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如何建構一個安全、有效、合理的民眾用藥環境

胡幼圃特聘教授
國防醫學院/台大醫學院

103年11月20日

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Section Ⅰ 健保體制下的國人用藥問題

1. 現階段民眾面臨的用藥問題-沈麗娟 臺大臨床藥學研究所副教授
2. 面對領不到藥的民眾-藥師的觀察-李蜀平 中華民國藥師公會全國聯合會理事長
3. 為民眾建構藥品取得無障礙的環境-蔡宛芬 民間監督健保聯盟/台灣女人連線秘書長
4. 以病人為中心的藥品給付政策-黃達夫 和信治癌中心醫院院長

2

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Section II
擁有世界第一健保的美譽，該如何達成名副其實的藥品供應?

1. 藥品支付制度之國際概觀-陳鴻儀 中國醫藥大學 藥學院藥學系 副教授

2. 現行藥品給付制度的問題與建議-陳世雄 中華民國西藥代理商業同業公會理事長

3. 引進民眾所需的外國藥品-責任與困境-楊志平 中華民國開發性製藥研究協會理事長

4. 製造民眾所需的高品質藥品-責任與困境-陳志麟 臺灣製藥工業同業公會 主任委員

3

The provision of access to medicines depends on four factors:

1. Rational selection and use of medicines-Medical Doctor and Pharmacist
2. Affordable prices
3. Sustainable financing
4. Reliable health and supply systems-Pharmaceutical Industry

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Strategies to increase affordability of medicines include (I) :

1. Reducing taxes, tariffs and margins, and developing pricing policies.
2. Promoting competition for multi-source products.
3. Generic medicines including generic substitution.
4. Good procurement practices.

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Strategies to increase affordability of medicines include (II) :

5. Equity pricing and competition for single-source products.
6. Differential pricing (sometimes also called tiered pricing). Differential pricing has reduced the cost of many anti-retroviral HIV/AIDS therapies by up to 90% in low-income countries.
7. Price information and therapeutic substitution.
8. Promotion of competition, use of safeguards compatible with the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), such as parallel importation and compulsory licensing.

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Safety Net Hospitals for Pharmaceutical Access

About Safety Net Hospitals for Pharmaceutical Access (SNHPA)

(SNHPA) is a nonprofit organization of over 1,000 public and private nonprofit hospitals and health systems throughout the U.S., was formed in 1993 to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations.

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Safety Net Hospitals for Pharmaceutical Access

There are 11 results for Pharmaceutical accessibility (I)

340B Patients Speak Out
July 15, 2014

Making a Strong Case for 340B in Virginia and Tennessee
May 23, 2014

Making a Strong Case for 340B in Virginia and Tennessee
May 23, 2014

Making a Strong Case for 340B in Tennessee
May 19, 2014

Kentucky Hospitals Meet To Discuss Preserving Vital Drug Discount Program
May 16, 2014

SNHPA Statement on the Comprehensive 340B Program Regulation
April 09, 2014

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There are 11 results for Pharmaceutical accessibility (II)

340B Hospital Group Responds to Misleading Report from Big Pharma
March 25, 2014

Statement from SNHPA President and CEO Ted Slafsky on the bipartisan 2014 budget agreement
January 14, 2014

About
May 23, 2013

SNHPA Comments on Major Drug Pricing Case Before the U.S. Supreme Court Tomorrow
January 18, 2011

Safety-Net Health Care Providers File Brief in Major Drug Pricing Case Before the U.S. Supreme Court
December 21, 2010

Safety Net Hospitals for Pharmaceutical Access (SNHPA) is a 501(c)(6) non-profit organization of over 1000 public and private non-profit hospitals and health systems throughout the U.S. that participate in the Public Health Service 340B drug discount program.

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The Drug Shortage Crisis in the United States Causes, Impact, and Management Strategies

C. Lee Ventola, MS

1. Drug shortages are caused by many factors, including difficulties in acquiring raw materials, manufacturing problems, regulatory issues, and business decisions, as well as many other disturbances within the supply chain.

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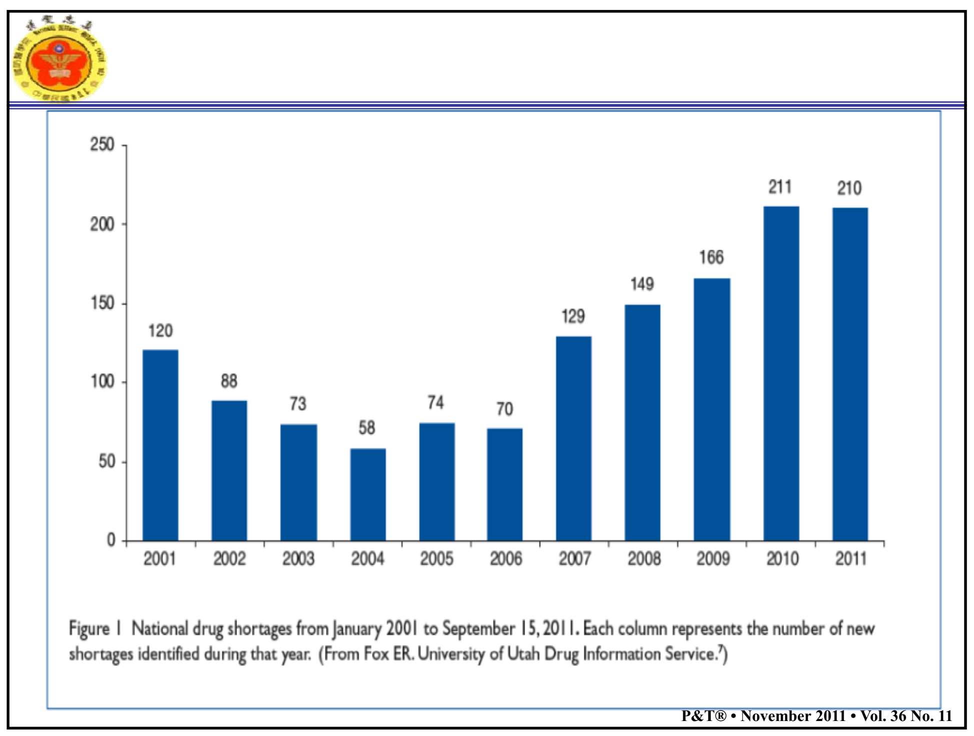

Figure 1 National drug shortages from January 2001 to September 15, 2011. Each column represents the number of new shortages identified during that year. (From Fox ER. University of Utah Drug Information Service.[7])

Recommendations Made at the Drug Shortages Summit

1. On November 5, 2010, the ASHP, ISMP, ASA, and ASCO, hosted a summit on drug shortages in Bethesda.

2. The recommendations included improved communication between the FDA and the manufacturer as well as increased transparency regarding manufacturing and inventory problems. Recommendations to relax drug Importation laws to use tax breaks to promote the upgrading of manufacturing lines.

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Conclusion

1. Drug shortages have a profound impact on patient safety.

2. Establishing clear procedures and guidelines for managing drug shortages is essential.
3. Proper information-gathering, extensive collaboration, and timely communication strategies are critical elements of an effective drug shortage management plan.

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National Pharmaceutical Drug Shortages

First Drafted (2010):
CFMS members at large

First Revision (2014):
Nadia Clarizia (n.clarizia@mail.utoronto.ca)
Tinya Lin (tlin2016@meds.uwo.ca)

Approved: 2010

Revised: 2014

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The Multi-Stakeholder Steering Committee on Drug Shortages (MSCC)

- In 2012, Health Canada and Alberta Health launched the Multi-Stakeholder Steering Committee on Drug Shortages (MSSC). Their aim was to focus on the prevention, notification and communication, and mitigation and crisis management of drug shortages.

Principles

1. All Canadians should have the ability access medical care, including access to pharmaceutical drugs

2. Pharmaceutical drugs in Canada should be safe, effective, and delivered to the highest standard of care

3. The federal, provincial, and territorial governments are accountable to shaping the necessary policies that will create fiscally sustainable and accessible health care that is effective for Canadians.

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Recommendations

1. We urge the Government of Canada to consider the challenge of pharmaceutical drug shortages as a federal priority.

2. It is critical that policy changes are introduced to minimize both the occurrence and impact of future drug shortages. Changes to policies such as changes to policies incentivising quality in the manufacturing process of these drugs could encourage companies to re-invest in quality management instead of refocusing on other drugs with more profitable margins.

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一、二代健保改革之核心價值

衛生福利部

支付制度
以品質為導向

資訊揭露
公開品質資訊
與財務報告

品質
民眾

財源籌措
擴大費基
計收補充保險費

醫界
Accountability
健保署
衛生福利部

公平

效率

簡化作業
整併監理費協二會
補充保險費
採就源扣繳方式

權責相符、擴大參與
收支連動
舉辦公民活動
增加付費者代表

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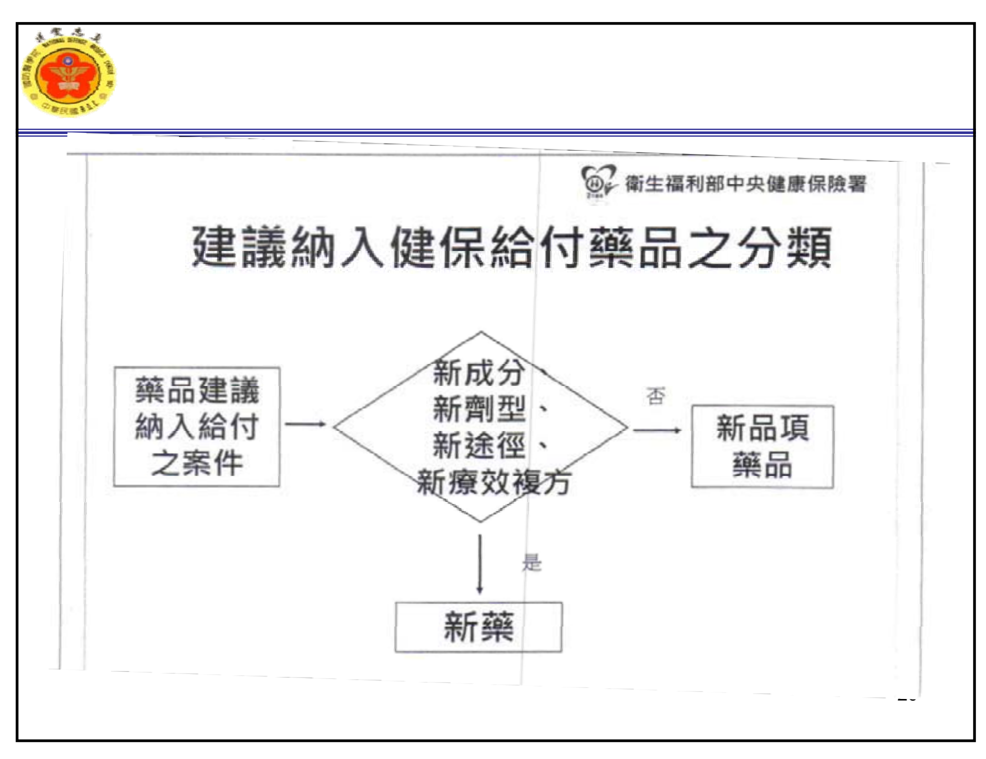

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健保藥品核價之相關鼓勵措施(2)
-------鼓勵國內首發

核價方式
參考市場交易價
參考成本計算法
參考治療類似品之十國藥價

備註：
藥品以我國為國際間第一個上市，且臨床療效有明顯改善之新成分新藥或為治療特定疾病之第一個新成分新藥，其支付價格之訂定，從上列方法擇一核價。

健保藥品核價之相關鼓勵措施(3)
------------鼓勵創新

創新條件	最高加算比例
比核價參考品療效佳*	15%
比核價參考品安全性高*	15%
在使用上，較核價參考品更具方便性*，如用藥間隔較長、用藥途徑較優、療效與安全性監測作業較簡化、安定性較穩定、效期較長、攜帶方便、調製較方便、使用較方便、安全包裝	15%
具臨床意義之兒童製劑**	15%

備註： *：自93年10月起實施；**：自99年1月起實施

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新品項藥品之核價

- 原開發廠藥品之核價
  - 參考十國中位數核價
- 學名藥品之核價
  - BA/BE學名藥為同成分規格原廠藥品價格之8折或9折；一般學名藥8折
  - 同成分同規格學名藥之最低價
  - 廠商建議價格

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總額協定-歷年總額協商差異

	97年	98年	99年	100年	101年	102年	103年
經建會核定上限額(A)	5.0%	5.1%	3.5%	3.6%	4.7%	6.0%	4.45%
健保會協定結果(B)	4.47%	3.455%	2.976%	2.692%	4.241%	4.427%	2.989%
核定結果	89.42%	67.74%	79.88%	74.77%	90.23%	73.78%	67.16%

參考資料:103年協商指標要覽

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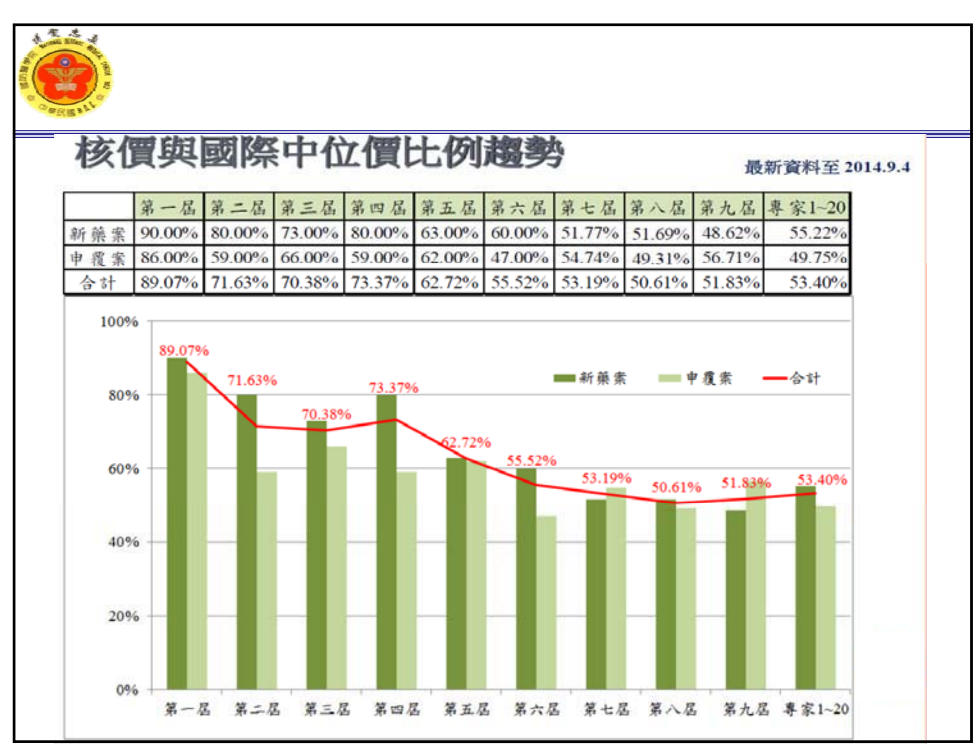
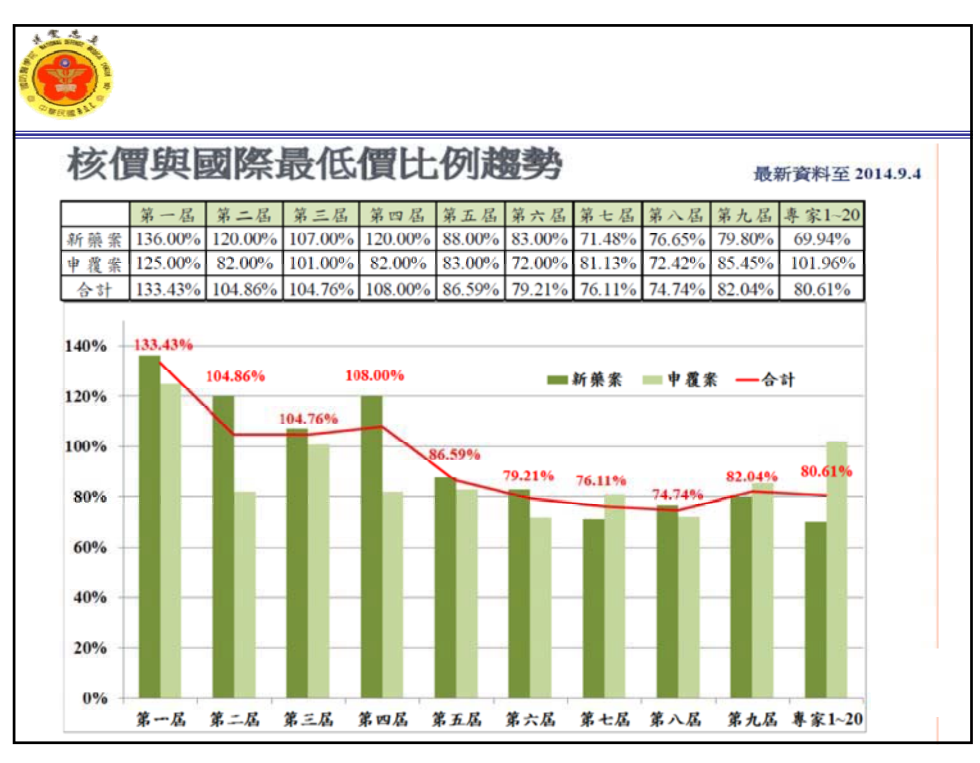


核價與國際中位價比例趨勢

最新資料至 2014.9.4

	第一屆	第二屆	第三屆	第四屆	第五屆	第六屆	第七屆	第八屆	第九屆	專家1~20
新藥案	90.00%	80.00%	73.00%	80.00%	63.00%	60.00%	51.77%	51.69%	48.62%	55.22%
申覆案	86.00%	59.00%	66.00%	59.00%	62.00%	47.00%	54.74%	49.31%	56.71%	49.75%
合計	89.07%	71.63%	70.38%	73.37%	62.72%	55.52%	53.19%	50.61%	51.83%	53.40%



核價與國際最低價比例趨勢

最新資料至 2014.9.4

	第一屆	第二屆	第三屆	第四屆	第五屆	第六屆	第七屆	第八屆	第九屆	專家1~20
新藥案	136.00%	120.00%	107.00%	120.00%	88.00%	83.00%	71.48%	76.65%	79.80%	69.94%
申覆案	125.00%	82.00%	101.00%	82.00%	83.00%	72.00%	81.13%	72.42%	85.45%	101.96%
合計	133.43%	104.86%	104.76%	108.00%	86.59%	79.21%	76.11%	74.74%	82.04%	80.61%

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新藥取得健保生效時間需花費一年以上

*送件至健保價格生效	新藥		癌症新藥	
	平均次數	平均天數*	平均次數	平均天數*
1	2.5	471	3.3	614
2A	2.2	486	4.5	968
2B	1.4	317	2.3	547
Others	1.8	411	0	0
Total	1.74	382	3.4	726

癌症新藥分類
Category 1: Vidaza (x6), Signifor, Thado; (Mozobil cancer-related)
Category 2A: Tykerb (6 years), Avastin (~6 years), Revlimid (x5) , Torisel, Nexavar (mRCC), Afinitor (mRCC/ SEGA), Inomustin
Category 2B: TS-1 (pancreatic cancer), Gliadel (Brain tumor), Firmagon (x3), Hycamtin oral, Xgeva, Votrient, Giotrif

新藥取得健保生效時間需花費一年以上

*送件至健保價格生效	新藥		癌症新藥	
	平均次數	平均天數*	平均次數	平均天數*
第8屆DBC	1.8	356	3.8#1	812#1
第9屆DBC	1.7	393	2.7	553#2
第1屆PBRS	1.8	415	4	934#3
G1 + G2	1.74	382	3.4	726

新增適應症取得健保生效時間約需花費一年

*送件至健保價格生效	新適應症		癌症新適應症	
	平均次數	平均天數*	平均次數	平均天數*
第8屆DBC	1.1	295	1.1	287
第9屆DBC	1.9	459	1.7	450#4
第1屆PBRS	1.1	321	1.3	381
G1 + G2	1.3	340	1.3	350

#1: Avastin (x11, ~6 years); #2: Torisel, Revlimid, Vidaza; #3: Tykerb (x9, 6 years), TS-1, Firmagon
#4: Nexavar HCC (x4, 2.3 years);

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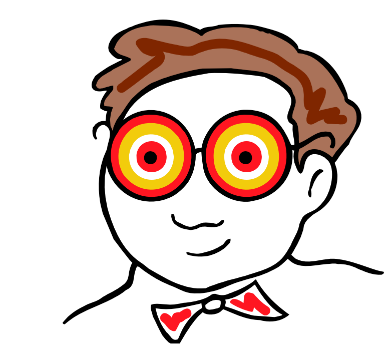

Thank you for your attention!

Prof. Oliver Yoa-Pu Hu, Ph.D.,FAAPS

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