走山路入山,參觀巴剎縣 Y TY 依荻鄉之草果種植
(三)	15:30-18:30	搭車前往安沛省
	19:00-21:00	参訪林安盛桂林公司之肉桂採收及加工過程
	08:30-13:00	搭車前往文安縣 Xuan Tam 春興鄉,參觀肉桂採收
10/31	14:00-16:30	搭車前往河內參訪越南藥料公司
(四)	18:00	參加越南臺灣試務委員會阮進洪秘書長及駐越南台北 經濟文化辦事處陳錦玲公使主持之晚宴
,	09:00-13:00	拜會中央醫藥材料研究所(NIMM)
11/1	10:30-12:00	拜會衛生部傳統醫藥管理局(TMA)
(五)	12:30-14:00	拜會駐越南台北經濟文化辦事處
	14:00	返台

### 二、拜會老街省農業暨農村發展廳

老街口岸連結中國雲南省,是毗鄰中國最近的口岸,有法國及蘇俄等國發展過。與中國有鐵道、公路及河運等交通,從中國昆明經老街至海防的鐵路只有854公里。目前老街生產的作物有橡膠、咖啡豆、腰果、三七、肉桂、草果及菸葉等,肉桂年產值3000萬越南盾(約新台幣1,287萬);礦產有煤、水泥及石膏等。老街省人口數為73萬人,城市人口數有17萬人,有25個民族;下有1個省轄市、8個行政區及164個鄉鎮。具有700萬公頃的種植面積,種植有川芎、白朮、桔梗、大茴香、草果及膨大海等藥材,肉桂栽種面積3萬公頃,每年生產7,00公噸、草豆蔻1,200公噸、檸檬香茅315公噸,其經濟栽種作物均符合世界衛生組

織(GACP-WTO)之VIE7-GAP生產標準。

老街省農業暨農村發展廳正在建置檢驗實驗室,希望未來能提供 出口臺灣中藥材之檢驗證明文件,也會輔導當地廠商與臺商對接,提 高越南產製中藥材輸入臺灣之出口量;並提供臺商貿易協助。臺商反 應能輔導當地農民栽種三七等中藥材出口臺灣。

#### 三、參訪草果種植地(巴剎縣 Y TY 依荻鄉)

老街省巴剎縣 Y TY 依荻鄉位於偏僻山區,從老街市出發,搭 9 人座小型車,車程約 4 小時。其連外道路為單線產業道路,幾乎沒有柏油路面。道路寬度僅 4-5 米,只可容納 2 輛小型車會車,無法容納大型貨車進出,路況。

產地栽種草果,該種植區達十餘公頃,年產值約數萬公噸。沒有田畦田渠等田間管理,雜草叢生,屬於純人工施作栽種。沒有使用現代化大型農業機具輔助農作物種植、採收及運送,較無法提升農作物產率。由於農民乾燥草果係以燃燒柴火直接加熱烘烤方式進行,所以草果會殘留大量環境汙染物 2-苯基苯酚(2-phenyl phenol),影響殘留農藥檢測結果。

### 四、參訪林安盛桂林公司之肉桂採收及加工過程

林安盛桂林公司係一家由當地廠商與臺灣廠商合作的專門產製 肉桂相關中藥材的藥材製造商,未實施GMP製程管理;員工約40名, 廠方面積約3000坪,年營業額2-3百萬美元。生產桂皮、桂枝、桂尖、 桂心、桂蒂及桂子等中藥材,並將肉桂心材剝片製造膠(三)合板販售, 提升肉桂植物利用率。

現場發現僅桂枝採機械切製,其餘之桂皮板皮、去外皮等加工程 序均採人工方式進行;並採天然材料包裝,減少環境汙染。由於該公 司有臺商投資,有專業中藥臺商參與管理,對於製造的肉桂程序有要 求(如已加工之桂皮不接觸地面、桂枝陰乾期近1年以消除天然甲醛殘 留及去除肉桂外皮減少污染物殘留等),以致其製造的肉桂產品之桂皮醛(肉桂精油)含量高、污染物少及賣相佳,品質優良;有大量外銷訂單,外銷臺灣、大陸、韓國及印度等國家。

### 五、前往安沛省文安縣 Xuan Tam 春興鄉,參觀肉桂採收

安沛省文安縣 Xuan Tam 春興鄉肉桂產區,係一偏僻山區,僅有產業道路,無法容納大型貨車進入,交通不便。當地農民採收肉桂後以機車載運集至工寮暫時儲存,然後由中小型貨車統一運載至各工廠加工。工寮儲放桂皮沒有用獨立可密閉空間;又直接堆放於地面,容易受潮及產生蟲蛀情形,沒有專業管理。

肉桂在山坡上栽種,栽種區沒有田畦田渠等田間管理,在山坡上直接砍伐肉桂,剝取桂皮,容易跌倒受傷,施作環境危險;無大量雜草叢生,可能有施用農藥。純人工栽種,沒有現代化大型農業機具輔助,如能多利用農業機械及加入有規劃之田間管理,應該能提升種植中藥材等作物產率。

由於肉桂栽種至採收需要 20-30 年以上,且栽種地市保護區僅能由當地原住民栽種,一般公司無法聘雇大量人力進行經濟栽種採收,又栽種肉桂所得不高(一顆 25 年樹齡肉桂僅能販賣近兩、三千元臺幣),當地原住民多傾向砍伐肉桂林地將朝向種植水果等高經濟作物替代肉桂。臺商擔憂越南無法長期供應肉桂銷售臺灣。

# 六、參訪越南藥料公司(VIETNAM MEDICINAL MATERIALS JOINT STOCK COMPANY)

由副總裁陳平源先生接待及簡報,越南藥料公司於2011年成立,有GLP、GMP及GSP(GOOD STORAGE PRACTICE)認證,其實驗室另已通過國際ISO17025實驗室認證;具有多功能萃取機、真空循環式濃縮機、噴霧乾燥機及流床乾燥設備。有生產山藥、白朮、川芎、肉桂、鉤藤、黃連及黃耆等近百種中藥材,供應越南國內中醫醫療機構、食

品業者及國外廠商(如印度、泰國等);並生產含維生素及胺基酸等成分 之膠囊狀保健品。

由於該公司中藥材產品賣相好,我方之臺商代表有興趣採購,惟 該公司沒有安排專門會中文的工作人員及時間短促,無法詳談交易細 節,無法即時促成雙方貿易。

#### 七、拜會中央醫藥材料研究所(NIMM)

由阮所長接見及簡報,NIMM 成立於 1961 年,為衛生部轄下單位。 其業務有保育發展越南傳統草藥,有保存 5 千多種保育物種;其保育物種能種植及供應農民耕作;也開發現有品種萃取加工技術,製成藥品、食品及化妝品等。有跟臺灣之陽明大學、國家中醫藥研究所進行藥草研究合作。

衛生部將提供可選擇栽種之藥用植物名單,臺灣業者可從名單或 名單外選擇需要的藥材,該所可協助提供栽種技術予越南農民栽種, 銷售臺灣。該所已有輔導越南農民栽種大茴香及槐花等中藥材,每年 有3萬公噸以上產值銷往中國。輸臺中藥材該所也可以提供檢驗報告, 協助出口。

### 八、拜會衛生部傳統醫藥管理局(TMA)

由阮副局長及裴科長等官員接見,阮副局長表示雙方能在平等雙贏原則下進行兩國貿易交流;可以栽種台灣需要的藥材,有關雙方部分,該局可提供臺商法律協助與諮詢及越南優良藥材供應商名單;希望雙方能提供優勢產品給兩國人民。當場提供越南有關中藥產品事務聯絡人員資料(阮公梁先生及陳文卿先生之聯絡電話及電郵)予臺商。

會場外有安排 2 家越南中藥材供應商,因為時間短促(僅 10 分鐘對談),我方之臺商代表雖有興趣採購,卻無法詳談交易細節,提高雙方貿易往來可能性。

#### 九、拜會駐越南台北經濟文化辦事處

由石瑞琦大使、陳錦玲公使及經濟組曾組長接見,自 2016 年起至 2018 年止,臺越航班增加 3.5 倍(2018 年 348 航次/周),越南訪臺人數增 加 3 倍(2018 年達 490,774 人次),越南留學台灣學生超過 3 倍(2018 年 12,983 人),臺越貿易額增加 25.2%(2018 年達 163.79 億美元);臺灣為越南第 4 大外來投資國。基於臺越貿易及人民往來日漸增加,希望臺灣廠商能多投資越南及購買越南產品,提升臺越兩國友好關係。

### 參、心得及建議

此次越南中藥材考察行,越南廠商及官方展現極度的熱情。其老街 省農業暨農村發展廳及中央醫藥材料研究所皆主動提供輸臺中藥材檢 驗及開立報告之服務,衛生部傳統醫藥管理局並提供越南得栽種之藥用 植物清單及中藥貨品事務聯繫人員窗口,使此行臺灣廠商代表除表示讚 嘆外,並因參觀肉桂栽種及加工情形,提升對越南產製中藥材信心,增 加採買越南產製中藥材可行性。

此次所參觀的越南中藥材產地,並未實施田間管理,與中國大陸及臺灣栽種方式有很大落差,越南栽種廠商亦無機會提供其栽種、加工等方式及施藥與否等細節說明,雖然越南出示的中藥材產品賣像佳,但臺商對此中藥材品質如二氧化硫、重金屬、黃麴毒素及農藥殘留等問題仍感疑慮。當地廠商也沒有熟擅中文人員任職,臺灣廠商未具優良外語能力,無法與越南廠商面對面溝通,雙方有語言隔閡。

惟此行時間短促,且越方多提供越南文之資料(如越南中藥材供應商名單僅越南文,也沒有聯絡人姓名、電話及電郵等內容),英文或中文參考資料未能提供,無法立即深入了解越南法律規定、當地中藥材含異常物質限量標準及如何確保輸臺中藥材貨品品質與流向管理等細節;暨與當地廠商就購買中藥材細節進行意見交換。越方也沒有進行說明臺商在當地投資種植之獎勵等措施,無法即時釐清臺商疑慮及增加臺商購買越南中藥貨品或投資栽種之可能性。

臺北市進出口商業同業公會及臺商代表希望,越方官方及廠商能組 團來臺,並提供中(或英)文說明資料、中藥材貨樣及說明輸臺中藥材貨 品品質保證與在越南投資種植中藥材之獎勵措施等細節,進行溝通。

因為需要了解越南廠商能否長期穩定供應中藥材、臺商投資保障 (獎勵)措施及如何確保輸臺中藥材品質等節,臺北市進出口商業同業公 會建議,越方能提供相關細部規劃說明,釐清臺商疑慮,提升臺商前往 越南採購意願。

### 肆、致謝

誠摯的感謝經濟部國際貿易局及駐越南臺北文化經貿辦公室,協助安排出訪越南,考察老街及安沛等地之中藥材栽種,並擔任翻譯,讓本次考察得以順利圓滿結束。

### 伍、附件

### 一、2019年赴越南中藥草考察團團員名冊

### (一)廠商代表團員名單

		D = -121 =	81
No.	Company	Position	Name
1	台北市進出口商業同業公會	秘書長/團長	黃文榮
	Importers and Exporters Association of Taipei	Secretary General/	PETER W.J. HUANG
		Mission Leader	post X & P
2	集昌股份有限公司	負責人	馬逸才
	TSIH CHUANG TRADING CO., LTD.	Owner	MA I-TSAI
3	綺蔘貿易股份有限公司	董事長	葉甘霖
	JAPPSON ENTERPRISE INC.	President	YEH KAN-LIN
4	金義豐有限公司	負責人	黃文苑
	GOLDEN YIEE FORN CO., LTD.	Owner	HUANG WEN-YUAN
5	金義豐有限公司	經理	黄采晴
	GOLDEN YIEE FORN CO., LTD.	Manager	HUANG TSAI-CHING
6	久代貿易有限公司	顧問	陳子博
	JEOU DAI TRADING CO., LTD.	Consultant	CHEN TZU-PO
7	太和春蔘藥行	執行長	歐怡伶
	TAI HE CHUN HERBAL MEDICINE STORE	CEO	OU YI-LING
8	廣營貿易有限公司	負責人	黃龍達
	GUANGWIN TRADE CO., LTD.	Owner	HUANG LUNG-TA
9	漢方正元堂生技有限公司	負責人	朱志偉
	ZHENG YUAN TANG BIOTECH CO., LTD.	Owner	CHU CHIH-WEI
10	振泰檢驗科技股份有限公司	總經理	章嘉明
	JTTEC SERVICE CORPORATION	CEO	CHANG CHIA-MING
11	益壽蔘藥行	經理	林琮凱
	YI SHOU HERBAL MEDICINE STORE	Manager	LIN TSUNG-KAI
12	德和蔘茸有限公司	經理	林士傑
	THE HO GINSENG & YOUNG ANTLERS CO., LTD.	Manager	LIN SHIH-CHIEH
13	英喬貿易有限公司	負責人	陳羿興
	YIN CHIAU TRADING CO., LTD.	Owner	CHEN YI-HSING
14	錦謚行貿易有限公司	執行長	林孟漢
	JIN YI HANG TRADING CO., LTD.	CEO	LIN MENG-HAN
15	錦謚行貿易有限公司	經理	蔣欣怡
	JIN YI HANG TRADING CO., LTD.	Manager	CHIANG HSIN-I
16	天一中藥房	經理	吳長興
	TIAN-YI CHINESE HERBAL SHOP	Manager	WU CHANG-HSING
17	天一中藥房	經理	柯明秀
	TIAN-YI CHINESE HERBAL SHOP	Manager	KO MING-HSIU

No.	Company	Position	Name
18	台北市進出口商業同業公會	國內業務組 組長	林雯雯
	Importers and Exporters Association of Taipei	Chief of Domestic	小安安 LIN WEN-WEN
		Affairs Section	LIIV VV LIN-VV LIN
19	台北市進出口商業同業公會	國內業務組 專員	謝宗憲
	Importers and Exporters Association of Taipei	Coordinator of Domestic	砌木思 HSIEH TSUNG-HSIN
		Affairs Section	TISIET ISONO-TISIN

### (二)官方機構代表團員名單

No.	Government Agency	Position	Name
1	經濟部國際貿易局	雙邊貿易一組 組長	戴婉蓉
	Bureau of Foreign Trade, Ministry of	Director of First	AMELIA W.J DAY
	Economic Affairs	Bilateral Trade Division	AIVIELIA VV.J DAT
2	行政院農委會國際處	副處長	林志鴻
	Department of International Affairs, Council	Deputy	LIN CHIH-HUNG
	of Agriculture, Executive Yuan	Director-general	LIN CHIH-RONG
3	行政院農委會國際處	   國際合作科 技正	張志仁
	Department of international Affairs, Council	Specialist	CHANG CHIH-JEN
	of Agriculture, Executive Yuan	Specialist	CHANG CHITPJEN
4	衛生福利部中醫藥司	事員	黄彦豪
	Department of Chinese Medicine and	マラー Executive Officer	與多家 HUANG YEN-HAO
	Pharmacy, Ministry of Health and Welfare	Executive Officer	HUANG TEN-HAU
5	行政院經貿談判辦公室	薦任科員	黃偉倫
	Office of Trade Negotiations, Executive Yuan	Officer	WEI-LUN HUANG

### (三)我國駐越南官方代表團員名單

No.	Representative Office	Position	Name	
1	駐越南台北經濟文化辦事處	經濟組 組長	曾顯照	
	Taipei Economic and Cultural Office in	Director of Economic	TSENG	
	Vietnam	Division	HSIEN-CHAO	
2	駐越南台北經濟文化辦事處	經濟組 秘書	許孟岡	
	Taipei Economic and Cultural Office in	Secretary of Economic	日本中 HSU MENG-KANG	
	Vietnam	Division	HSU WENG-KANG	
3	駐越南台北經濟文化辦事處	經濟組 雇員	申氏芳江	
	Taipei Economic and Cultural Office in	Assistant of Economic	THAN THI PHUONG	
	Vietnam	Division	GIANG	

### 二、相片

### 拜會老街省農業暨農村發展廳





### 至老街省巴剎縣 Y TY 依荻鄉,參觀草果種植區





### 參訪林安盛桂林公司之肉桂採收及加工過程



文安縣 Xuan Tam 春興鄉,參觀肉桂採收



### 參訪越南藥料公司





### 拜會中央醫藥材料研究所(NIMM)





### 拜會衛生部傳統醫藥管理局(TMA)





### 拜會駐越南台北經濟文化辦事處



### 三、攜回資料名稱及內容:

### (一)越南進出口藥材廠商名單

TT	Tên công ty 公司名	Địa chỉ 公司地址
1	Công ty cổ phần dược Trung ương Mediplantex	Số 358 đường Giải Phóng, quận Thanh Xuân, thành phố Hà Nội
2	Công ty cổ phần được Sơn Lâm	Tầng 3, TT DVTM Thanh Trì, Km 1 0 + 400 đường Ngọc Hồi, huyện Thanh Trì, thành phố Hà Nội
3	Công ty TNHH Thiên Ân Dược	Lô BT34 – BT39 Khu dân cư dịch vụ đấu giá và tạo vốn xây dựng CSHT, xã Đình Bảng, huyện Từ Sơn, thành phố Bắc Ninh
4	Công ty cổ phần được liệu Hà Nội	Khu Lạch Trũng, Tổ 2, phường Thạch Cầu, quận Long Biên, thành phố Hà Nội
5	Công ty TNHH Dược Ninh Giang	Khu Só Lai, xã Ninh Hiệp, huyện Gia Lâm, thành phố Hà Nội
6	Công ty cổ phần Đông Y Dược Thăng Long	Km3 Quốc lộ 21B, thôn Thạch Bích, xã Bích Hòa, huyện Thanh Oai, thành phố Hà Nội
7	Công ty TNHH Đông Dược Đồng Hưng Đường	Xóm 7, xã Tân Thành, huyện Vụ Bản, tỉnh Nam Định
8	Công ty cổ phần dược phẩm Trường Thọ	Lô M1, Đường N3, KCN Hòa Xá, xã Lộc Hòa, tỉnh Nam Định
9	Công ty cổ phần dược phẩm Khang Minh	Số D19/37K Hương lộ 80B, Ấp 4, xã Vĩnh Lộc B, huyện Bình Chánh, thành phố Hồ Chí Minh
10	Công ty cổ phần dược phẩm OPC	Số 1017 Hồng Bàng, phường 12, quận 6, thành phố Hồ Chí Minh
11	Công ty cổ phần Đầu tư và phát triển Y dược Thăng Long	Số 516 Hà Huy Tập, huyện Gia Lâm, thành phố Hà Nội

ТТ	Tên công ty 公司名	Địa chỉ 公司地址
12	Công ty cổ phần dược liệu Việt Nam	Khu 8, xã Phù Ninh, huyện Phù Ninh, tỉnh Phú Thọ
13	Công ty cổ phần dược liệu Trường Xuân	Lô số CN – 08 – 2 Cụm công nghiệp Ninh Hiệp, xã Ninh Hiệp, huyện Gia Lâm, thành phố Hà Nội
14	Công ty cổ phần dược phẩm Bắc Ninh	Lô C1–1, Khu công nghiệp Quế Võ, huyện Quế Võ, tỉnh Bắc Ninh
15	Công ty cổ phần thương mại Dược Vật tư Y tế Khải Hà	Số 2A, đường Lý Bôn, phường Tiền Phong, thành phố Thái Bình, tỉnh Thái Bình
16	Công ty cổ phần hóa dược Việt Nam	Số 192 Đức Giang, phường Thượng Thanh, quận Long Biên, thành phố Hà Nội
17	Công ty cổ phần dược phẩm Hà Tây	Số 242 đường Bia Bà, phường La Khê, quận Hà Đông, thành phố Hà Nội
18	Công ty TNHH Đông Dược Văn Hương	Thôn Hạ Trung, xã Bảo Ninh, thành phố Đồng Hới, tỉnh Quảng Bình
19	Công ty cổ phần được Nam Yên	Kho 1, Tổng kho Phú Cát, đường 21A, thôn 7, xã Phú Cát, huyện Quốc Oai, thành phố Hà Nội.
20	Chi nhánh Công ty TNHH Dược phẩm Bách Thông	Khu Thượng, xã Tráng Liệt, huyện Bình Giang, tỉnh Hải Dương
21	Công ty cổ phần dược phẩm Nam Hà	Lô H10, Khu công nghệ Hòa Xá, thành phố Nam Định, tỉnh Nam Định
22	Công ty cổ phần dược phẩm Thành Phát	Lô CN1, Khu công nghiệp Phú Nghĩa, xã Phú Nghĩa, huyện Chương Mỹ, thành phố Hà Nội
23	Công ty TNHH Đông Dược Dân Lợi	Số 1201 Đại lộ Hùng Vương, phường Cam Phúc Bắc, thành phố Cam Ranh, tỉnh Khánh Hòa
24	Công ty cổ phần được liệu Ninh Hiệp	Lô E4 – Cụm công nghiệp đa ngành Đông Thọ, huyện Yên Phong, tỉnh Bắc Ninh.
25	Công ty cổ phần xuất nhập	Lô CN-02-10 cụm công nghiệp Ninh Hiệp,

ТТ	Tên công ty 公司名	Địa chỉ 公司地址
	khẩu dược liệu Dương Thư	Xã Ninh Hiệp, huyện Gia lâm, thành phố Hà Nội
26	Công ty TNHH MTV dược liệu Tấn Hải	Số 18 đường 868, phường 1, thị Xã Cai Lậy, tỉnh Tiền Giang
27	CN Công ty cổ phần đầu tư quốc tế Việt Á	Thôn Vân Cốc 3, Xã Vân Trung, Huyện Việt Yên, Tỉnh Bắc Giang
28	Công ty cổ phần thương mại phát triển Dược Thảo Việt Nam	
29	Công ty TNHH Dược Phẩm FITOPHARMA	26 Bis/ 1 Khu phố Trung, phường Vĩnh Phú, thị xã Thuận An, Tinh Bình Dương
30	Công ty TNHH Vạn Xuân	Đường số 3, cụm Công nghiệp Liên Hưng, ấp Bình Tiền 2, xã Đức Hòa Hạ, huyện Đức Hòa, tỉnh Long An
31		7A54 An Hạ, xã Phạm Văn Hai, huyện Bình Chánh, thành phố Hồ Chí Minh
32	Công ty cổ phần Việt Nam GHP	Thôn An Lạc, xã Trung Trắc, huyện Văn Lâm, tỉnh Hưng Yên
33	Công ty cổ phần xuất nhập khẩu dược liệu Việt Nam	Cụm công nghiệp Yên Mỹ, xã Yên Mỹ, huyện Lạng Giang, tỉnh Bắc Giang
34	Công ty TNHH dược liệu Trang Minh	Cụm công nghiệp xã Trung Thành, huyện Vụ Bản, tỉnh Nam Định

### (二)可輸臺之越南產製中藥草清單(越南 2020-2030 年 100 種優先發 展中草藥材清單(越文))

BỘ Y TẾ

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM Độc lập - Tự do - Hạnh phúc

Số: 3657 /QĐ-BYT

Hà Nội, ngày 20tháng 8 năm 2019

#### QUYÉT ÐINH

Về việc ban hành Danh mục 100 được liệu có giá trị y tế và kinh tế cao để tập trung phát triển giai đoạn 2020-2030

#### BỘ TRƯỞNG BỘ Y TẾ

Căn cứ Nghị định số 75/2017/NĐ-CP ngày 20 tháng 6 năm 2017 của Chính phủ quy định chức năng, nhiệm vụ, quyền hạn và cơ cấu tổ chức của Bộ Y tế;

Căn cứ Thông báo số 220/TB-VPCP ngày 12 tháng 5 năm 2017 của Văn phòng Chính phủ thông báo kết luận của Thủ trướng Chính phủ tại Hội nghị toàn quốc về phát triển được liệu Việt Nam;

Xét đề nghị của Cục trưởng Cục Quản lý Y, Dược cổ truyền.

#### QUYÉT ĐỊNH:

- Điều 1. Ban hành kèm theo quyết định này Danh mục 100 dược liệu có giá trị y tế và kinh tế cao để tập trung phát triển giai đoạn 2020-2030 là cơ sở cho các địa phương, doanh nghiệp, đơn vị lựa chọn loài, nhóm loài phù hợp để phát triển dược liêu.
- Điều 2. Đối với các được liệu ngoài Danh mục kèm theo Quyết định này, Bộ Y tế căn cứ vào nhu cầu sử dụng và thực tế phát triển được liệu để xem xét điều chính hoặc bổ sung cho phù hợp.
  - Điều 3. Quyết định này có hiệu lực kể từ ngày ký ban hành.
- Điều 4. Các Ông, Bà: Chánh Văn phòng Bộ, Cục trưởng Cục Quản lý Y, Dược cổ truyền, Giám đốc Sở Y tế các tính thành phố trực thuộc Trung ương và các tổ chức cá nhân liên quan chịu trách nhiệm thi hành Quyết định này./.

#### Nơi nhận:

- Như điều 4:
- Bộ trương (để b/cáo);
- Các Thứ trường (để biết);
- Cục Quản lý Dược; Cục KHCN&ĐT;
- Viện dược liệu;
- Hiệp hội được liệu Việt Nam;
- Tổng công ty được Việt Nam;
- UBND các tính và TP trực thuộc TW;
- Sơ Y tế các tính và TP trực thuộc TW;
- Luu: VT, YDCT.

KT. BỘ TRƯỞNG THỂ TRƯỞNG

- CONC

Nguyễn Viết Tiến

#### Phụ lục Danh mục 100 loại cây được liệu có giá trị y tế và kinh tế cao để tập trung phát triển.

(Ban hành kèm theo Quyết định số 3657/QĐ-BYT ngày 20 tháng 8 năm 2019 của Bộ trường Bộ Y tế)

STT	Tên dược liệu	Tên khoa học
1	Actiso	Cynara scolymus L Asteraceae
2	Ba kích	Morinda officinalis F.C.How Rubiaceae
3	Bạc hà	Mentha arvensis L Lamiaceae
4	Bách bệnh	Eurycoma longifolia Jack - Simaroubaceae
5	Bách bộ	Stemona tuberosa Lour Stemonaceae
6	Bạch cập	Bletilla striata (Thunb.) Reichb. F Orchidaceae
7	Bạch chi	Angelica dahurica (Fisch. ex Hoffm.) Benth.et Hook.f. – Apiaceae
8	Bạch giới tử	Sinapis alba L. – Brassicaceae
9	Bạch hoa xà thiệt thảo	Hedyotis diffusa Willd. – Rubiaceae
10	Bách hợp	Lilium spp Liliaceae
11	Bạch truật	Atractylodes macrocephala Koidz Asteraceae
12	Bán chí liên	Scutellaria barbata D. Don Lamiacae
13	Bảy lá một hoa	Paris spp Trilliaceae
14	Bề bồ	Adenosma indianum (Lour.) Merr Scrophulariaceae
15	Bồ công anh	Lactuca indica L Asteraceae
16	Bồ kết	Gleditsia australis F. B. Forbes & Hemsl Fabaceae
17	Cam thảo	Glycyrrhiza spp. – Fabaceae

STT	Tên dược liệu	Tên khoa học
18	Cát cánh	Platycodon grandiflorum (Jacq.) A.DC. – Campanulaceae
19	Cát sâm	Callerya speciosa (Champ.) Schot - Fabaceae
20	Câu đẳng	Uncaria spp. – Rubiaceae
21	Cầu tích	Cibotium barometz (L.) J. Sm Dicksoniaceae
22	Cốt khí củ	Reynoutria japonica Houtt Polygonaceae
23	Cốt toái bổ	Drynaria fortunei (Kuntze ex Mett.) J. Sm., Drynaria bonii H. Christ, Drynaria quercifolia (L.) J.Sm. – Polypodiaceae
24	Cũ mài (Hoài sơn)	Dioscorea persimilis Prain et Burkill – Dioscoreaceae
25	Cúc hoa vàng	Chrysanthemum indicum L Asteraceae
26	Đảng sâm	Codonopsis javanica (Blume.) Hook.f. – Campanulaceae
27	Dành dành	Gardenia jasminoides J. Ellis Rubiaceae
28	Dâu tầm	Morus alba L Moraceae
29	Đậu ván trắng	Lablab purpureus (L.) Sweet - Fabaceae
30	Dây đau xương	Tinospora sinensis (Lour.) Merr Menispermaceae
31	Dây thìa canh	Gymnema sylvestre (Retz.) R.Br. ex Sm Asclepiadaceae
32	Diệp hạ châu đắng	Phyllanthus amarus Schumach. & Thonn Euphorbiaceae
33	Dinh lăng	Polyscias fruticosa (L.) Harms – Araliaceae
34	Đỗ trọng	Eucommia ulmoides Oliv. – Eucommiaceae
35	Độc hoạt	Angelica pubescens Maxim Apiaceae
36	Đương quy	Angelica sinensis (Oliv.) Diels – Apiaceae

STT	Tên dược liệu	Tên khoa học
37	Dương quy di thực	Angelica acutiloba (Sieb. et Zucc) Kitagawa - Apiaceae
38	Gấc	Momordica cochinchinensis (Lour.) Spreng Cucurbitaceae
39	Hạ khô thảo	Prunella vulgaris L Lamiaceae
40	Hà thủ ô đỏ	Fallopia multiflora (Thunb.) Haraldson Syn. Polygonum multiflorum Thumb)- Polygonaceae
41	Hoắc hương	Pogostemon cablin (Blanco) Benth Lamiaceae
42	Hoàng bá	Phellodendron chinense C.K. Schneid.  Phellodendron amurense Rupr Rutaceae
43	Hoàng bá nam (Núc nác)	Oroxylum indicum (L.) Kurz Bignoniaceae
44	Hoàng đằng	Fibraurea tinctoria Lour., Fibraurea recisa Pierre Menispermaceae
45	Hoàng kỳ	Astragalus membranaceus (Fisch.) Bunge. var. mongholicus (Bunge.) P.G. Xiao. Syn. Astragalus propinquus Schischkin – Fabaceae
46	Hoàng liên	Coptis spp Ranunculaceae
47	Hòe	Styphnolobium japonicum (L.) Schott, Syn. Sophora japonica L.J - Fabaceae
48	Hồi	Illicium verum Hook.f. – Illiciaceae
49	Hồng hoa	Carthamus tinctorius L Asteraceae
50	Hương nhu tía	Ocimum tenuiflorum L Lamiaceae
51	Huyền sâm	Scrophularia ningpoensis Hemsl Scrophulariaceae
52	Huyết giác	Dracaena cambodiana Pierre ex Gagnep. – Dracaenaceae

STT	Tên dược liệu	Tên khoa học
53	Hy thiêm	Sigesbeckia orientalis L. – Asteraceae
54	Ké đầu ngựa	Xanthium strumarium L Asteraceae
55	Kê huyết đẳng	Spatholobus suberectus Dunn. – Fabaceae
56	Kim ngân	Lonicera japonica Thunb; L. dasystyla Rehd; L. confusa DC; L. cambodiana Pierre ex Danguy – Caprifoliaceae
57	Kim tiền thảo	Desmodium styracifolium (Osbeck) Merr - Fabaceae
58	La hán	Momordica grosvenorium Swingle - Cucurbitaceae
59	Lá khôi	Ardisia gigantifolia Stapf - Myrsinaceae
60	Lạc tiên	Passiflora foetida L Passifloraceae
61	Lan kim tuyến	Anoectochilus roxburghti (Wall.) Lindl Orchidaceae
62	Linh chi	Ganoderma lucidum (Curtis) P. Karst Ganodermataceae
63	Mạch môn	Ophiopogon japonicus (Thunb.) Ker-Gawl. – Asparagaceae
64	Mạn kinh	Vitex trifolia L., (Syn. V.rotundifolia L.f.) – Verbenaceae
65	Mộc hương	Saussurea lappa (Decne.) Sch.Bip Asteraceae
66	Nần nghệ	Dioscorea collettii Hook. f Dioscoreaceae
67	Ngũ gia bì chân chim	Schefflera heptaphylla (L.) Frodin - Araliaceae
68	Ngũ gia bì gai	Acanthopanax trifoliatus (L.) Voss Araliaceae
69	Ngũ gia bì hương	Acanthopanax gracilistylus W.W.Sm Araliaceae
70	Ngũ vị từ	Schisandra spp Schisandraceae

STT	Tên dược liệu	Tên khoa học
71	Ngưu tất	Achyranthes bidentata Blume - Amaranthaceae
72	Nhân trần	Adenosma caeruleum R.Br., Adenosma bracteosum Bonati - Scrophulariaceae
73	Nữ trình tử	Ligustrum lucidum Ait Oleaceae
74	Ô đầu	Aconitum carmichaeli Debx Ranunculaceae
75	Quế	Cinnamomum cassia (L.) J.Presl - Lauraceae
76	Sa nhân	Amomum spp. – Zingiberaceae
77	Sâm Lai Châu	Panax vietnamensis var. fuscidiscusAraliaceae
78	Sâm Ngọc Linh	Panax vietnamensis Ha et Grushv – Araliaceae
79	Sen	Nelumbo nucifera Gaertn - Nelumbonaceae
80	Sinh địa	Rehmannia glutinosa (Gaertn.) DC Scrophulariaceae
01	Son tra	Malus doumeri (Bois) A. Chev.
81	(Táo mèo)	Docynia indica (Wall.) Decne Rosaceae
82	Tam thất	Panax notoginseng (Burk.) F.H.Chen ex C.H.ChowAraliaceae
83	Tang ký sinh	Scurrula parasitica L. (Syn. Taxillus parasitica (L.) Ban) -Loranthaceae
84	Thạch hộc	Dendrobium spp. – Orchidaceae
85	Thạch xương bồ lá to	Acorus gramineus Soland Araceae
86	Thảo quyết minh	Senna tora (L.) Roxb.; Syn. Cassia tora L Fabaceae
87	Thiên môn đông	Asparagus cochinchinensis (Lour.) Merr Asparagaceae
88	Thiên niên kiện	Homalomena occulta (Lour.) Schott - Araceae
89	Thổ phục linh	Smilax glabra Roxb Smilacaceae

STT	Tên dược liệu	Tên khoa học
90	Trà hoa vàng	Camellia spp Theaceae
91	Trắc bách diệp	Platycladus orientalis (L.) Franco – Cupressaceae
92	Trạch tả	Alisma orientalis (Sam.) Juzep – Alismataceae
93	Tục đoạn	Dipsacus japonicus Miq. Dipsacus asper Wall. ex C.B. – Dipsacaceae
94	Tỳ giải	Dioscorea tokoro Makino ex Miyabe – Dioscoreaceae
95	Vàng đắng	Coscinium fenestratum (Gaertn.) Colebr Menispermaceae
96	Viễn chí	Polygala spp. – Polygalaceae
97	Xa can	Belamcanda chinensis (L.) DC Iridaceae
84	Xà sàng	Cnidium monnieri (I.) Cuss - Apiaceae
99	Xuyên khung	Ligusticum wallichii Franch Apiaceae
100	रं वा	Cotx tachryma-jobi L. – Poaceae

(三)越南政府第652017ND-CP號議定-有關規範生產及使用中草藥材 之品種、資金及技術之特別政策:

THE GOVERNMENT

SOCIALIST REPUBLIC OF VIETNAM

Independence - Freedom - Happiness

No.65/2017/ND-CP

Hanoi, May 19, 2017

#### DECREE

# PROVIDING FOR SPECIFIC POLICIES ON VARIETIES, FUNDING AND TECHNOLOGY FOR PRODUCTION AND USE OF HERBAL INGREDIENTS

Pursuant to the Law on Government Organization dated June 19, 2015;

Pursuant to the Law on Pharmacy dated April 16, 2016;

At the request of the Minister of Agriculture and Rural Development;

The Government promulgates a Decree on specific policies on varieties, funding and technology for production and use of herbal ingredients.

#### Chapter I

#### **GENERAL PROVISIONS**

#### Article 1. Scope and regulated entities

- 1. This Decree provides for a number of special policies on varieties, funding and technology for production and use of herbal ingredients derived from plants and animals.
- 2. This Decree applies to organizations and individuals involved in production and use of herbal ingredients in the territory of the Social Republic of Vietnam.

#### **Article 2. Definition**

For the purpose of this Decree, the terms below shall be construed as follows:

- 1. 'herbal variety' refers to a plant variety or animal breed from which a herbal ingredient is produced.
- 2. "original herbal variety" refers to the initial variety of perennial plants and garden of initial plants of perennials or dominant plants (maternal plants) and variety of annual plants reinvigorated or domesticated from nature or production or prototypal breed, grandparental breed, parental breed or nucleus stock.
- 3. "commercial herbal variety" refers to the variety used for creation of herbal ingredients for purposes other than propagation.
- 4. 'local herbal variety' refers to a variety created during natural evolution which are available in local authorities.

#### Article 3. Principles for policy adoption

- 1. Direct provision of assistance for organizations and individuals running herbal ingredient projects shall be given in a public and transparent manner to the right beneficiaries. Eligible funding recipients must use the funding provided for the right purpose.
- 2. An organization or individual that is eligible to more than one level or type of assistance may select the most beneficial level or type of assistance.
- 3. Assistance shall be provided as per regulations of the policy according to the state budget balancing capacity.

#### Chapter II

#### **SPECIFIC POLICIES**

#### Article 4. Priority given to recognition of herbal varieties

- 1. Local herbal varieties may be considered to be included in the list of animal breeds or permissible herbal varieties for production and trading in Vietnam without going through assay and recognition of new plant varieties or animal breeds specified in Ordinance on plant varieties 2004 and Ordinance on animal breeds 2004 and guiding documents thereof.
- 2. New herbal varieties developed by organizations or individuals shall be proposed for exceptional recognition under regulations in Ordinance on plant varieties 2004 and its guiding documents (for plant varieties) or regulations in Ordinance on animal breeds 2004 and its guiding documents (for animal breeds).

#### Article 5. Assistance in herbal variety production

- 1. A lump sum assistance shall be 50% of total cost for infrastructure investment including reform of farm, irrigation system and internal traffic for such farm, net house, greenhouse, breeding facilities, maintenance house and environmental issue handling which is given to intensive propagation facilities which own at least 2 ha of land for herb cultivation and 0.5 ha of land for animal breeding for the purpose of herbal ingredient production but not exceeding 2 billion VND/facility. Assistance given to herbal variety producers which apply hi-technology according to criteria issued by the Minister of Agriculture and Rural Development must not exceed 3 VND billion/producer.
- 2. A lump sum assistance shall be 60% of the cost for production of original herbal varieties or 30% of the cost for production of commercial varieties according to economic-technical restrictions issued by the Minister of Agriculture and Rural Development. In case hi-technology for production is applied, the assistance given shall be 80% and 50% of production costs for original varieties and commercial varieties, respectively.
- 3. An assistance of 100% of the cost for technical training offered to the variety producer according to standard expenditure specified in Decree No.02/2010/ND-CP dated January 08, 2010 of the Government on agricultural encouragement and guiding documents shall be given.

# Article 6. Assistance in application of technology for production and use of herbal ingredients to follow the practice of good herbal ingredient production and use

- 1. Develop a model for applying technology for production and use of herbal ingredients, give an assistance of 100% of the cost of varieties, fertilizers and pesticides for herb cultivation and the cost of breeds, feed and veterinary drugs for animal breeding according to economic-technical regulations issued by the Minister of Agriculture and Rural Development.
- 2. Give a lump sum assistance of 100% of the cost for issuance of certificate of eligibility for production and use of herbal ingredients
- 3. Give an assistance of 100% of the cost for technical training offered to the herb cultivator and user according to standard expenditure specified in Decree No.02/2010/ND-CP dated January 08, 2010 of the Government on agricultural encouragement and guiding documents.

#### Article 7. Assistance in concentrated herbal ingredient production

Provide a lump sum assistance of 15 VND million/ha for infrastructure construction and

variety purchase of the concentrated herbal ingredient production project with the scale of at least 5 ha of cultivating land or 2 ha of land for intensive breeding project.

#### Article 8. Land incentives

Organizations and individuals running projects on investment in research, propagation and production of herbal ingredients may be entitled to the following incentive policies on land:

1. If the land or water surface used for farming and construction of factory and storage warehouse is leased from the State, the aforementioned entities may be exempted from land rent and water surface rent as per provisions of the Law on Land.

The unit price of leased land

Annual unit price equals (=) rate (%) multiplied by land price. Where:

The rate (%) to calculate the unit price is 0.5%.

Land price equals (=) Land price calculated according to equivalent using purpose specified in the land price list multiplied by the coefficient for land price adjustment.

In case the leased land area is in more than one locality with different land prices and land price adjustment coefficients, the land price for calculation of land rent shall be determined based upon the average land price of the whole leased land area.

- 2. Assistance in land gathering
- a) In case the land or water surface is leased from family households or individuals, the State shall give a maximum assistance of 40% of the land rent or water surface rent in the first 5 years from the day on which the project is run; assistance amount shall be determined according to the unit price of leased land specified in Clause 1 Article 8 herein.
- b) In case receiving the land use right transferred from family households or individuals, the entities may be exempted from charge for issuance of land use right certificate as per law soft provisions.

#### Article 9. Conditions for receiving assistance

Projects that are entitled to specific policies specified in Article 5, 6, 7 and 8 of this 6, Decree must satisfy the following requirements:

1. Herbal varieties must be named in the list of herbal varieties permitted for production and

trading in Vietnam or recognized to be new varieties by the Ministry of Agriculture and Rural Development.

- 2. Projects for production of herbal ingredients run by private organizations and individual investors specified in Article 7 herein must be approved by provincial People's Committees. Other cases must be approved by competent authorities.
- 3. The area for herb cultivation must be included in the development plan or planning approved by the competent regulatory agency or must be permitted by provincial People's Committees in case no plan or planning is approved.
- 4. The investor shall make a commitment on reciprocal capital provision in order to perform tasks specified in the approved project (in addition to state assistance). In case assistance for the project is contributed by asking for bank loans, a loan contract or loan-proving document is required.

#### Chapter III

#### FUNDING SOURCES AND ASSISTANCE PROVISION MECHANISM

#### Article 10. Funding sources

- 1. Funding for provision of assistance shall be provided from state budget including local and central government budget.
- 2. State investment credit loans
- 3. Available sources, reciprocal capital contributed by organizations and individuals and other sources legally accepted

#### Article 11. Assistance provision mechanism

- 1. With regard to state budget
- a) Central government budget shall provide funding for assistance prescribed in Article 5, 6, 7 and 8 herein for central projects and projects run in areas with poor conditions for socio-economic development and dedicated funding shall be given to local government authorities that fails to balance their local budget;
- b) Local government budget shall provide funding for assistance prescribed in Article 5, 6, 7 and 8 herein for local projects, except for those run in local areas receiving assistance

specified in Point a Clause 1 this Article.

2. Projects for production and use of herbal ingredients named in the list of State investment credit loan projects may be funded by investment credit loans under current regulations.

#### Article 12. Application and procedure for proposing new herbal varieties

- 1. Application and procedure for proposing new herbal varieties specified in Clause 1 Article 4 herein shall be stipulated as follows:
- a) The application includes:

A written proposal;

A technical declaration which describes origin and characteristics of the variety, use and cultivation history, cultivation size and place and production process (according to Form No.01 provided in the Appendix issued thereto)

#### b) Procedure

Provincial People's Committees shall send a proposal for adding new herbal varieties into the list of herbal varieties permitted for production and trading in Vietnam to the Ministry of Agriculture and Rural Development.

The Ministry of Agriculture and Rural Development shall assign its affiliated entity to receive the application. The receiving agency shall establish a scientific council for appraisal and send the aforesaid proposal to the Minister for approval within 30 days from the day on which the satisfactory application is received. The procedure for council establishment and council operation regulations must be made in conformity with current regulations on recognition of plant varieties and animal breeds.

In case the application is found ineligible, the Ministry of Agriculture and Rural Development shall send a notice to the applicant for completing such application.

- 2. Eligible funding recipients prescribed in Article 5 and 6 herein shall ask for assistance in investment according to the project schedule. The procedure for proposing, appraising and approving the project shall be made in conformity with provisions of the Law on Public Investment and the Law on State Budget and guiding documents.
- 3. Eligible funding recipients prescribed in Article 7 herein shall ask for post-investment assistance. Application and procedure:

#### a) The application includes:

A proposal of assistance provision (according to Form No.02 provided in the Appendix issued thereto)

A project report

#### b) Procedure

Before running the project, the applicant shall send 3 applications to the Department of Investment and Planning in the place where the production registration is made.

The Department of Investment and Planning shall send a verification report (according to Form No.3 provided in the Appendix issued thereto) to provincial People's Committees for considering whether to make a commitment on assistance provision for the applicant (according to Form No.4 provided in the Appendix issued thereto) within 10 working days.

In case the funding for provision of assistance is allocated from central government budget, provincial People's Committees shall send the application with written proposal of project running (according to Form No.5 provided in the Appendix issued thereto) to the Ministry of Planning and Investment.

The Ministry of Planning and Investment shall ask for opinions from the Ministry of Finance and consider the budget balance capacity in order to make a commitment on assistance provision (according to Form No.6 provided in the Appendix issued thereto) and send it to the provincial People's Committees and the applicant within 20 working days.

After completing the first stage of infrastructure investment and herb cultivation according to the plan in the first planning year, the organization/individual running the project shall send a written request for project acceptance to the provincial People's Committee.

The provincial People's Committee shall carry out the acceptance within 10 working days. The record of acceptance for completion of the project (Form No.7 provided in the Appendix issued thereto) shall be considered a basis for disbursement of funding provided.

After receiving the acceptance record, such organization/individual shall send a written proposal for disbursement of funding provided (Form No.8 provided in the Appendix issued thereto) with the acceptance record and decision on assistance provision issued by the competent authority to provincial State Treasury.

#### Chapter IV

#### **IMPLEMENTATION**

#### Article 13. Responsibilities of central-level ministries

- 1. The Ministry of Agriculture and Rural Development shall:
- a) receive and appraise the additional application and recognize new varieties and add such new varieties to the list of plant varieties or animal breeds permitted for production and trading in Vietnam;
- b) grant approval for scientific tasks and investment assistance projects funded by central government budget under management of the Ministry of Agriculture and Rural Development;
- c) include the funding provided in its annual budget estimate to the competent authority for approval;
- d) issue economic-technical restrictions on propagation, develop a model for applying technology for production and use of herbal ingredients to follow the practice of good herbal ingredient production and use.
- 2. The Ministry of Health shall:
- a) take charge of formation and promulgation of national regulations on quality of plant varieties and animal breeds used for production of herbal ingredients;
- b) grant approval for scientific tasks and investment assistance projects funded by central government budget under management of the Ministry of Health;
- c) include the funding provided in its annual budget estimate which is sent to the competent authority for approval;
- 3. The Ministry of Science and Technology shall:
- a) Give priority to proposal for additional science and technology tasks concerning herbal varieties, production and use of herbal ingredients;
- b) promote development of scientific and technological resources of scientific and technological organizations for the purpose of herbal ingredient production;
- c) grant approval for scientific tasks and investment assistance projects funded by central government budget under management of the Ministry of Science and Technology;

- c) include the funding provided in its annual budget estimate which is sent to the competent authority for approval;
- 4. The Ministry of Education and Training shall:
- a) grant approval for scientific tasks and investment assistance projects funded by central government budget under management of the Ministry of Education and Training;
- b) include the funding provided in its annual budget estimate which is sent to the competent authority for approval;
- 5. The Ministry of Planning and Investment shall:
- a) allocate funding for provision of assistance in investment according to state funding received as assigned;
- b) commit to give assistance to organizations and individuals involved in concentrated production of herbal ingredients as prescribed in Point b Clause 3 Article 12 herein
- 6. The Ministry of Finance shall:
- allocate non-business funding according to the state funding received as authorized and assigned
- 7. The Ministry of Natural Resources and Environment shall:
- a) cooperate with the Ministry of Agriculture and Rural Development and Ministry of Health in managing import of herbal ingredient gene as regulated;
- b) grant approval for scientific tasks and investment assistance projects funded by central government budget under management of the Ministry of Natural Resources and Environment;
- c) include the funding provided in its annual budget estimate which is sent to the competent authority for approval;

#### Article 14. Responsibilities of provincial People's Committees

1. Send applications for including local herbal varieties to the list of plant varieties or animal breeds permitted for production and trading in Vietnam to the Ministry of Agriculture and Rural Development for appraisal purpose

附件1

2. Prepare and approve plan or planning for the areas of concentrated production and cultivation of herbal varieties

3. Balance funding from local government budget to ensure financial assistance in investment as prescribed herein

4. Grant approval for scientific tasks and investment assistance projects funded by local government budget.

5. Send a proposal for charge for issuance of land use right as regulated in Point b Clause 2 Article 8 herein to provincial People's Councils for approval.

#### Article 15. Effect

1. This Decree comes into force from July 05, 2017.

2. This Decree will replace regulations on provision of assistance for production of herbal ingredients specified in Article 12 of Decree No.210/2013/ND-CP dated December 19, 2013 of the Government on incentive policies for enterprises investing in agricultural and rural development.

3. The enterprise that runs approved project on herbal ingredient production and is eligible to receive assistance shall receive a subsidy under regulations herein if not provided with financial support as specified in Decree No.210/2013/ND-CP. If having received assistance as specified in Decree No.210/2013/ND-CP, such enterprise shall continue to be provided with financial assistance under regulations in the aforementioned Decree.

4. Ministers and Directors of ministerial agencies and Governmental agencies, Chairpersons of provincial People's Councils and People's Committees and relevant agencies shall take responsibility to implement this Decree./.

PP. THE GOVERNMENT PRIME MINISTER

Nguyen Xuan Phuc

#### **APPENDIX**

#### LIST OF FORMS

(Issued together with Decree No.65/2017/ND-CP dated May 19, 2017 of the Government)

	Technical declaration of herbal varieties proposed to be added into the list of plant varieties or animal breeds permitted for production and trading in Vietnam
	Application for post-investment assistance for the project on production of herbal ingredients specified in Decree No/2017/ND-CP dated of the Government
Form No.03	Report on the result of verification of post-investment assistance provision (made by the Department of Planning and Investment)
Form No.04	Written commitment on funding provision (applied to local government budget)
	Written proposal for implementation of the project on herbal ingredient production funded by central government budget (by provincial People's Committees)
	Written commitment on funding provision by the Ministry of Planning and Investment
Form No.07	Acceptance record
Form No.08	Proposal for funding disbursement

Form No.01

# **SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness**

(Location and date)

#### TECHNICAL DECLARATION OF HERBAL VARIETIES

Proposed to be added into the list of plant varieties or animal breeds permitted for production and trading in Vietnam

1. Name of variety:	;
2. Origin and production method:	······;
3. Detailed description of variety's and animal with photos or drawing)	characteristics (characteristics of variety's form for plant
4. Economic-technical norms: Grov	ving time and useful value
5. History of cultivation and use (Sp place for planting or use, land area	pecify the time for initial appearing or initial planting, for cultivation and output);
6. Technical procedure for cultivation	on and use;
7. Other relevant information (if an	y):
	(Location and date)  Declarant  (Sign and seal)
	Form No.02
[NAME OF PROPOSER]	SOCIALIST REPUBLIC OF VIETNAM  Independence - Freedom - Happiness
No	(Location and date)
	VESTMENT FUNDING FOR HERBAL INGREDIENT RODUCTION PROJECT
(According to Decree No	/2017/ND-CP dated of the Government)
То:	•••••
Name of enterprise:	;

Tel:		*************************	Fax no	************
	on certifica	te/business registr	ration certificate/business ope	
I. REGISTRATON	OF POST	INVESTMENT	FUNDING RECEIPT	
1. Name of the proje	:ct:			;
2. Field:			;	
3. Project location:			;	
4. Objectives and sca	ale:		•••••••••••••••••••••••••••••••••••••••	;
5. Total investment:.	••••••		·····;	
6. Land area reserve	d for herb	cultivation:		;
7. Average number of	of workers	in the year:		;
8. Schedule:	•••••	•••••	·····;	
9. Expected outputs materials in month		. , ,	terials for processing (mo	nths) to total
II. REQUEST FOR Government):	R FUNDIN	G (According to	Decree No/2017/ND-CP	of the
	C1!			
Activities that need	runaing:			

#### III. COMMITMENT:

1. Accuracy of the aforemention	ned information;	
2. Compliance with provisions of Vietnamese laws./.		
	(Location and date)  Job title of the representative  (Sign and seal)	
	Form No.03	
PEOPLE'S COMMITTEE OF DEPARTMENT OF PLANNING AND INVESTMENT	SOCIALIST REPUBLIC OF VIETNAM  Independence - Freedom - Happiness	
No	(Location and date)	
	VERIFICATION DOSSIER	
	To: People's Committee of	
funding for (name of the proje	and attached project dossier, below is the report on results funding given to the investor in (name of the project) as 7/ND-CP:	
1. Application no.:		
2. Project report:		
3. Record of field inspection (if	any):	
4. Opinions from relevant agend	cies:	
5 Other relevant decuments (if	any)	

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II. PROJECT INFORMATION

1. Name:
2. Field:
3. Objectives and scale (outputs, number of labor expected, investment items and land area)
4. Authority deciding investment guidelines of the project (if any as per provisions of the Investment Law):
5. Person deciding project investment (name of investor):
6. Project location:
7. Estimated total investment:
8. Requested state funding:
9. Implementation time:
10. Other relevant information (if any):
III. OPINIONS FROM COOPERATING ENTITIES
Make a consolidated report on opinions from cooperating agencies
IV. OPINIONS ABOUT THE VERIFICATION FROM GOVERNING AGENCY
1. Funding provision:
- Conditions for receiving funding:
- Amount:
- Duration:
2. Other opinions:
V. CONCLUSION
This report on verification of incentives and funding given to the(name of the investor) running the will be submitted to People's Committee of for consideration./.

# DIRECTOR DEPARTMENT OF PLANNING AND INVESTMENT

(Sign, full name and seal)

Form No.04

PEOPLE'S COMMITTEE	SOCIALIST REPUBLIC OF VIETNAM
OF	Independence - Freedom - Happiness
No	(Location and date)
COMMITMEN	T ON FUNDING PROVISION
(Applied fo	or local government budget)
	P dated of the Government on specific policies on production and use of herbal ingredients;
Pursuant to application no dated by for (name of the project);	y the (name of the applicant) for provision of funding
-	HDT dated by the Department of Planning and a of incentives and funding given to the (name of the
Below is commitment on funding provide (name of the project):	vision for the (name of the investor) to run
1. Amount:	
2. Duration:	

The investor is required to perform tasks included in the registered project./.

#### **CHAIRPERSON**

(Sign, full name and seal)

Form No.05

PEOPLE'S COMMITTEE	SOCIALIST REPUBLIC OF VIETNAM
<b>OF</b>	Independence - Freedom - Happiness
No	(Location and date)
P	Project location
To: Minist	ry of Planning and Investment
	CP dated of the Government on specific policies on production and use of herbal ingredients;
At the request of the Department of provision of assistance given to the provision of assistance given to the provision of the provision of the provision of the provision of the Department of	regarding verification of sources of funding for roject
•	e(name of investor) permission to run the (name of lanning and Investment to provide funding for such
1. Name of the project:	
2. Name of the organization/individua	al running such project:
3. Project location:	
4. Estimated total investment (specify	sources of investment and particular amount):
5. Implementation time:	
6. Other information (if any):	
7. Enclosure:	

- Application for funding provision

- Project report	
- Report on verification of funding p	provision
- Other relevant documents (if any)	
	CHAIRPERSON
	(Sign, full name and seal)
	Form No.06
MINISTRY OF PLANNING	SOCIALIST REPUBLIC OF VIETNAM
AND INVESTMENT	Independence - Freedom - Happiness
. No	(Location and date)
PRO	OJECT INFORMATION
То:.	
funding provision for run by the	by People's Committee of regarding application of e, below are opinions from the Ministry of Planning of opinions from relevant ministries and capacity for entral government budget:
1. Name of the project:	
2. Name of the organization/individ	lual running such project:
3. Project location:	
4. Total investment:	
II. FUNDING PROVISION:	
1. Amount:	
2. Duration:	

3. Source:

4. Other opinions:

#### MINISTER

(Sign, full name and seal)

Form No.07

PEOPLE'S COMMITTEE OF DISTRICT	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness
No	(Location and date)
AC	CCEPTANCE RECORD
(Name o	of the organization/individual)
1. Name of the project:	
2. Project location:	
3. Participants:	
a) Acceptance council (specify name of the document on representative as	e, job title, workplace of its representative(s) and number ssignment)
b) Organization/Individual running t	the project:
- Legal representative and person in	charge of project investment:
4. Acceptance time:	
Beginning date and time	
Ending date and time	

Acceptance place:				
5. Assessment of the project/project tasks:				
a) Documents as b	oasis for	acceptance:		
- Written commit	nent on f	funding provision		
- Investment project report				`.
- Internal acceptar	- Internal acceptance record			
b) Acceptance for	complet	ion of the project (compa	ared to standard fundin	g provided):
Name of task	Unit	Name of the proposer	On-site acceptance	Amount (VND million)
c) On-site acceptance for completion of tasks: Scale quality amount provided:				
d) Other opinions	from par	rticipants (if any)		
6. Conclusion by the host:				
- Concur with the funded by state by	-	nce for completion of the	project which meets re	equirements and is
- Request for remedy and other opinions (if any)				
Participants shall take legal responsibility for the acceptance decision; This record shall be made into copies with equal legal validity; Two copies will be kept by the organization/individual running the project, one will be sent to the State Treasury and one for each participant. /.				

SIGNATURES OF PARTICIPANTS

HOST

(Full name and seal)

ORGANIZAION/INDIVIDUAL

(Sign, full name and seal)

Form No.08

## [NAME OF ORGANIZATION/INDIVIDUAL]

#### SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

(Location and date)

To: State budget
Pursuant to Decree No/2017/ND-CP dated of the Government
Name of organization/individual:
Headquarters:
Tel: Fax no.:
Account no opened at
- Disbursement reasons: According to (attached)
- Funding provision
+ Activities that need funding:
+
Advance amount: (in words):
- Enclosure:

Job title of the representative

(Sign and seal)

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(四)越南政府第 572018ND-CP 號議定 -有關企業投資農業及鄉村發展之優惠措施:

THE GOVERNMENT

THE SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

No.: 57/2018/ND-CP

Hanoi, April 17, 2018

#### **DECREE**

## INCENTIVE POLICIES FOR ENTERPRISES INVESTING IN AGRICULTURE AND RURAL DEVELOPMENT SECTOR

Pursuant to the Law on Government Organization dated June 19, 2015;

Pursuant to the Law on State Budget dated June 25, 2015;

Pursuant to the Law on Investment dated November 26, 2014;

Pursuant to the Law on Public Investment dated June 18, 2014;

Pursuant to the Law on Construction dated June 18, 2014;

Pursuant to the Law on Enterprises dated November 26, 2014;

Pursuant to the Law on assistance for small and medium-sized enterprises dated June 12, 2017;

Pursuant to the Land Law dated November 29, 2013;

Pursuant to the Law on Science and Technology dated June 18, 2013;

Pursuant to the Law on Technology Transfer dated June 19, 2017;

At the request of the Minister of Planning and Investment;

The Government promulgates a Decree on incentive policies for enterprises investing in agriculture and rural development sector.

#### Chapter I

#### GENERAL PROVISIONS

#### Article 1. Scope

This Decree deals with a number of additional incentives to investment and procedures for giving incentives to enterprises investing in agriculture and rural development sector.

#### Article 2. Regulated entities

This Decree applies to:

- 1. Enterprises that are eligible to receive incentives and subsidies, duly established under the Law on enterprises and have investment projects prescribed in Clauses 3, 4, 5 Article 3 herein.
- 2. Authorities, organizations and individuals involved in providing incentives and subsidies for investment in compliance with regulations herein.

#### Article 3. Interpretation of terms

- 1. "rural area" refers to an administrative division, excluding areas situated in the vicinity of a ward of a district-level town, district or city.
- 2. "business lines eligible for investment incentives in agricultural and rural development sector" include the business lines specified in the Appendix enclosed herewith (Appendix I) and the others decided by the Prime Minister in each period.
- 3. "agriculture project eligible for special investment incentives" means a project of investment in one of the business lines specified in the Appendix I in an extremely disadvantaged area as defined in the Law on investment.
- 4. "agriculture project eligible for investment incentives" means a project of investment in one of the business lines specified in the Appendix I in a disadvantaged area as defined in the Law on investment.

- 5. "encouraged agriculture project" means a project of investment in one of the business lines specified in the Appendix I in a rural area other than the one prescribed in Clause 3 or Clause 4 of this Article.
- 6. "agriculture sector prescribed herein" covers agriculture, forestry, aquaculture and salt production (including cultivation of herbs).
- 7. "agricultural products" means products generated by agriculture, forestry, aquaculture and salt production.
- 8. "new small and medium-sized agricultural enterprise" refers to an enterprise that invests in the agriculture and rural development sector only, has operated for not more than 05 years from the date of issuance of its Certificate of enterprise registration, and satisfies all of requirements laid down in the Law on assistance for small and medium-sized enterprises.
- 9. "enterprise joining a value chain" refers to an enterprise that enters into a purchase agreement of agricultural products on a regular basis (for at least 36 months) with farmers or their representative.

#### Article 4. Rules for applying investment incentives and subsidies

- 1. The Government shall provide investment incentives by means of exemption and reduction of taxes, fees and charges and simplification of administrative procedures for qualified enterprises.
- 2. The Government shall provide subsidies to partially cover investment expenditures or pay interest rate difference incurred by an enterprise.
- 3. An enterprise that has an agriculture project eligible for special investment incentives, or investment incentives, or an encouraged investment project shall be eligible to receive investment incentives and subsidies as regulated herein.
- 4. Investment made by startups as defined in Clause 2 Article 3 of the Law on assistance for small and medium-sized enterprises, and enterprises that develop material zones and enter into cooperate agreements with farmers shall be given priority.
- 5. If an investment project is eligible for different investment incentives and subsidies within a specific period of time, the enterprise is entitled to select the most advantageous one.
- 6. An enterprise may self-finance or mobilize capital to implement its investment project in a business line eligible for investment incentives in agriculture and rural development sector.

The Government shall provide post-investment subsidies according to the level of subsidy for each work item announced by the Provincial-level People's Committee; procedures for providing subsidies shall be performed according to regulations herein.

#### Chapter II

#### POLICIES ON INVESTMENT INCENTIVES AND SUBSIDIES

#### Article 5. Exemption or reduction of land levy

An enterprise that has an agriculture project (which is eligible for either special investment incentives or investment incentives, or is an encouraged agriculture project) shall have a land area allocated by the Government or be permitted to change the use purpose of an existing land area for building house for workers as prescribed in Article 55 of the Law on land and exempted from payment of fees for changing land use purpose and the land levy of that land area after change of use purpose.

### Article 6. Exemption or reduction of land rental and water surface rental payable to the Government

- 1. If an enterprise that has an agriculture project eligible for investment incentives or an encouraged agriculture project leases land and/or water surface from the Government, land rental and/or water surface rental shall be calculated according to preferential land prices announced by the Provincial-level People's Committee and fixed for at least 05 years.
- 2. An enterprise that has an agriculture project eligible for special investment incentives shall be exempted from payment of land rental and/or water surface rental from the date on which it has land and/or water surface leased by the Government.
- 3. An enterprise that has an agriculture project eligible for investment incentives shall be exempted from payment of land rental and/or water surface rental for the first fifteen years from the date on which it has land and/or water surface leased by the Government and shall have 50% of land rental and/or water surface rental reduced in subsequent 07 years.
- 4. An enterprise that has an encouraged agriculture project shall be exempted from payment of land rental and/or water surface rental for the first eleven years from the date on which it has land and/or water surface leased by the Government and shall have 50% of land rental and/or water surface rental reduced in subsequent 05 years.
- 5. An enterprise that has an agriculture project (which is eligible for either special investment incentives or investment incentives, or is an encouraged agriculture project) and has land

leased by the Government to build house for workers or to use for non-farm purposes (construction of warehouse, workshop, drying ground, road or planting of trees), or changes the use purpose of an existing land area to serve the purposes specified in this Clause, shall be exempted from payment of land rental.

6. A new small and medium-sized agricultural enterprise shall be exempted from payment of land rental and/or water surface rental for the first five years from the date on which the project officially starts its operation and shall have 50% of land rental and/or water surface rental reduced in subsequent 10 years.

#### Article 7. Subsidies for land consolidation

- 1. An enterprise that has an agriculture project eligible for special investment incentives and leases or sub-leases land and/or water surface from households or individuals for implementing such project may receive a subsidy from the Government, equivalent to 20% of the land rental and/or water surface rental for the first five years from the date on which the project officially starts its operation. The land rental and/or water surface rental shall be calculated as regulated in Clause 1 Article 6 herein.
- 2. An enterprise that has an agriculture project (which is eligible for either special investment incentives or investment incentives, or is an encouraged agriculture project) and receives land contributed as capital by a household or individual for establishment of a material zone shall be eligible to receive a subsidy which is VND 50 million/ha but shall not exceed VND 10 billion/project from the Government, and is not required to convert the form of use of such land area into leased land.
- 3. If an enterprise that consolidates land under both forms specified in Clause 1 and Clause 2 of this Article, it shall receive all of the subsidies granted according to these clauses from the Government.
- 4. During the lease period of an enterprise investing in agriculture and rural development sector, the Government shall not adjust the land use plan so as to avoid adverse influence on the project, except the case where the Government must appropriate the land according to regulations in Article 61 and Article 62 of the Law on land and special case where the land use plan must be adjusted according to regulations in Clause 1 and Clause 2 Article 46 of the Law on land.
- 5. Enterprises using land for agricultural or aquaculture purposes are encouraged to build accompanying agricultural product processing plant and infrastructure facilities (such as warehouse, head office, internal roads and waste treatment systems). Procedures for change of

land use purpose and construction shall be carried out in accordance with the Law on land and the Construction Law.

#### Article 8. Credit subsidies

- 1. An enterprise investing in agriculture and rural development sector shall receive interest rate subsidies on commercial loans from local government budget upon the completion of investment project. To be specific:
- a) The subsidy is equal to the difference between the commercial loan interest rate and the Government's concessional loan interest rate on the actual outstanding loan balance at the time of considering the application for subsidy.
- b) The period for receiving interest rate subsidy, calculated from the disbursement date specified in the credit contract signed with the commercial bank, shall not exceed:
- 08 years for an agriculture project eligible for special investment incentives; 06 years for an agriculture project eligible for investment incentives; 05 years for an encouraged agriculture project. A new small and medium-sized agricultural enterprise shall receive interest rate subsidy on its project for a period of 08 years.
- An enterprise joining a value chain shall receive interest rate subsidy for a period equal to the production cycle of related product.
- c) Subsidized loan limit: The maximum loan amount shall not exceed 70% of total investment of a project.
- d) Policies and method of granting interest rate subsidies shall be promulgated by the Provincial-level People's Council in conformity with local conditions.
- 2. Structures on land (including net house, green house, poly house and hydraulic structures) of an enterprise receiving subsidies shall be considered as collaterals offered to commercial banks for loans.

#### Article 9. Subsidies on research, transfer and application of hi tech to agriculture

1. Subsidies will be given to implement scientific research themes or acquire patents, technologies or scientific research and technological development findings for generating new products or innovating technology, technologies for minimizing environmental pollution and saving materials, fuels and energy. To be specific:

- a) The subsidy is equal to 80% of the funding for implementation but shall not exceed VND 300 million/ project (or patent or technology).
- b) Eligibility requirements for subsidy:
- The revenue earned by the enterprise in previous year must be 10 times the subsidy amount.
- The patient or technology to be acquired or transferred by the enterprise must be conformable with its business orientations.
- If a scientific research theme's outputs are applied to reality, the full amount of subsidy shall be paid. Otherwise, 50% of the subsidy shall be paid.
- 2. Subsidies will be given to enterprises that implement projects on trial production with application of advanced technologies, hi tech or production of new products:
- a) Enterprises that participate in or take charge of science and technology projects funded by state budget shall be given priority.
- Enterprises are invited to perform contents of a science and technology project or construct models of a science and technology scheme implemented in the local area where the enterprise's head office is located;
- The priority is given to enterprises' proposals for the procurement of science and technology projects to be approved and implemented in the form of selection or direct assignment;
- The priority is given to enterprises that own valuable and rare genetic resources to implement national genetic resource projects with the aims of generating new commercial products.
- b) The subsidy is equal to 70% of the funding for implementing science and technology tasks under an agriculture project eligible for special investment incentives, and 50% of the same under an agriculture project eligible for investment incentives or an encouraged agriculture project provided that it shall not VND 01 billion. c) Eligibility requirements for subsidy:
- A project on trial production with application of advanced technologies or hi tech or production of new products must be given a written approval by a scientific agency affiliated to a Ministry or Provincial-level People's Committee.
- Science and technology tasks must be conformable with business orientations of the enterprise applying for subsidy.

- 3. Enterprises are entitled to own outputs from their scientific research themes which have been duly assessed and accepted and given priority to develop science and technology products thereof:
- a) An enterprise that leads a state-funded science and technology project is entitled to develop the plant varieties or animal breeds, which are the project's outputs and duly assessed as satisfactory, in a large scale within a period of 03 years from the completion of its project.
- b) An enterprise that leads a state-funded science and technology project is entitled to develop the new products, which are the project's outputs, duly assessed as satisfactory and acceptable in markets, in a large scale within a period of 02 years from the completion of its project.
- c) Product quality testing results provided by an enterprise that leads a state-funded science and technology project and has laboratories meeting ISO/IEC 17025 standards will be accepted when it submits the application for product registration to a competent authority.
- 4. An enterprise that has a project on plant propagation by tissue culture shall receive the following subsidy:
- a) The subsidy is equal to 80% of the funding for construction of infrastructure facilities, equipment and environmental remediation but shall not exceed VND 05 billion/project.
- b) Eligibility requirements for subsidy: At least 01 million plants are propagated per year. The subsidy will increase in proportion to the project's scale provided that it shall not exceed VND 10 billion/project.
- 5. An enterprise that has a project on production of plant varieties, animal breeds or aquatic species or trial cultivation of new plant species with high economic value, which has been given approval by the Provincial-level People's Committee, shall receive a subsidy equal to 70% of funding for construction of infrastructure facilities, equipment, environmental remediation and plant varieties provided that it shall not VND 03 billion/project.
- 6. An enterprise investing in hi-tech agricultural park, zone or project shall receive a subsidy equal to VND 300 million/ha for covering expenditure for building infrastructure facilities, equipment and environmental remediation.

#### Article 10. Subsidies on personnel training and market development

1. An enterprise that has an agriculture project eligible for special investment incentives or investment incentives or an encouraged agriculture project shall receive the following subsidies from state budget:

a) A subsidy as VND 02 million/month/employee is given to the enterprise directly organizing personnel training courses for a period of not more than 03 months.

If an enterprise joining a value chain provides training and technical instructions for farmers, it shall receive a subsidy equal to VND 500 thousand/farmer to be trained. Period for receiving subsidy is 03 months.

- b) The enterprise shall receive a subsidy as 50% of expenses for advertising and creating brand names of national and provincial key products, and a subsidy as 50% of expenses for attending domestic and/or overseas trade fairs or exhibitions upon the approval by a competent authority.
- 2. The subsidies specified in Clause 1 of this Article shall be given to every eligible investment project. Total amount of subsidies given to each project shall not exceed 10% of total investment of that project and not exceed VND 01 billion.
- 3. Subsidy shall be given to an enterprise in charge of establishing and managing the electronic portal for "National agricultural market" (or eNAM portal).
- a) Eligibility requirements for subsidy:
- The enterprise must have at least 05 years of experience in e-commerce and at least VND 10 billion as collateral.
- The eNAM portal must be created in at least three languages (including Vietnamese, English and Chinese) and maintained for at least 10 years. Information concerning products provided by enterprises must be retained for at least 03 years.
- The Government shall give subsidy when there are at least 500 enterprises introducing their products on this eNAM portal.
- b) The Government shall give subsidy which is equal to VND 05 million/enterprise introducing its products on eNAM portal to the enterprise in charge of creating and managing this eNAM portal. Total amount of subsidies shall not exceed VND 05 billion. c) In case there are several enterprises wishing to participate in building and management of eNAM portal, the qualified one shall be selected via bidding.
- 4. Enterprises investing in agriculture and rural development sector are entitled to proactively purchase raw agricultural products generated by cultivation and breeding for storing and processing according to their standards.

Agricultural products generated by cultivation and breeding of plants and animals shall be freely sold in the market. Competent authorities shall not adopt administrative procedures for certification of origin of raw agricultural products and other administrative procedures to cause difficulties in harvesting, transport, sale and export of agricultural products, except the case concerning national security and epidemics harming community health as prescribed in specialized laws.

# Article 11. Subsidies on investment in agricultural product processing and storage facilities, slaughterhouses, manufacturing of agricultural machinery, equipment and parts, and production of auxiliary products

- 1. The Government shall give subsidies to enterprises having investment projects in agricultural product processing facilities, slaughterhouses, manufacturing facilities of agricultural machinery, equipment and parts thereof, or production facilities of auxiliary products. To be specific:
- a) With regard to agricultural product processing facilities and slaughterhouses: The subsidy equal to 60% of investment funding but not exceeding VND 15 billion/project is given to construct waste treatment systems, traffic, electrical and water systems, workshops and acquire necessary equipment.
- b) With regard to manufacturing facilities of agricultural machinery, equipment and parts thereof, and production facilities of auxiliary products: The subsidy equal to 60% of investment funding but not exceeding VND 05 billion/project is given to construct waste treatment systems, traffic, electrical and water systems, workshops and acquire necessary equipment.
- c) Each investment project in agricultural product processing facility must satisfy the requirement that the value of processed agricultural products increases at least 1.5 times the value of raw agricultural products.
- 2. Subsidies on storage of agricultural products:

An enterprise investing in agricultural product storage facilities (including drying, irradiation, chilling, freezing and biopreservation of foods) may receive the following subsidy from state budget.

a) The subsidy equal to 70% of investment funding but not exceeding VND 02 billion/project is given to construct waste treatment systems, traffic, electrical and water systems, workshops and acquire necessary equipment.

- b) Eligibility requirements for subsidy:
- Capacity of a drying plant must be at least 100 tons/ day if drying rice, maize, potatoes, cassava and forest products; or 50 tons/day if drying aquatic by-products.
- Capacity of storage facility must be at least 1,000 tons/ facility if it is used to preserve fresh vegetables, fruits, teas, peppers and cashew nuts; or 100 tons/ facility if it is used to store plant varieties.
- 3. Subsidies on purchase of vessels: An enterprise that purchases fishing vessel may receive a subsidy from state budget, which shall not exceed 60% of purchasing amount and is calculated according to the vessel's capacity: VND 30 million/ DWT; the vessel's loading capacity is at least 200 DWT; the maximum level of subsidy is VND 10 billion/vessel.
- 4. In case an enterprise, which is established under regulations in Article 6 of the Government's Decree No. 118/2014/ND-CP dated December 17, 2014 on re-structuring, development and improvement of performance of agriculture and forestry companies, has constructed a processing facility as prescribed in Clause 1 of this Article, it may receive an additional subsidy to build infrastructure facility for its material zone; the subsidy is VND 50 million/ha and shall not exceed VND 05 billion/project.
- 5. When processed agricultural products prescribed in Point a Clause 1 of this Article are certified as national key products, the investment project is given an additional subsidy as VND 03 billion in addition to the abovementioned subsidies to invest in infrastructure facilities.

#### Article 12. Subsidies on investment in beef and dairy cattle farms

Each enterprise investing in diary or beef cattle farm shall receive the following subsidy from state budget:

- 1. The subsidy as VND 05 billion/project is given to construct waste treatment systems, traffic, electrical and water systems, workshops and acquire necessary equipment.
- 2. In addition to the subsidy specified in Clause 1 of this Article, if an enterprise imports and directly breeds or cooperates with farmers in breeding of high-yielding cattle breeds, it may receive an additional subsidy as VND 10 million/cow.

Article 13. Subsidies given to enterprises providing public services and investing in infrastructure facilities in rural areas.

- 1. An enterprise having project on supply of clean water to a rural area shall receive subsidies as follows:
- a) A subsidy as VND 03 million/m³/day-night is given to a new water supply plant or a subsidy as VND 02 million/m³/day-night is given to upgrade and expand an existing water supply plant.
- b) A subsidy of not exceeding 50% of total expenses for installing major pipelines transporting water to residential areas where there are at least 10 households each shall be given.
- 2. An enterprise investing in a project on collection and treatment of municipal solid water or domestic wastewater in a rural area, or collection and treatment of waste from trade villages, shall receive a subsidy which is equal to 60% of expenses for purchasing equipment and building treatment systems but not exceeding VND 05 billion/project.
- 3. An enterprise investing in an aquaculture project whose scale is not less than 05 ha receives a subsidy as VND 200 million/ha to build infrastructure facilities, water supply and drainage systems and environmental remediation systems. This subsidy increases in proportion to the aquaculture area. The subsidy shall not exceed VND 10 billion/project.
- 4. An enterprise investing in projects on construction of wharf to serve the transport of agricultural, forest and aquatic products, anchoring zone, advanced irrigation and drainage system or hydraulic structure serving agricultural production may receive a subsidy equal to 50% of total funding of an investment project approved by a competent authority. The subsidy shall not exceed VND 20 billion/project.
- 5. Subsidies on construction of social houses for workers: If an enterprise invests in agriculture and rural development sector and employs at least 100 workers who work at its factories on a regular basis, it may receive subsidies to build social houses for workers. The subsidy is VND 01 million/m<sup>2</sup> of building area of a grade-4 house and VND 02 million/m<sup>2</sup> of building area of a house of two stories or taller.
- 6. Outside-the-fence subsidies: If an enterprise has an investment project in agriculture and rural development sector as regulated herein but the traffic system meeting grade-V standards for mountainous region, electrical system and water supply and drainage system outside the project fence are not available to serve the project's operations, the enterprise shall receive an additional subsidy which is equal to 70% of expenses for constructing these work items but not exceeding VND 05 billion.

#### Chapter III

#### FUNDING SOURCES AND SUBSIDIES POLICIES

#### Article 14. Funding sources

- 1. The central government budget shall allocate at least 5% of its annual funding for investment and development to give subsidies to agriculture; each provincial government budget shall allocate at least 5% of its annual funding for provincial government budget expenditure to give subsidies to agriculture. Additionally, ministries and local governments may consider using funding from social and economic development programs/projects and legal funds to provide subsidies for enterprises investing in agriculture and rural development sector according to regulations herein.
- 2. Ministry of Planning and Investment takes charges and cooperates with Ministry of Finance shall, based on balancing capacity in each period and in each year as well as demands for subsidies of enterprises in each province, request the Government to make decision on sources of funding for giving subsidies to agriculture as regulated herein.

#### Article 15. Post-investment subsidies

#### 1. Central government budget:

The Prime Minister shall decide and specify the total funding amount for medium-term and annual assistance to each provincial government at the "Program on subsidies for enterprises investing in agriculture and rural development sector" item in the public investment plan. Ministry of Planning and Investment shall consider and decide the list of qualified projects and specific funding amount given to each project in accordance with regulations of the Law on public investment.

- 2. Provincial government budget: Shall be used to fund local projects which meet regulations herein.
- 3. Decisions on approval for investment policies for the list of qualified projects specified in Point a Clause 1 Article 16 herein and written commitments to providing subsidies made by competent authorities shall be used as the basis for allocating funding from state budget to qualified enterprises.
- 4. State budget shall provide post-investment subsidies: When investment items of a project have been completed, tested and accepted according to relevant requirements, 70% of total amount of subsidies for these investment items shall be disbursed. Upon the completion of

project commissioning and the project has officially started its operation, the remaining 30% of subsidies is given.

- 5. The unused amount of the predetermined funding for an enterprise in a budget year shall be carried forward to the following budget year. After 02 budget years, if the predetermined funding for an enterprise is not yet fully granted to the enterprise, the remains shall be transferred to another qualified enterprise according to regulations herein.
- 6. Funding sources and procedures for giving subsidies for foreign-invested enterprises (as defined in Clause 1 Article 23 of the Law on investment) and state-owned enterprises investing in agriculture and rural development sector shall be performed according to specific law regulations.
- 7. Funding from state budget shall be not included in taxable income of a receiving enterprise. This funding amount is guaranteed by the Government when the receiving enterprise applies for loans from commercial banks to have funding for implementing its project.

#### Chapter IV

#### INVESTMENT PROCEDURES AND FORMALITIES

#### Article 16. Investment procedures

- 1. Combined performance and simplification of administrative procedures:
- a) The Provincial-level People's Committee promulgates a decision on approval for investment policies for list of encouraged investment projects in agriculture (using the form No. 01 stated in the Appendix II enclosed herewith).
- b) The decision prescribed in Point a of this Clause is also the decision on approval for investment policy as prescribed in Point a Clause 1 Article 32 of the Law on investment.

In case two or more enterprises jointly apply for implementing an investment project at the same site, the qualified investor shall be selected in accordance with regulations of the Law on bidding.

c) Competent authorities shall provide necessary information or issue planning permit to the enterprise having a project in the list of projects specified in Point a of this Clause to prepare the 1/500 planning. Information shall be provided or planning permit shall be issued within 15 days from the date of receipt of enterprise's request.

- d) Appraisal of fundamental designs of projects of the list of projects mentioned in Point a of this Clause shall be carried out in accordance with regulations in Point b Clause 4 Article 57 of the Law on construction.
- dd) Construction works located in a rural area where urban development planning is not available or in an industrial park, export processing zone or hi-tech park, or in a hi-tech agricultural park with an approved 1/500 planning shall be exempted from building permits according to regulations in Clause 2 Article 89 of the Law on construction.
- e) All projects are not subject to the appraisal of technology, except the projects prescribed in Article 30, Article 31 and Point b Clause 1 Article 32 of the Law on investment and Article 13 of the Law on technology transfer.
- 2. Project investors are allowed to carry out at the same time or combine procedures for land, environment, construction and investment subsidy issues.
- 3. Local governmental authorities are not allowed to conduct inspection or auditing under any forms of the investment project which is in the list of projects prescribed in Point a Clause 1 of this Article but is not yet put into operation, unless otherwise required by law or it commits violations against laws as proved by clear evidence.

#### Article 17. Application and procedures for getting subsidies

- 1. Application for subsidies:
- a) The enterprise shall submit 03 sets of application, which includes the investment project and the application form for subsidy, to the Provincial Department of Planning and Investment (using form No. 02 stated in the Appendix II enclosed herewith).
- b) Within 10 working days, the Provincial Department of Planning and Investment shall consider the application and send report thereof the Provincial-level People's Committee (using form No. 03 stated in the Appendix II enclosed herewith); Within 05 working days, the Provincial-level People's Committee shall make a written commitment to provide funding for the enterprise (using form No. 04 stated in the Appendix II enclosed herewith). If an application is refused, the Provincial-level People's Committee shall send a written explanation for refusal to the enterprise.
- c) If the central government budget is used, regulations of the law on public investment shall govern.
- 2. Commissioning of investment items or entire project:

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- a) Based on the application for commissioning submitted by the enterprise, the Provincial Department of Agriculture and Rural Development, within 05 working days, shall take charge of and invite relevant agencies to act as members of the commissioning council.
- b) Commissioning contents: Investment items or entire project shall be checked and tested according to the level of subsidy for each work item announced by the Provincial-level People's Committee.
- c) The commissioning report made by the commissioning council (using form No. 05 stated in the Appendix II enclosed herewith) shall be used as the basis for allocating funding to the enterprise. Competent authorities are not allowed to request the enterprise to present documents other than this commissioning report.
- 3. Procedures for getting subsidy:

The enterprise shall submit an application for disbursement of subsidy, including the commissioning report and the decision on provision of funding made by competent authority, to the State Treasury to get subsidy within 05 working days.

#### Chapter V

#### IMPLEMENTION PROVISIONS

#### Article 18. Responsibility of Ministries

- 1. Ministry of Planning and Investment shall:
- a) take charge and cooperate with Ministry of Finance and Ministry of Agriculture and Rural Development to instruct the implementation of this Decree.
- b) take charge and cooperate with Ministry of Finance to consolidate and determine medium-term and annual funding allocated to provincial government budgets in conformity with the balancing capacity of the central government budget so as to implement incentive policies specified herein; and then report competent authorities to make decision thereof in accordance with regulations of the Law on state budget and the Law on public investment.
- c) formulate plan for implementation of this Decree, implement and inspect the plan implementation.
- 2. Ministry of Finance shall:

- a) cooperate with Ministry of Planning and Investment to monitor and inspect the implementation of this Decree.
- b) cooperate with Ministry of Planning and Investment, and Ministry of Agriculture and Rural Development to instruct the implementation of this Decree.
- 3. Ministry of Agriculture and Rural Development shall:
- a) promulgate the list of national key agricultural products, and standards of high-yielding dairy and beef cattle.
- b) take charge and cooperate with Ministry of Science and Technology to promulgate criteria for hi-tech agriculture projects.
- c) cooperate with Ministry of Planning and Investment and Ministry of Finance to instruct and inspect the implementation of this Decree.
- 4. Ministry of Science and Technology shall promulgate the list of technological products/themes requiring further research or patents as prescribed in Article 9 herein.
- 5. Ministry of Industry and Trade shall:
- a) take charge and cooperate with Ministry of Agriculture and Rural Development to promulgate the list of mechanical products, agricultural machinery, equipment and parts thereof, and auxiliary products in agriculture and rural development sector eligible for subsidies as regulated in Article 11 herein.
- b) instruct the implementation of regulations in Clause 3 Article 10 herein.
- 6. Ministry of Natural Resources and Environment shall instruct the implementation of regulations in Clause 2 Article 8 herein.7. Ministry of Agriculture and Rural Development, Ministry of Industry and Trade, Ministry of Natural Resources and Environment and Ministry of Construction shall annually review and simplify administrative procedures in their managing sectors in order to facilitate enterprises investing in agriculture and rural development sector, and submit reports thereof to the Prime Minister.

#### Article'19. Responsibility of provincial governments

- 1. Provincial-level People's Council shall:
- a) review and promulgate specific incentive policies for enterprises investing in agriculture

and rural development sector, including credit policies as regulated in Article 8 herein, policies on provision of interest rate subsidies for projects and funding amount from provincial government budget used to provide subsidies for enterprises.

- b) promulgate policies on land consolidation and accumulation so as to attract enterprises to invest in agriculture and rural development sector within its competence and in conformity with relevant laws.
- 2. Provincial-level People's Committee shall:
- a) issue decision on approval for investment policies for list of encouraged investment projects in agriculture as prescribed in Clause 1 Article 16 herein. The validity of this decision is 05 years. The Provincial-level People's Committee shall annually review and adjust this decision, where necessary.
- b) promulgate the list of provincial key agricultural products.
- c) decide the level of subsidy for each investment item in conformity with levels of subsidies prescribed herein.
- d) instruct the implementation and evaluate the implementation of this Decree in the province in previous year, and send reports thereof to the Ministry of Planning and Investment by March 31 of every year.
- dd) assign the Provincial Department of Planning and Investment to take charge and cooperate with the Provincial Department of Finance and the Provincial Department of Agriculture and Rural Development in preparing and submitting the list of eligible projects and levels of subsidies for eligible enterprises to the Provincial-level People's Committee for consideration.
- 3. Responsibility of enterprises:
- a) consider giving approval for investment projects, technical designs, cost estimates, construction or hiring of construction contractors.
- b) An enterprise may include subsidies granted by the Government as regulated herein in its charter capital according to regulations of the Law on enterprises.

#### Article 20. Transition and entry into force

1. This Decree comes into force from the date of promulgation and supersedes the

Government's Decree No. 210/2013/ND-CP dated December 19, 2013 on incentive policies for enterprises investing in agriculture and rural development sector.

- 2. If an enterprise has the investment project which meets the requirements for getting subsidies prescribed herein and is implemented after the date of entry into force of the Decree No. 210/2013/ND-CP but does not yet receive subsidies, the enterprise will be provided with subsidies for the remaining period of the project in accordance with regulations herein.
- 3. An enterprise enjoying investment incentives according to regulations of the Decree No. 61/2010/ND-CP dated June 04, 2010 and the Decree No. 210/2013/ND-CP may continue enjoying investment incentives given under these Decrees or apply for investment incentives as regulated in this Decree for the remaining operating period of the project if it satisfies all requirements for investment incentives and subsidies herein.
- 4. An enterprise that has the investment project in progress and meets requirements for investment incentives and subsidies prescribed in the Decree No. 210/2013/ND-CP may continue enjoying investment incentives and subsidies under the regulations of Decree No. 210/2013/ND-CP or the regulations herein.
- 5. Investment projects which are in progress as regulated in Decree No. 210/2013/ND-CP and for which procedures for investment, land, environment and construction issues are not yet completed may apply regulations on administrative procedures in Article 16 herein.
- 6. Ministers, heads of ministerial-level agencies, heads of the Government's affiliates, Chairpersons of People's Councils, Chairpersons of People's Committees of provinces and central-affiliated cities and heads of relevant agencies shall implement this Decree./.

ON BEHALF OF THE GOVERNMENT PRIME MINISTER

Nguyen Xuan Phuc

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### (五)越南衛生部第 192019TT-BYT 號公告-有關中草藥料 GACP 規定 及採集天然中草藥材之原則及標準

MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness

No. 19/2019/TT-BYT

Hanoi, July 30, 2019

#### **CIRCULAR**

GOOD AGRICULTURAL AND COLLECTION PRACTICES FOR HERBAL

MATERIALS

AND PRINCIPLES AND STANDARDS FOR COLLECTING NATURAL HERBAL

MATERIALS

Pursuant to the Law on Pharmacy No. 105/2016/QH13 dated April 06, 2016;

Pursuant to Decree No. 75/2017/ND-CP dated June 20, 2017 of the Government on functions, tasks, powers, and organizational structure of the Ministry of Health;

At the request of the Director General of the Traditional Medicine Administration of Vietnam,

The Minister of Health promulgates the Circular on the good agricultural and collection practices for herbal materials and principles, standards for collecting natural herbal materials.

#### Chapter I

#### GENERAL PROVISIONS

#### Article 1. Scope

This Circular prescribes issuance, application and inspection of compliance with good agricultural and collection practices for herbal materials and principles and standards for collecting herbal materials; the roadmap for application thereof by herbal material cultivation and collection facilities and natural herbal material collection facilities.

#### Article 2. Regulated entities

- 1. This Circular applies to herbal material cultivation and collection facilities (hereinafter referred to as "facilities") and organizations whose operations involve management of herbal material cultivation and collection.
- 2. This Circular does not apply to persons cultivating and collecting herbal materials and persons collecting natural herbal materials.

#### Article 3. Term interpretation

In this Circular, terms below are construed as follows:

- 1. "Good agricultural and collection practices of herbal materials" (hereinafter referred to as "GACP for herbal materials") refer to the appropriate principles and technical standards adopted during the cultivation, collection, primary processing, transport and storage of herbal materials to ensure adequate quality, safety and effectiveness of the herbal materials and products of herbal origin.
- 2. "Principles and standards for collecting natural herbal materials" refer to the appropriate methods and techniques adopted during the collection, primary processing, processing, transport and storage of natural herbal materials to ensure adequate quality, safety and effectiveness of the herbal materials and products of herbal origin.

#### Article 4. Fees and charges

Facilities applying for inspection, periodic inspection and inspection of change with respect to GACP – compliant herbal materials and principles and standards for collecting natural herbal materials must pay appraisal fees as set forth under Circular No. 277/2016/TT-BTC dated November 14, 2016 of the Ministry of Finance on fee amount, fee collection, submission, management and use in pharmacy and cosmetics.

#### Chapter II

# ISSUANCE AND APPLICATION OF GOOD AGRICULTURAL AND COLLECTION PRACTICES OF HERBAL MATERIALS AND PRINCIPLES AND STANDARDS FOR COLLECTING NATURAL HERBAL MATERIALS

### Article 5. Issuance, application of good agricultural and collection practices of herbal materials and principles and standards for collecting natural herbal materials

- 1. Vietnam's "Good agricultural and collection practices of herbal materials and extracting principles, standards of natural herbal materials" (Vietnam GACP) are provided in Annex III attached to this Circular.
- 2. Publicize the principles and standards of "Good agricultural and collection practices of herbal materials" recommended by the World Health Organization (GACP WHO) under the Annex IV attached to this Circular.

### Article 6. Application of good agricultural and collection practices of herbal materials and principles and standards for collecting natural herbal materials

- 1. The herbal material cultivation and collection facilities or natural herbal material collection facilities must comply with Vietnam's GACP mentioned in the Annex III attached to this Circular by January 01, 2030.
- 2. The GACP WHO mentioned in the Annex IV attached to this Circular and updated documents publicized on the website of the Ministry of Health or the Traditional Medicine Administration of Vietnam shall be voluntarily applied by facilities.

#### Article 7. Updating of GACP - WHO documents

- 1. If World Health Organization revises "Good agricultural and collection practices of herbal materials" provided in the Annex IV attached to this Circular, the Traditional Medicine Administration of Vietnam shall translate the revisions and publicize translations thereof on its website and website of Ministry of Health for review, updating and application purposes.
- 2. Every facility must apply the updated GACP WHO documents no later than 12 months from the date on which such documents are publicized on the website of the Ministry of Health or the Traditional Medicine Administration of Vietnam.

#### **Chapter III**

# INSPECTION OF COMPLIANCE WITH GACP FOR HERBAL MATERIALS AND PRINCIPLES AND STANDARDS FOR COLLECTING NATURAL HERBAL MATERIALS

Article 8. Cases for of inspection, periodic inspection, inspection of change, revocation of Certificate of compliance with GACP for herbal materials certificate and its effective period

- 1. A facility shall apply for inspection of compliance with GACP for herbal material in the following cases:
- a) Its herbal material has not been inspected, declared compliant with GACP or issued with the Certificate of GACP for herbal material or the valid notice of receipt of declaration of compliance with GACP issued before the effective date of this Circular;
- b) Its herbal material has been declared compliant with or issued with the Certificate of compliance with GACP but it changes or opens a herbal material cultivation and collection site in the area whose geography, soil and climate are different from those of the herbal material cultivation and collection site previously complying with GACP; or changes its entire herbal material cultivation, collection and processing process..
- 2. It applies for inspection of maintenance of compliance with GACP when the effective period publicized on the website of the Traditional Medicine Administration of Vietnam ends or when the effective period of the Certificate of compliance with GACP for herbal materials ends.
- 3. It applies for inspection of change during the effective period of the declaration or the GACP qualification if any change is made, except for the case specified in Point b Clause 1 of this Article.
- 4. The Certificate of compliance with GACP for herbal materials is revoked or the declaration of compliance with GACP posted on the website of the Traditional Medicine Administration of Vietnam is removed in any of the following cases:
- a) The herbal material cultivation and collection facility fails to comply with GACP;
- b) The facility fails to take corrective actions within the time limit, delays corrective actions or deliberately fails to take corrective actions.

5. The effective period of the declaration of compliance with GACP or the Certificate of compliance with GACP for herbal materials is 03 years from the date of declaration or issuance.

### Article 9. Documents used as the basis for inspection of compliance with GACP

- 1. An application form made by following Form No. 1A in the Annex I to this Circular.
- 2. A verified copy of the establishment decision or the business registration certificate or the investment license (with respect to the case specified in Point a Clause 1 Article 8 of this Circular).
- 3. An organizational structure (which specifies key personnel of each department: full names, titles, qualifications and experience). If the facility includes multiple households, attach a list of full names, address, cultivation and collection sites, their area, and the procurement contracts between the facility and the households/their representatives.
- 4. A map indicating plots of the cultivation and collection sites and descriptions of the cultivation, primary processing, processing and storage areas.
- 5. The plan, contents and results of the GACP training provided for the employees of the facility in the year of submission.
- 6. The herbal material cultivation, collection and processing process developed by the facility or developed by applying the scientific research results or published documents.
- 7. The results of self-inspection conducted according to criteria provided in the Annex II to this Circular.
- 8. A verified copy of packing list of forestry products confirmed by the forest protection authority according to Circular No. 27/2018/TT-BNNPTNT dated November 26, 2018 of the Minister of Agriculture and Rural Development on management and tracing of forest products with respect to natural herbal materials.

### Article 10. Documents used as the basis for periodic inspection of compliance with GACP

1. An application form for periodic inspection of compliance with GACP, which is made by following Form No. 1B under Annex I to this Circular.

2. A report on operation of the facility after 03 years of GACP implementation, which is made by following Form No. 5A under Annex I to this Circular. The report must clearly indicate the changes taking place during the operation and thus affecting the GACP maintenance and compliance (if any).

# Article 11. Documents used as the basis for inspection of change with respect to GACP-compliant herbal materials

- 1. An application form for change made by following Form No. 1C under Annex I to this Circular.
- 2. A report on changes, which is made by following Form No. 5B under Annex I to this Circular. The report must clearly indicate the changes taking place during the operation and thus affecting the GACP maintenance and compliance.
- 3. Documents specified in Clauses 2, 3, 4, 5, 6, 7 and 8 Article 9 of this Circular if any change is made.

### Article 12. Procedures and sequence of inspection of compliance with GACP

### 1. Receipt of application:

The facility applying for inspection of compliance with GACP shall submit 01 application and 01 CD or USB containing the documents specified in Article 9 of this Circular and pay the appraisal fee as set forth by the Minister of Finance to the Traditional Medicine Administration of Vietnam (hereinafter referred to as "the receiving authority") whether in person, by post or online through the online public service system of Ministry of Health

- 2. Sequence of receipt and appraisal of the application:
- a) Upon receiving the complete application, the receiving authority shall a note of receipt following Form No. 02 under Annex I to this Circular. If the application is incomplete as per law, the receiving authority shall request the facility to complete the application if it is submitted in person or within 10 working days from the date on which the application is received, the receiving authority shall request the facility in writing to complete the application as per law if it is submitted by post or online.
- b) Within 05 working days from the date on which the satisfactory application is received, the receiving authority shall establish an inspectorate and send the facility the decision on inspectorate establishment, which specifies the estimated time of the site inspection.

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Within 15 working days from the date of issuing the decision, the inspectorate shall carry out a site inspection at the facility.

### 3. Inspection procedures:

- a) Step 1. The inspectorate shall publish the establishment decision, inspection purposes, contents and plan at the facility;
- b) Step 2. The facility shall produce a brief on organizational structure, personnel and application of GACP or the specific contents based on the details of the inspection session.
- c) Step 3. The inspectorate shall conduct site inspection of application of GACP at the facility. If the facility enters one or some stages of the manufacturing process, only GACP applied to such stages is inspected;
- d) Step 4. The inspectorate shall have a talk with the facility about deficiencies detected during the inspection process (if any); discuss with the facility if it disagrees with the inspectorate about each deficiency or about level of GACP compliance;
- dd) Step 5. An inspection record is prepared and signed as follows:

After the site inspection is done, the inspectorate shall prepare an inspection record following Form No. 4A under Annex I to this Circular. The inspection record must illustrate the members of the inspectorate, location, date and scope of the inspection, and disagreements between the inspectorate and the facility (if any). The head of the facility and chief of the inspectorate then sign the inspection record. The record shall be made into 03 copies: 01 copy shall be archived at the facility, 02 copies shall be archived at the receiving authority.

e) Step 6. The inspection report is finalized as follows:

The inspectorate shall prepare a GACP inspection report following Form No. 4B under Annex I to this Circular.

The inspectorate must complete the inspection within 20 days.

### 4. Level of GACP compliance:

The inspection of facility's compliance with GACP provided in the Annex V to this Circular shall be carried out according to the following 03 levels:

a) GACP level 1 facility;

- b) GACP level 2 facility;
- c) GACP level 3 facility.

### Article 13. Processing results of inspection of compliance with GACP

1. If the GACP inspection report concludes GACP level 1 facility set forth under Point a Clause 4 Article 12 of this Circular:

Within 10 working days from the date on which the inspection record is signed, the receiving authority shall publish results of GACP inspection on its website following Form No. 06 under Annex I to this Circular. If the facility applies for both issuance of the certificate of compliance with GACP for herbal materials and inspection of GACP compliance, the receiving authority shall issue the said qualification following Form No. 03 under Annex I to this Circular.

- 2. If the GACP inspection report concludes GACP level 2 facility set forth under Point b Clause 4 Article 12 of this Circular:
- a) Within 05 working days from the date on which the inspection record is signed, the receiving authority shall send the GACP inspection report to the facility;
- b) After completing deficiency rectification, within 30 days, the facility must issue a rectification report including a plan and evidence (documents, files, photos, videos or other documentary evidence) showing the completion of rectification of the deficiencies specified in the GACP inspection report;
- c) Within 20 days from the date on which the rectification report is received, the receiving authority shall assess the result of deficiency rectification by the facility and conclude the level of its GACP compliance:
- If the result of deficiency rectification makes the facility comply with GACP: the receiving authority shall publish a list of herbal materials that have undergone inspection of compliance with GACP following Form No. 06 under Annex I to this Circular. If the facility applies for both issuance of the Certificate of compliance with GACP for herbal materials and inspection of GACP compliance, the receiving authority shall issue the said qualification following Form No. 03 under Annex I to this Circular;
- If the result of deficiency rectification shows that the facility still fails to comply with GACP, the receiving authority shall issue a notice specifying reasons thereof.

- d) Within 06 months from the date on which the additional documents are requested in writing by the receiving authority, the facility shall submit them as requested. If the facility fails to satisfy such request by the mentioned deadline or the application is not satisfactory within 12 months from the first time it is submitted, the application will be rejected.
- 3. If the GACP inspection report concludes GACP level 3 facility set forth under Point c Clause 4 Article 12 of this Circular, within 05 working days from the date on which the inspection record is signed, the receiving authority shall send a notice of failure to satisfy GACP together with the GACP inspection report to the facility.
- 4. If the facility disagrees with the deficiency stated by the inspectorate, within 30 days from the date on which the inspectorate issues the GACP inspection report or the rectification inspection report, the facility shall send a written representation to the receiving authority together with the evidence (documents, files, photos, videos or other relevant documentary evidence).

Within 10 working days from the date on which the written representation of the facility is received, the receiving authority shall review the GACP assessment report and the written representation of the facility, and if necessary, consult relevant experts and respond the facility in writing. The written response must specify the agreements and disagreements with the written representation sent by the facility. The abovementioned length of time shall not add to the time limit for inspection period.

## Article 14. Sequence and process of periodic inspection of maintenance of compliance with GACP

- 1. Before 30 days from the expiration date of the Certificate of compliance with GACP for herbal materials or the expiration date publicized on website of Traditional Medicine Administration of Vietnam, the facility shall submit 01 application for the periodic inspection of the maintenance of compliance with GACP as specified in Article 10 of this Circular to the receiving authority directly, via post offices or online via the online public service system of the Ministry of Health.
- 2. If the facility fails to submit the application for periodic inspection of maintenance of compliance with GACP before the deadline specified in Clause 1 of this Article, within 15 days from the expiration date of the Certificate of compliance with GACP for herbal materials, the receiving authority shall request the facility in writing to submit the periodic inspection application as per law.

3. Within 45 days from the date on which the receiving authority issues the request, the facility must submit the periodic inspection application for compliance with GACP together with an explanation for the delayed submission. If the facility fails to submit the dossier after such deadline, the receiving authority shall examine and inspect the GACP satisfactory maintenance of the facility as per law, prepare the record following Form No. 4C under Annex I to this Circular.

The dossier acceptance, appraisal procedures and the process of periodic inspection of GACP satisfactory maintenance shall comply with provisions under Clause 2 and Clause 3 Article 12 of this Circular.

4. After submitting the application mentioned above before the deadline specified in Clause 1 of this Article, the facility may continue their herbal material cultivating activities complying with GACP until the results of the periodic inspection of maintenance of compliance with GACP are produced.

# Article 15. Processing results of periodic inspection of maintenance of compliance with GACP

1. If the GACP inspection report concludes GACP level 1 facility set forth under Point a Clause 4 Article 12 of this Circular:

Within 10 working days from the date on which the inspection record is signed, the receiving authority shall publicize on their website the GACP satisfactory results following Form No. 06 under Annex I to this Circular. If the facility applies for both issuance of the Certificate of compliance with GACP for herbal materials and inspection of GACP compliance, the receiving authority shall issue the said qualification following Form No. 03 under Annex I to this Circular.

- 2. If the GACP inspection report concludes GACP level 2 facility set forth under Point b Clause 4 Article 12 of this Circular:
- a) Within 05 working days from the date on which the inspection record is signed, the receiving authority shall send the GACP inspection report to the facility to enable them to rectify, remedy the deficiencies and send the rectification report to the receiving authority;
- b) Within 30 days from the date on which the receiving authority sends the GACP inspection report, the facility must issue the rectification report including the plan and evidence (documents, files, photos, videos, certificates or other documentary evidence) showing the rectification remediate of the deficiencies specified in the GACP inspection report;

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- c) Within 20 days from the date on which the rectification report is received, the receiving authority shall assess the result of deficiency rectification by the facility and conclude the level of its GACP compliance:
- If the result of deficiency rectification makes facility comply with GACP: The receiving authority shall update information on the maintenance of GACP compliance of the facility on their website. If the facility applies for the Certificate of compliance with GACP for herbal materials in the inspection application, the receiving authority shall issue the said certificate following Form No. 03 under Annex I to this Circular.
- If the result of deficiency rectification shows that the facility still fails to comply with GACP, the receiving authority shall issue a notice about contents that need to be continuously rectified and submitted in additional reports. The extension period for additional rectification and report is 45 days from the date on which the notice is issued.
- d) Within 90 days from the date on which the inspection record is signed and the facility fails to submit the rectification report or the rectification results fail to meet the requirements after rectifying as set forth under Point c of this Clause, the receiving authority shall issue a notice on failure to comply with GACP and depending on the nature and severity of the violations, the receiving authority shall adopt any of the measures under Point a and Point b Clause 3 of this Article.
- 3. If the GACP inspection report concludes third-degree compliant facility as specified in Point c Clause 4 Article 12 of this Circular, depending on the nature and severity of the violations, within 10 working days from the date on which the inspection report is issued, the receiving authority shall adopt any of the following measures:
- a) Revoke the issued Certificate of compliance with GACP for herbal materials and removed the published GACP compliance inspection results uploaded on website of the receiving authority;
- c) Impose administrative sanctions according to administration sanction laws.
- 4. Within 05 working days from the date on which the facility is concluded that they have satisfied the maintenance of GACP compliance or from the date on which the decision to revoke the Certificate of compliance with GACP for herbal materials is made due to failure to maintain the GACP compliance of the facility, the receiving authority shall update the GACP compliance condition on their website with respect to the GACP compliant facility or communicate with the facility that fails to maintain the GACP compliance.

5. If the herbal material specimen collected by the inspectorate during the inspection process is found to violate the quality, the receiving authority shall take actions against the violation as per law.

# Article 16. Procedures for inspection and processing results of inspection of change of GACP compliance

### 1. Receipt of application:

The facility applying for inspection of change of compliance with GACP shall submit 01 application and 01 CD or USB containing the documents specified in Article 11 of this Circular and pay the appraisal fee as set forth by the Minister of Finance to the Traditional Medicine Administration of Vietnam (the receiving authority) whether in person, by post or online through the online public service system of the Ministry of Health.

2. Sequence of receipt and appraisal of the application:

Upon receiving the complete application, the receiving authority shall issue a notice of receipt following Form No. 02 under Annex I to this Circular. If the application is incomplete as per law, the receiving authority shall request the facility to complete the application if it is submitted in person or within 10 working days from date on which the application is received, the receiving authority request the facility in writing to complete the application as per law if it is submitted by post office or online.

- 3. After the date on which the receiving authority furnishes the facility with the receipt form, the facility may conduct any of the following revisions:
- a) Revisions to the establishment decision or the certificate of satisfaction of business conditions;
- b) Revisions to the organizational structure and personnel of the facility while ensuring the requirements and conditions of the technical department in charge of the herbal material cultivation and collection of the facility.
- 4. Within 01 month from the date on which a satisfactory application is received, the receiving authority shall appraise the application, carry out site inspection at the facility as specified in Clause 2 and Clause 3 Article 12 of this Circular if the facility:
- a) changes the area of any herbal material cultivation and collection site in the areas sharing the same soil and climate conditions; or

- b) changes breeds, breed selection procedures, propagation procedures; or
- c) makes changes during the herbal material cultivation process: the fertilizer/feed ratio, time for fertilizing/providing supplements; or
- d) makes changes during the herbal material collection and processing process: collection time, collection methods, processing conditions (temperature, humidity, excipient/additive ratio); or
- dd) makes other changes, thereby causing serious impacts to the quality of the herbal materials; or
- e) makes changes other than those specified in Clause 3 of this Article.
- 5. In case of an site inspection specified in Clause 4 of this Article, the handling of the revised GACP satisfactory inspection results shall comply with Article 13 of this Circular.

# Article 17. Reissuance of Certificate of compliance with GACP for herbal materials in the event of loss or damage

- 1. The facility shall submit an application form for the Certificate of compliance with GACP for herbal materials following Form No. 1D under Annex I to this Circular.
- 2. Within 05 working days from the date on which such application is received, the receiving authority shall reissue the Certificate of compliance with GACP for herbal materials following Form No. 03 under Annex I to this Circular.

#### Chapter IV

### INSPECTORATE CONDUCTING INSPECTION OF COMPLIANCE WITH GACP FOR HERBAL MATERIALS AND PRINCIPLES AND STANDARDS FOR COLLECTING NATURAL HERBAL MATERIALS

### Article 18. Composition and standards to be satisfied by members of an inspectorate

- 1. An inspectorate consists of:
- a) the chief and the secretary affiliated to the receiving authority;
- b) at least 01 member: the representative of the National Institute of Medicinal Materials;

- c) 01 member: the representative of the Department of Health of a province or central-affiliated city (hereinafter referred to as "Department of Health") where the herbal material cultivation, collection, processing and storage area is available;
- d) at least 01 member: affiliated to the receiving authority;
- e) other members at the request of the chief of the inspectorate.
- 2. A member of the inspectorate must satisfy the following standards:
- a) He/She must obtain at least a bachelor's degree and has been trained in pharmacy or agriculture, plant protection, agronomy, herbal material quality control and pharmaceutical management;
- b) He/She has been trained in GACP, GACP inspection, and has a thorough grasp of GACP principles and standards;
- c) He/She must be honest, objective and stringently compliant with the regulations of law during the inspection process and must not create any conflict of interest with the inspected facility as specified in Clause 3 of this Article;
- d) The chief of the inspectorate must have at least 02 (two) years of experience in pharmaceutical or traditional medicine management.
- 3. Principles of assessment of conflict of interest: A member of the inspectorate shall be considered to have a conflict of interest with the inspected facility in any of the following cases:
- a) He/She used to work or participate in providing consulting services for the inspected facility in the last 05 years;
- b) He/She is receiving financial benefits from the inspected facility;
- c) His/Her spouse, child, parent, biological sibling, father or mother-in-law is working for the inspected facility.

### Article 19. Responsibilities and powers of inspectorate

- 1. The inspectorate has the responsibilities to:
- a) assess the whole operation of the facility according to GACP principles and standards respectively specified in Article 5 of this Circular, updated versions of GACP principles and



standards and relevant regulations; clearly record inspection contents and deficiencies found, prepare GACP inspection records and reports;

- b) report the inspection results or provide an explanation to the GACP inspection report provided the facility has any disagreements with the report;
- c) maintain confidentiality of all information relating to the inspection contents and the herbal material cultivation, collection, quality control, storage and distribution unless otherwise agreed upon by the facility or requested by the competent authority.
- 2. The inspectorate has the power to:
- a) examine all of the areas related to herbal material cultivation, collection, processing and storage owned by the inspected facility;
- b) request the facility to provide relevant documents;
- c) collect documents, evidence (by copying documents, taking photos or recording videos) of deficiencies found during the inspection process;
- d) collect samples of herbal materials to test for their quality as per law;
- dd) make records, request the facility to suspend totally or partially its operations related to the violations; if the inspectorate finds that the facility commits a violation which severely affects the quality of the herbal materials during the inspection process it is required to notify the competent person thereof.

### Chapter V

#### IMPLEMENTATION PROVISIONS

#### Article 20. Entry into force

- 1. This Circular comes into force from September 27, 2019.
- 2. Circular No. 14/2009/TT-BYT dated September 03, 2009 of the Minister of Health expires from the effective date of this Circular.

#### Article 21. Transition clauses

1. The documents submitted before the effective date of this Circular shall be process as prescribed in the Circular No. 14/2009/TT-BYT dated September 03, 2009 of the Minister of

Health on guidelines for application of "Good agricultural and collection practices of medicinal plants" principles and standards according to recommendation of the World Health Organization.

- 2. With respect to the facilities issued with notice of receipt of declaration of compliance with GACP WHO before the effective date of this Circular:
- a) The notice of receipt of declaration of compliance with GACP WHO shall remain effective until its expiry;
- b) From the effective date of this Circular, in case the facility applies for the Certificate of compliance with GACP for herbal materials instead of the valid notice of receipt of declaration of compliance with GACP WHO, it shall apply for re-issuance of the Certificate of compliance with GACP for herbal materials as specified in Article 17 of this Circular. The Certificate of compliance with GACP for herbal materials is valid until the expiration date of the previous declaration of GACP WHO manufactured herbal material acceptance form.

#### Article 22. Terms of reference

In the cases where any of the legislative documents and regulations referred to in this Circular is amended or replaced, the newest one shall prevail.

#### Article 23. Responsibility for implementation

- 1. The Traditional Medicine Administration of Vietnam shall have the responsibilities to:
- a) organize the implementation, examine and inspect the implementation of this Circular on a nationwide scale;
- b) issue the GACP herbal material qualification;
- c) update the list of GACP-qualified facility on the website of the Ministry of Health or the website of the Traditional Medicine Administration of Vietnam;
- d) handle complaints about inspection of compliance with GACP for herbal materials as per law;
- dd) take actions violations committed by GACP-compliant herbal material cultivation and collection facilities nationwide as per law.

- 2. The Departments of Health of provinces and central-affiliated cities shall have the responsibilities to:
- a) organize the implementation, examine and inspect the implementation of this Circular within their provinces;
- b) participate in the GACP inspectorate to assess the local facilities at the request of the receiving authority.
- 3. The herbal material cultivation and collection facilities, must submit annual reports on the yield of collected herbal materials that have undergone inspection of GACP compliance and have been declared compliant with GACP.
- 4. Chief of the Ministry Office, Ministry Inspectorates, Directors General of Departments, General Departments affiliated to the Ministry of Health, Directors of Health Departments of provinces and central-affiliated cities and other relevant agencies, organizations, units and persons shall implement this Circular.

Difficulties that arise during the implementation of this Circular should be promptly reported to the Traditional Medicine Administration of Vietnam - Ministry of Health.

PP. MINISTER
DEPUTY MINISTER

Nguyen Viet Tien

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