六年藥學教育接軌藥事執業之客觀環境探討

~2007-10-27-Asian Association of College of Pharmacy會議表達之看法~

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~ 2007-11-05-台北醫學大學藥學院座談共識 ~

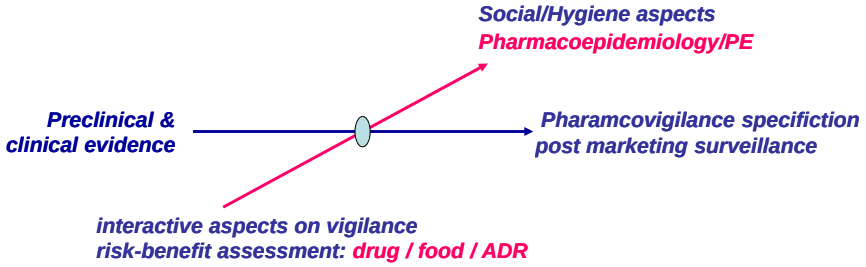
Global Trend

由產品經濟到知識經濟管理⇒ 由科學到風險管理之環構

ICH E2E Guideline 2005

From Risk management of individual medicine

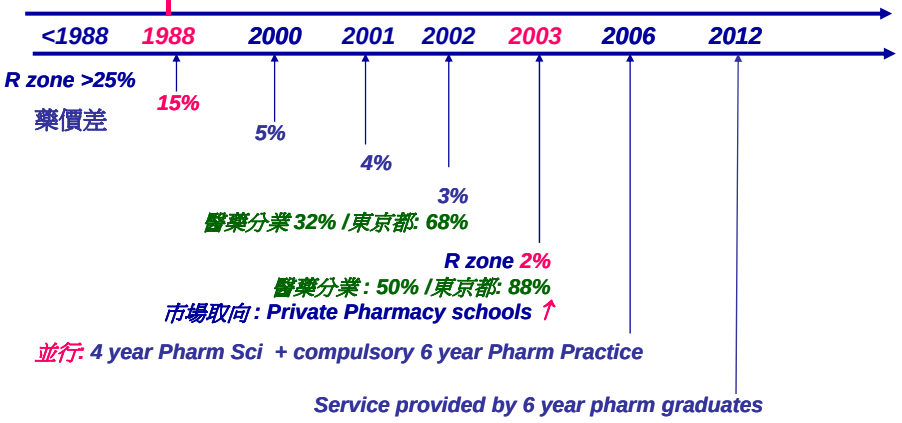
To PvP: system building for risk minimization in medication



台灣中藥西藥切割/進口國產藥切割無法接軌國際

Japanese Experience

1. 藥品專利過後成為學名藥，給付價↓至原價之40%
2. 15年準備期將健保學名藥價差從>15%降到2%（新藥藥價差為5%）
3. 藥師健保給付之處方籤不得>40張/日
4. 藥局每日來自同一醫院所之處方籤不得>70%



台灣: 藥師再好民眾不一定安全

Good Pharmacy & Delivery Practice

Pharmacists

人流物流資訊流集中風險
醫藥分業是落實PvP的前提

健保運行方式

Against International Norm

1984 USA: Hatch-Waxman Amendment
— drug pricing competition & patent term restoration act

??

藥事法40之1之2

4

台灣：不患寡而患不均的藥事經濟

1. 基層限量調劑(80張/天)，醫院未限量調劑，慢性病處方籤未釋出
2. 藥師:醫院+診所46% (6141/21148)，藥局31%
3. 藥局: 健保45% (1815/4003，1/3為門前藥局)、雜貨店化55% (2188/4003)
5. 藥師無開立藥局之意願

↓

先定調教改六年之目標

	Taiwan	OECD
病人每年平均看診數（次/年）	15.2	5.9
藥品品項數(品項/處方)	4.2	1.9
健保藥品支出佔率	25%	~15%
醫院藥師調劑量	151	37
藥局藥師調劑量(包括門前藥局)	33*	
慢性病處方籤開立率	18%	--
慢性病處方籤釋出率	2%	100
健保特約藥局	45%	--

2006 健保資料

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總結: 定義及背景

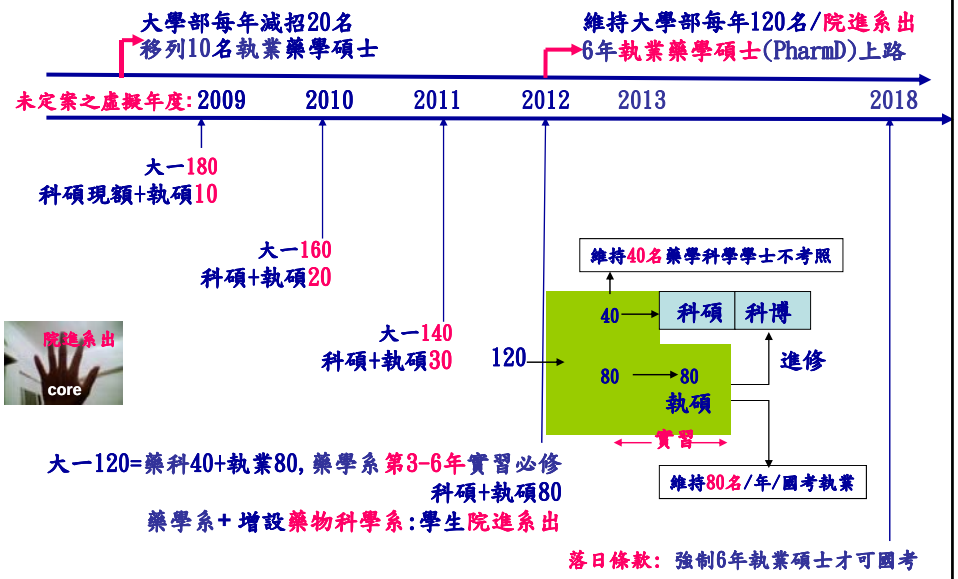
1. 定義：藥師執業為pharmacy practice非clinical pharmacy 。
2. 趨勢：環構(ICH E2E 2005) -- from product to risk management
   multidiscipline ⇒ inter- & integrative discipline ⇒ Interprofessional
   HPW etal JFDA, 15 (12) 2007, from Pharmacovigilance to vigilance planning.
3. 美國： *(體制內interprofessional --王惠玲, 如果能夠重頭來過, 台大藥刊, 31, pp3-10，1994.)*
   方式: 受教場所非框架(校進系出、自助餐check out式認學分、上下車)
   學程: pharmacy practice獲PharmD學位需六年
   目標: 提昇執業藥師品質
   內容: 強化臨床教學(clinical pharmacy)
4. 日本：以 15年時間健保變革 ⇒ 驅動處方釋出 ⇒ 驅動醫藥分業
   社會需要社區藥師 ⇒ 為提昇執業品質驅動六年教育(學界成立task force)
   學程: pharm practice + pharm sciences + hygiene pharmacy
5. 台灣：社會制度:賣場式醫療 against risk minimization
   醫藥分業變質：租牌、門前藥局、藥局雜貨店化
   教育資源切割: 中藥/西藥 ⇒ against integrative discipline
   執業資源切割: 社區/醫院 ⇒ 對提昇執業水準缺乏共識機制及平台
   藥學教育: 缺乏interprofessional之規畫
   接軌國際為目標?? ：社會制度是否接軌國際??

總結：教改

1. 定義：目標 -- 提昇執業水準
   學制 -- 執業藥學*(Pharmacy Practice)*
   課程-- 加強臨床藥學
2. 條件：需評估執業環境及教育資源，避免在受教者選系時失去競爭力
3. 方向：可選擇藥物科學或執業藥學或公衛藥學，臨床藥學有排他性。
4. 方法：符合國情，四年得學士，二年得碩士，避免招生時喪失競爭力。
5. 課程：實質變革重於學制之型式變革，逐步進行課程增刪整合
6. 學制：落實直昇制度，讓學士接執碩士，鼓勵修讀執業藥學碩士(=PharmD)
7. 環境：台灣 fee for medicine導向配藥，不利就業
8. 訴求：公衛藥學(risk management)推動藥師每日合理調劑量，驅動醫藥實質分業及藥事計價(fee for service)，再變更為強制六年教育
9. 教改：以學士名額換碩士方式，大學部逐年減招，移列執業藥學碩士。

	USA	Japan	Taiwan
醫藥分業	與生俱來	<20% to 54%	總錢5% / 慢錢<2%
工作地點	社區	社區	醫院
工作態勢	Fee for service諮詢	Fee for service諮詢	Fee for medicine配藥
藥師需求	High	Growing	low

逐年教改計畫模擬建議案--北醫觀點



~ 知識經濟

~Shel Silverstein~

敬請指教 ~

THANK YOU

參考資料

藥學教育的窗子：跟著趨勢走

教育範疇：非排他性 core to multi- & inter-discipline

1. 藥物科學 pharmaceutical sciences
2. 執業藥學 Pharmacy practice: 強化臨床藥學
3. 公共衛生 Hygiene pharmacy: 強化管理方法學

Multi-discipline

培養具有科學訓練與行為科學管理能力之藥學生

1. 科學訓練
2. 藥物流行病學: 風險因子分析/data treatment訓練
2. 知識經濟學: 健保與理性用藥的管理
3. 接軌公共衛生： Inter-professional discipline
4. 小眾健康照護：情境管理/風險管理
5. 公共政策訓練：管理之規畫者 not only order practitioner

台灣: 製造問題的速度>解決問題的能力

請三思！ 先解決產生問題的原因

進口藥 / 國產藥

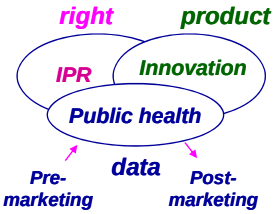
原廠藥 / 學名藥

專利+資料保護

智財保護藥 | 無保護藥

學名藥

藥事法40條之1之2修法論點



USA 1984: Hatch-Waxman Amendment
— drug pricing & patent term restoration act

台灣如何落實IPR？

藥事法40條之1/之2
Generics: products of which IPR is expired.

Japanese Prescription Release

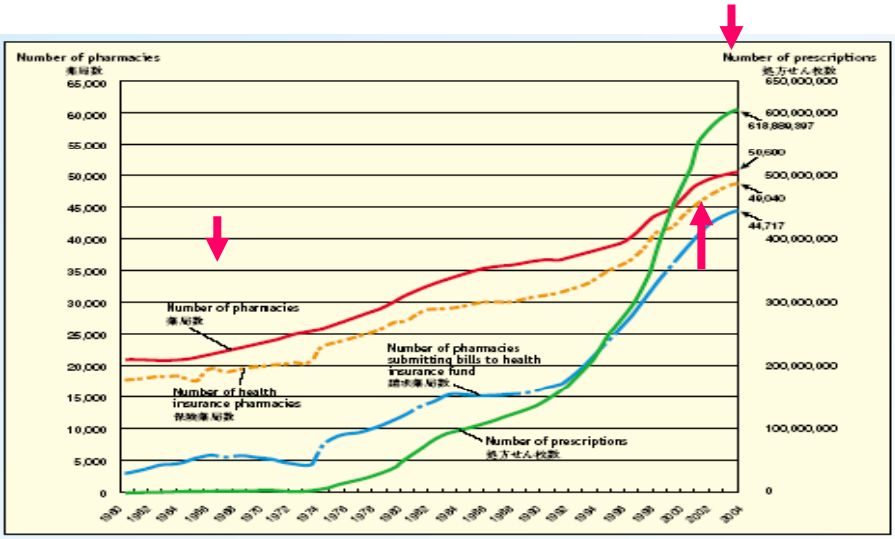


Fig. 11 Changes in the Numbers of Pharmacies and Prescriptions
図11. 薬局数、処方せん枚数等の推移

Japanese SDP

醫藥分業執行率: 20.3% (1995) 53.8% (2004)

Table 3 Changes in the Numbers of Pharmacies and Prescriptions
表3. 薬局数、処方せん枚数の推移

Year 年	Number of Pharmacies (Number of Health Insurance Pharmacies) 薬局数 (保険薬局数)	Number of Community Pharmacists 薬局薬剤師 *1	Number of Prescriptions dispensed by pharmacists per year 処方せん枚数	*Bungyo* ratio 処方せん受け取り率 *2	National Health Expenditures (billion yen) 国民医療費(10億円) *3
1995	39,433 (35,915)	—	265,867,021	20.3	26,957.7
1996	40,310 (37,190)	69,870	296,430,739	22.5	28,454.2
1997	42,412 (39,265)	—	337,821,439	26.0	28,914.9
1998	44,085 (41,251)	81,220	400,061,313	30.5	29,582.3
1999	45,171 (42,471)	—	455,369,390	34.8	30,701.9
2000	46,763 (44,349)	94,760	506,203,134	39.5	30,141.8
2001	48,252 (45,893)	—	559,595,974	44.5	31,099.8
2002	49,332 (47,331)	106,892	584,615,153	48.8	30,950.7
2003	49,956 (48,182)	—	598,121,520	51.6	31,537.5
2004	50,600 (49,040)	116,303	618,889,397	53.8	—

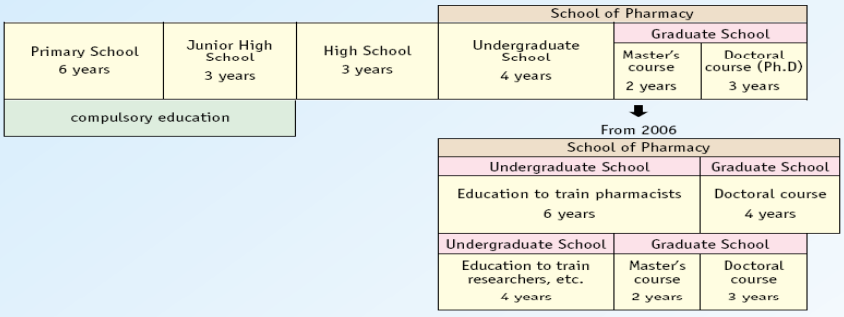
*1 Data from MHLW 厚生労働省「医師・歯科医師・薬剤師調査」
*2 Bungyo ratio is the ratio of prescriptions dispensed by pharmasits to the total estimated prescriptions which physicians and dentists issued for outpatients.
分業率は、医科診療（入院外）と歯科診療の投薬対象数に対する、処方せん枚数の割合を指す。
*3 Data from MHLW 厚生労働省「国民医療費」

3. Current State of the *Bungyo*

- *Bungyo* means the separation of drug prescribing and dispensing. Under the *bungyo* system, physicians and pharmacists provide their professional services at their own discretion as professionals independent of each other. Pharmacy is also accredited as one of separated and independent institutions.
- The *bungyo* ratio* (number of legal prescriptions as a percentage of the total number of prescriptions) was 53.8% in 2004. The total number of legal prescriptions dispensed by pharmacist in the country was estimated to be 618,889,397 for 2004.
- In Japan, the government promulgated "isei" (medical system), the first medical law, in 1874. This law called for *bungyo*. However, *Bungyo* was not generally accepted for following reasons, such as an extremely small number of pharmacists at that time and *kampo* medicine (traditional Chinese medicine) which are dispensed traditionally by doctors.
- After World War II, the Pharmaceutical Affairs Law and other related laws (the so-called *bungyo* law) was promulgated in 1954 and brought into force in 1956. However, this law also failed to popularize *bungyo* because the Medical Law included a proviso that physician is allowed to dispense drugs of the patient he/she diagnosed, and patients were accustomed to receiving drugs from physicians.
- The government's policy to promote *bungyo* became clearer in 1974, when it raised the physician's prescription fee from 10 to 50 points (1 point = ¥10) in the health insurance system. The *bungyo* rate started gradually increasing after this reform as illustrated on page 18. This was followed by a series of measures designed to promote *bungyo* by the government and the JPA, such as promotion of *bungyo* model projects, and improvement of pharmacies' infrastructures to fill prescriptions. Coupled with people's increasing awareness of medical care, these measures have finally succeeded in popularizing *bungyo* nationwide.
- With the rapid progression of an aging society with fewer children, it is becoming increasingly difficult for the Japanese government to secure financial resources sufficient to maintain the current health insurance, nursing care insurance and pension systems. Under such circumstances, the quality of *bungyo* has also become an important issue. In order to further improve its quality, the JPA is carrying out various projects designed to popularize family pharmacists and pharmacies (accredited pharmacy) and encourage pharmacists and pharmacies to provide more appropriate drug information and pharmaceutical consultation based on medication records and to take thorough measures to prevent dispensing errors. The JPA is also continuing efforts to improve continuing professional development and training programs and to take measures related to 6-year pharmacy education system in order to further upgrade the quality of pharmacists.

Pharmacy Education

Fig. 7 General and Pharmacy Education Systems in Japan



National Licence Examination 薬剤師国家試験

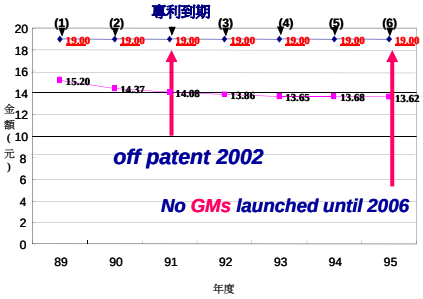
As stipulated in the Pharmacists Law, the graduates of the school of pharmacy must pass the national licence examination to obtain the pharmacist license (Articles 2, 3 and 15 of the Pharmacists Law). The examination is held once a year in spring.

(1) Basic pharmacy
(2) Clinical pharmacy
(3) Hygiene pharmacy
(4) Legislation and system related to pharmaceutical affairs

Following the introduction of the 6-year pharmacy education system, students who enter universities in April 2006 and onward will be qualified to take national licence examinations for pharmacists only when they complete the 6-year education as a general rule (amendment of the Pharmacist Law/15 June 2004).

The Impact of National Health Insurance Pricing Policy on Drug Utilization in Taiwan: Intellectual Property Aspects

YF Tseng, YL Lin, CL Wang, BH Chen, YC Lin, and HP Wang,



違背學名藥定義: amilodipine爲例

⇒ Undetermined risk

from 2003 to 2005

1. Amilodipine 用量↑ 24%
2. 行政保護 ⇒ 賣方市場
3. 賠了夫人又折兵?

Table 1. Impact of drug pricing policy on amilodipine consumption

year	Year off patent	OPM Price (P)	Highest GM price (G)	Price gap (P/G)	Market share of OPM (%)	Relative OPM consumption	NHI Extra payment on OPM (mNTD)*
2003	1	19.0	14.4	1.32	100	1.0	511
2005	3	19.0	14.4	1.32	100	1.24	632

* (P-G) xquantity

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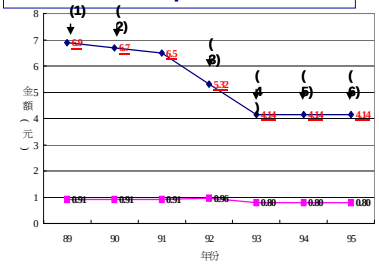
違背學名藥定義 ⇒ 市場失序: diclofenac 爲例

diclofenac Off-patent at 1986



From year 2003 to 2005:

1. Price of OPM: ↓ 36%.
2. Price gap: ↓ 18%.
3. NHI payment to OPM : ↓ 16%
4. OPM market share: ↓ 100%
5. NHI extra payment : ↓ 97%
6. Total consumption: stay steady.

Table 8. Impact of drug pricing on diclofenac consumption

year	Year off patent	Price gap (P/G)	Total annual consumption Million tab	Annual OPM consumption Million tab	Relative OPM consumption (%)	NHI payable share of OPM (%)	NHI Extra payment on OPM (mNTD)*
2003	18	4.56	35.2	3.53	1	19	179
2005	20	3.76	34.4	1.72	0.49	16	5

* (P-G) xquantity

18

Undetermined risk: 醫藥分業是落實PvP的前提

Table 1 and Fig. 8 Incidence of ESRD

年度	血液腹膜透析	洗腎人口比例
1997	20,697	1/1051
1998	23,758	1/923
1999	26,920	1/821
2000	29,937	1/744
2001	33,317	1/672
2002	35,965	1/626
2003	39,574	1/571
2004	42,550	1/533
2005	45,718	1/498

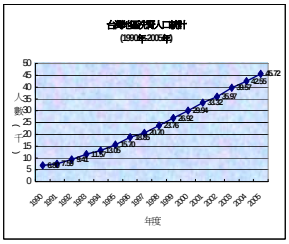


***Fig. 9.* Prevalence of ESRD**

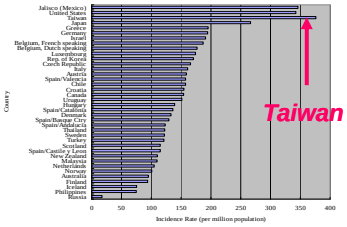


Table 2. Undetermined risk: ADR Reporting rate 1/17.9 lower than USA.

*	*診次 百萬 (a)*	*看診率 次/人年 (b)*	*處方籤 品項 (c)*	*用藥量 粗估 (d)=(b)x(c)*	*用藥量 比例*	*ADR 通報數 (b)*	*通報率 % (b/a)*	*通報率 比例*
Taiwan	*344*	*16*	*3.9*	*62.4*	*6.6*	*4629*	*0.00134*	*1*
USA	*1,746*	*5.9*	*1.6*	*9.4*	*1*	*422,889*	*0.024*	*17.9*

**Data of Taiwan: 2006; Data of USA: 2004.*

摘要

1. Clinical pharmacy為課程選項，不宜具排他性(忽視藥物科學及公衛藥學)。
2. 六年制為提昇執業藥學(pharmacy practice)水準，以臨床藥學為學制非international norm。
3. 學制變革需客觀評估執業環境及教育資源，冒然變更會在受教者選系時失去競爭力，因此本系學制之型式變革尚未有定案。
4. 教育內容之實質變革重於學制之型式變革，本系以能提昇執業水準為考量，已逐步進行課程增刪整合。
5. 本系以提供學生具有選擇**藥物科學**或**執業藥學**之走向為依歸。不因全面推展臨床藥學課程而犧牲藥物科學/產業發展。
6. 符合我國國情，以四年得學士學位，二年得碩士之既定學制為宜，避免招生時喪失競爭力。
7. 為讓四年學位接軌二年碩士，將落實直昇制度，鼓勵修讀執業藥學碩士(等同PharmD)。
8. 在客觀執業環境改善(主訴求:健保制定藥師每日合理調劑量以驅動醫藥實質分業)，藥學六年教育提供具有碩士學位之執業藥學畢業生人數亦逐年增加之後(次訴求為藥事服務計價fee for service)，再變更為強制六年教育才是最合理之規劃。
9. 附美國及日本六年制藥學教育之背景及我國六年藥師教育接軌藥事執業之客觀環境探討。