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Pharmacopoeia of the People's Republic of China (2010 Edition): A Milestone in Development of China's Healthcare

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Compilation of the Pharmacopoeia of the People's Republic of China (known as *the Chinese Pharmacopoeia 2010*) has been completed by the Ninth Chinese Pharmacopoeia Commission, which has been officially distributed in January 2010 and implemented on October 1st, 2010. After the first copy was established by the Chinese government in 1953, *the Chinese Pharmacopoeia* has enjoyed eight updates in 1963, 1977, 1985, 1990, 1995, 2000, 2005, and 2010, respectively, with an increasing authoritative treatises from 531 to 4615 in total.

The *Chinese Pharmacopoeia 2010* is composed of three volumes namely Chinese materia medica (Volume Ⅰ), chemical drugs (Volume Ⅱ), and biological products (Volume Ⅲ), with rather extensive revision in comparison with the 2005 edition. It takes in a total of 4615 items, of which 1358 are new admissions. Volume Ⅰ presents 2136 monographs in Chinese crude drugs and Yin-Pian (simplified Chinese: 饮片; traditional Chinese: 飲片; pinyin: yǐn piàn) — various prepared agents of Chinese crude drugs for the purpose of clinical practices, herbal extracts, and Chinese patent medicines, etc., including 990 new admissions (Tables 1 and 2) and 612 revisions. Volume Ⅱ covers 2348 monographs of chemical drugs, antibiotics, biochemicals, and radiopharmaceuticals, among which 340 are newly added and 1500 are revised. Volume Ⅲ focuses on biological products, and there are 131 monographs containing 28 new admissions and 103 revisions. One hundred and thirty monographs of pharmaceutical adjuvants are admitted into the *Pharmacopoeia*. Its appendices are revised as follows: 14 new admissions and 54 revisions in Volume Ⅰ; 15 new admissions and 70 revisions in Volume Ⅱ, and 18 new admissions and 38 revisions in Volume Ⅲ. This is the most comprehensive collection so far with the increases of 42% and 69% in new items and revisions, respectively. The *Pharmacopoeia* has showed standards of Yin-Pian and normal auxiliary materials in quite full aspects, which were once suspended problems in the national standards.

Modern analytical techniques are adopted more extensively in the requirements of the monographs admitted to this edition. For example, LC-MS, DNA molecular markers, and TLC chromatography are applied in identification and assay of Chinese crude drugs, ion chromatography and capillary electrophoresis are adopted in separation and identification of chemical drugs, and virus inactivation is employed for quality assurance of biological products.

Drug safety and quality standards have been improved. Ophthalmic drops/ointments must be manufactured from sterilized ingredients under rigidly aseptic conditions and meet the sterility requirements. The *Pharmacopoeia* has also established the standards for adhesive plasters for the first time. Eye drops and intravenous infusion are required to be determined in an additional item of osmotic pressure molar concentration.

Advanced techniques have been applied in effectiveness and controllable quality of drugs. More specific identification techniques are introduced for the

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Table 1 New admissions of Chinese materia medica and Yin-Pian in *the Chinese Pharmacopoeia 2010*

Simplified Chinese / traditional Chinese	Pinyin	Pharmaceutical Latin name	Plant species / Compound
一枝黄花/一枝黃花	yī zhī huáng huā	*Solidaginis Herba*	*Solidago decurrens* Lour.
三颗针/三顆針	sān kē zhēn	*Berberidis Radix*	*Berberis poiretii* Schneid.
			B. soulieana Schneid.
			B. vernae Schneid.
			B. wilsonae Hemsl.
大叶紫珠/大葉紫珠	dà yè zǐ zhū	*Callicarpae Macrophyllae Folium*	*Callicarpa macrophylla* Vahl
大豆黄卷/大豆黃卷	dà dòu huáng juǎn	*Sojae Semen Germinatum*	*Glycine max* (L.) Merr.
黑豆/黑豆	hēi dòu	*Sojae Semen Nigrum*	*Glycine max* (L.) Merr.
大皂角/大皂角	dà zào jiǎo	*Gleditsiae Sinensis Fructus*	*Gleditsia sinensis* Lam.
大青盐/大青鹽	dà qīng yán	*Halitum*	NaCl
大蒜/大蒜	dà suàn	*Allii Sativi Bulbus*	*Allium sativum* L.
山香圆叶/山香圓葉	shān xiāng yuán yè	*Turpiniae Folium*	*Turpinia arguta* Seem.
千里光/千里光	qiān lǐ guāng	*Senecionis Scandentis Herba*	*Senecio scandens* Buch. -Ham.
广东紫珠/廣東紫珠	guǎng dōng zǐ zhū	*Callicarpae Caulis* et *Folium*	*Gallicarpa kwangtungensis* Chun
飞扬草/飛揚草	fēi yáng cǎo	*Euphorbiae Hirtae Herba*	*Euphorbia hirta* L.
小驳骨/小駁骨	xiǎo bó gǔ	*Gendarussae Herba*	*Gendarussa vulgaris* Nees
木棉花/木棉花	mù mián hua	*Gossampini Flos*	*Gossampinus malabarica* (DC.) Merr.
艾片/艾片	ài piàn	*l-Borneolum*	*Blumea balsamifera* (L.) DC.
石吊兰/石吊蘭	shí diào lán	*Lysionoti Herba*	*Lysionotus pauciflorus* Maxim.
布渣叶/布渣葉	bù zhā yè	*Microctis Folium*	*Microcos paniculata* L.
龙脷叶/龍脷葉	lóng lì yè	*Sauropi Folium*	*Sauropus spatulifolius* Beille
北刘寄奴/北劉寄奴	běi líu jì nú	*Siphonostegiae Herba*	*Siphonostegia chinensis* Benth.
白屈菜/白屈菜	bái qū cài	*Chelidonii Herba*	*Chelidonium majus* L.
瓜子金/瓜子金	guā zǐ jīn	*Polygalae Japonicae Herba*	*Polygala japonica* Houtt.
冬凌草/冬凌草	dōng líng cǎo	*Rabdosiae Rubescentis Herba*	*Rabdosia rubescens* (Hemsl.) Hara
西青果/西青果	xī qīng guǒ	*Chebulae Fructus Immaturus*	*Terminalia chebula* Retz.
当药/當藥	dāng yào	*Swertiae Herba*	*Swertia pseudochinensis* Hara
杠板归/杠板歸	gàng bǎn guī	*Polygoni Perfoliati Herba*	*Polygonum perfoliatum* L.
巫山淫羊藿/巫山淫羊藿	wū shān yīn yáng huò	*Epimedii Wushanensis Herba*	*Epimedium wushanense* T. S. Ying
皂矾/皂礬	zào fān	*Melanteritum*	$FeSO_4 \cdot 7H_2O$
没药/沒藥	mò yào	*Myrrha*	*Commiphora myrrha* Engl.
			C. molmol Engl.
苦玄参/苦玄參	kǔ xuán shēn	*Picriae Herba*	*Picria fel-terrae* Lour.
制天南星/製天南星	zhì tiān nán xīng	*Arisaematis Rhizoma Preparatum*	*Arisaema erubescens* (Wall.) Schott
			A. heterophyllum Bl.
			A. amurense Maxim.
金龙胆草/金龍膽草	jīn lóng dǎn cǎo	*Conyzae Herba*	*Conyza blinii* Lévl.
金铁锁/金鐵鎖	jīn tiě suǒ	*Psammosilenes Radix*	*Psammosilene tunicoides* W. C. Wu et C. Y. Wu
乳香/乳香	rǔ xiāng	*Olibanum*	*Boswellia carterii* Birdw.
			B. bhaw-dajiana Birdw.
油松节/油松節	yóu sōng jié	*Pini Lignum Nodi*	*Pinus tabulieformis* Carr.
			P. massoniana Lamb.
茯苓皮/茯苓皮	fū líng pí	*Poriae Coutis*	*Poria cocos* (Schw.) Wolf
姜半夏/姜半夏	jiāng bàn xià	*Pinelliae Rhizoma Praeparatum cum Zingibere* et *Alumine*	*Pinellia ternata* (Thunb.) Breit.
清半夏/清半夏	qīng bàn xià	*Pinelliae Rhizoma Praeparatum Cum Alumine*	*Pinellia ternata* (Thunb.) Breit.
洪连/洪連	hóng lián	*Lagotidis Herba*	*Lagotis brevituba* Maxim.
桃枝/桃枝	táo zhī	*Persicae Ramulus*	*Prunus persica* (L.) Batsch
铁皮石斛/鐵皮石斛	tiě pí shí hú	*Dendrobii officinalis Caulis*	*Dendrobium officinale* Kimura et Migo
臭灵丹草/臭靈丹草	chòu líng dān cǎo	*Herba Laggerae*	*Laggera pterodonta* (DC.) Benth.

Simplified Chinese / traditional Chinese	Pinyin	Pharmaceutical Latin name	Plant species / Compound
狼毒/狼毒	láng dú	*Euphorbiae Ebracteolatae Radix*	*Euphorbia ebracteolata* Hayata
			E. fischeriana Steud.
高山辣根菜/高山辣根菜	gāo shān là gēn cài	*Pegaeophyti Radix* et *Rhizoma*	*Pegaeophyton scapiflorum* (Hook. f. et Thoms.) Marq. et Shaw
通关藤/通關藤	tōng guān téng	*Marsdeniae Tenacissimae Caulis*	*Marsdenia tenacissima* (Roxb.) Wight et Arn.
黄山药/黃山藥	huáng shān yào	*Dioscorea Panthaicae Rhizoma*	*Dioscorea panthaica* Prain et Burk.
黄蜀葵花/黃蜀葵花	huáng shǔ kuí huā	*Abelmoschi Corolla*	*Abelmoschus manihot* (L.) Medic.
荭蓂/荭蓂	xī mì	*Thlaspi Herba*	*Thlaspi arvense* L.
四季青/四季青	sì jì qīng	*Ilicis Chinensis Folium*	*Ilex chinensis* Sims
救必应/救必應	jìu bì yìng	*Ilicis Rotundae Cortex*	*Ilex rotunda* Thunb.
野马追/野馬追	yě mǎ zhuī	*Eupatorii Lindleyani Herba*	*Eupatorium lindleyanum* DC.
野木瓜/	yě mù guā	*Stauntoniae Caulis* et *Folium*	*Stauntonia chinensis* DC.
甜瓜子/甜瓜子	tián guā zǐ	*Semen Melo*	*Cucumis melo* L.
紫花前胡/紫花前胡	zǐ huā qián hú	*Peucedani Decursivi Radix*	*Peucedanum decursivum* (Miq.) Maxim.
紫珠叶/紫珠葉	zǐ zhū yè	*Callicarpae Formosanae Folium*	*Callicarpa formosana* Rolfe
紫萁贯众/	zǐ qí guan zhòng	*Osmundae Rhizoma*	*Osmunda japonica* Thunb.
筋骨草/筋骨草	jīn gǔ cǎo	*Ajugae Herba*	*Ajuga decumbens* Thunb.
蓍草/蓍草	shī cǎo	*Achilleae Herba*	*Achillea alpina* L.
蓝布正/藍布正	lán bù zhèng	*Gei Herba*	*Geum aleppicum* Jacq.
			G. japnicum Thunb. var. chinense Bolle
滇鸡血藤/滇雞血藤	diān jī xuě téng	*Kadsurae Caulis*	*Kadsura interior* A. C. Smith
榼藤子/榼藤子	kē téng zi	*Entadae Semen*	*Entada phaseoloides* (Linn.) Merr.
蜘蛛香/蜘蛛香	zhī zhū xiāng	*Valeriznze Jatamansi Rhizoma* et *Radix*	*Valeriana jatamansi* Jones
辣椒/辣椒	là jiāo	*Capsici Fructus*	*Capsicum annuum* L.
暴马子皮/暴馬子皮	bào mǎ zǐ pí	*Syringae Cortex*	*Syringa reticulata* (Bl.) Hara var. *mandshurica* (Maxim.) Hara
翼首草/翼首草	yì shǒu cǎo	*Pterocephali Herba*	*Pterocephalus hookeri* (C. B. Clarke) Höeck
翻白草/翻白草	fān bái cǎo	*Potentillae Discoloris Herba*	*Potentilla discolor* Bge.

Table 2 New admissions of oil, fats, and extractives in the *Chinese Pharmacopoeia 2010*

Simplified Chinese / traditional Chinese	Pinyin	English
人参茎叶总皂苷/人參莖葉總皂苷	rén shēn jīng yè zǒng zào gān	Total ginsenoside of ginseng stems and leaves
人参总皂苷/人參總皂苷	rén shēn zǒng zào gān	Total ginsenoside ginseng Root
三七三醇皂苷/三七三醇皂苷	sān qī sān chún zào gān	Notoginseng triol saponins
三七总皂苷/三七總皂苷	sān qī zǒng zào gān	Sanqi total saponins
大黄浸膏/大黃浸膏	dà huáng líu jìn gāo	Rhubarb liquid extract
山楂叶提取物/山楂葉提取物	shān zhā yè tí qǔ wù	Hawthorn leave extract
丹参总酚酸提取物/丹參總酚酸提取物	dān shēn zǒng fēn suān tí qǔ wù	Salvia total phenolic acids
丹参酮提取物/丹參酮提取物	dān shēn tóng tí qǔ wù	Tanshinones
北豆根提取物/北豆根提取物	běi dòu gēn tí qǔ wù	Asiatic moonseed root extract
灯盏花素/燈盞花素	dēng zhǎn huā sù	Breviscapine
肿节风浸膏/腫節風浸膏	zhǒng jié fēng jìn gāo	Glabrous sarcandra extract
茵陈提取物/茵陳提取物	yīn chén tí qǔ wù	Gapillary wormwood extract
穿心莲内酯/穿心蓮內酯	chuān xīn lián nèi zhǐ	Andrographolides
积雪草总苷/積雪草總苷	jī xuě cǎo zǒng gān	Gentella total glucosides
浙贝流浸膏/浙貝流浸膏	zhè bèi liú jìn gāo	Thunberg fritillary liquid extract
黄藤素/黃藤素	huáng téng sù	Fibriuretinin

corresponding Chinese materia medica. And more appropriate HPLC methods are given in contents determination of chemical drugs. Quality of raw and auxiliary materials of biological products is involved in more rigorous controls.

Drug standards are more reasonable than the previous ones. General requirements for auxiliary materials are complemented in the rule of pharmaceutical preparations. Visible particle detection methods are detailed in sampling, detection frequency, and time limit. Names of Chinese herbal materials are re-standardized to comply with the international system.

The *Pharmacopoeia* encourages technical innovation and international cooperation. HPLC fingerprint method, which is in accordance with integrity of TCM, has been established to ensure quality stabilities of Chinese materia medica. The *Pharmacopoeia* also introduces requirements for control of impurities in drug products and sterility tests which international organizations for mediation provided.

In addition, endangered and rare wild Chinese herbal species have been deleted from the *Pharmacopoeia*, based on the corresponding international conventions. Environmental-favored, resource-saving, and low-toxic detection methods are also included in the *Pharmacopoeia*. The 2010 edition is in harmony with the sustainable development of TCM and the protection of wild resources.

The 3rd International Conference on the Modernization of TCM 2010

The 3rd International Conference on the Modernization of Traditional Chinese Medicine (TCM) will be held during November 24–26, 2010, Chengdu, China, with the theme of "Traditional Chinese Medicine Innovation & Development". This high-level event will provide a unique opportunity for key stakeholders to discuss the current developments in TCM. This three-day conference aims to speed up the process of standardization, modernization, and internationalization of TCM. By bringing together well-known speakers from both the research based and generic pharma industry, institutions home and abroad, this conference will reflect on the newest achievements and seek to find consensus and agreement on how to move forward.

Topics for 5 panel meetings are 1) government forum on innovation and development of TCM, 2) sustainable utilization and development of TCM resources, 3) TCM innovation and industry development, 4) inheritance and development of TCM basic theories, and 5) disease prevention and therapeutic evaluation of TCM. The parallel events, including "International Science and Technology Exposition for Traditional Chinese Medicine 2010" and "The 64th Pharmchina" are going to be held.

TCM has the longest history of any system of medicine in the world and made an indelible contribution to human health and world civilization. The Chinese government has been working unremittingly to promote TCM inheritance and development. So far, two international conferences on the Modernization of TCM have been successfully launched in 2002 and 2005, respectively. The themes were "Traditional Chinese Medicine & Human health" and "Traditional Chinese Medicine Development & Modern Science and Technology", respectively. During the conferences, a few important documents have been released or authorized such as *Outline of Development for Modernization of Traditional Chinese Medicine*, *Chengdu Proposal*, and *Proposal for the Establishment of International Cooperation in Science and Technology of Traditional Medicines*. International Conference on the Modernization of TCM has been the greatest and regular forum sponsored by the Chinese government for international communication and cooperation in TCM development.

For more information, please visit http://www.icetcm.org

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