

親愛的消費者: 知識看不見

GMP一路走來有我相隨

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三本博士論文

1. 產品經濟 vs 知識經濟
2. 由人吃東西 探討台灣文化的知識切割
3. 摩登原始人-- 品質與品味不同

干擾: 來自政客、藝人、印刷廠的產品

美國民眾要求提升奈米產品規範的保護層級

10⁻⁹米分子產品 引爆潛在的健康危機?

研究顯示，任何一種物質，人造奈米粒子 (engineeringnanoparticle) 會累積不同的物理化學及生物特性，有些則可能比天然奈米粒子更難於排出體外及被清除。

文/陳維

△ (2006) 8月16日，國際
了「國際中心 (The
International Center for
Technology Assessment: CIA)
第一屆由消費者及健康機構專家
品聯合所成的團體，其目的與國家
品藥物管理局 (The Food and

的等標進行測量、標識及溝通，以
標識出這些奈米分子產品，有性
以協助消費者「選擇安全產品」。
舉例而言，包括一些化妝品、
藥品及奈米材料 (engineering
nanoparticle) 會累積不同的物理
化學及生物特性，有些則可能比



醫藥產品集世界之大成

→ 外交場域的較勁

→ 來自45度角的屈辱

中國的中藥仍缺乏安全性監測和評價 你吃的中藥安全嗎?

在藥品中，中藥是中國特有的重要組成部分。然而，由於中藥的複雜性，其安全性監測和評價一直是一個世界性的難題。本文將探討中藥的安全性問題，並提出一些建議。



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產品經濟 vs 知識經濟



4000\$

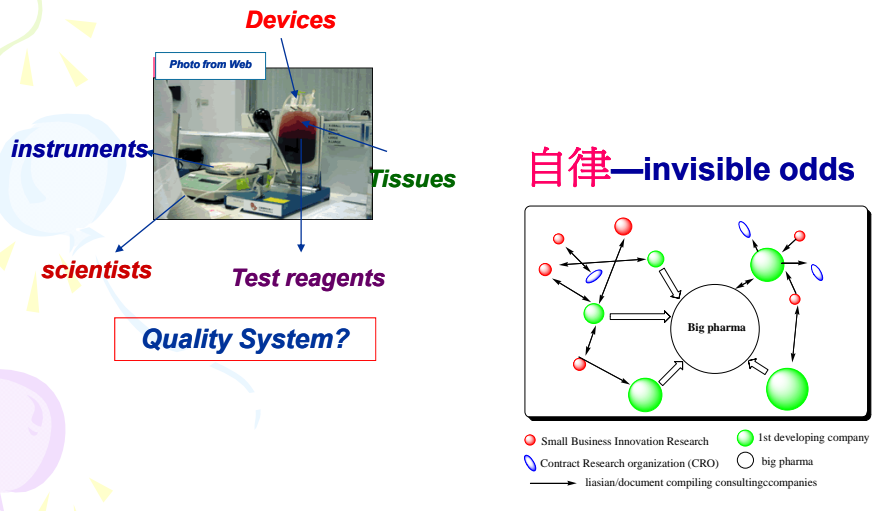


125\$



GMP的啓發

知識看不見



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~ Evidence-based medicine



Invisible odds and beauty~

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親愛的消費者: 知識看不見

優質用藥的環境建構-藥物知識經濟的風險
2006-09-廣州上海北京-王民寧基金會中國藥學會兩岸交流研討會

知識產業：品質+安全+療效

知識信任：靠品牌 品牌靠自律

知識管理：靠程序正義(監督)

知識交易：靠智財保護

知識風險：靠環境建構 -- *From GDP to GDDP*

知識專業：重風險管理 – *From PV to PVP*

知識服務：小而美才能分散/預防風險

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經典價值: 科技與人文對話

人 吃 東 西
medication vs medicine



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知識的產出

Preclinical & clinical evidence



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知識的累積

Pharmacovigilance Specification (risk monitoring)

Preclinical & clinical evidence

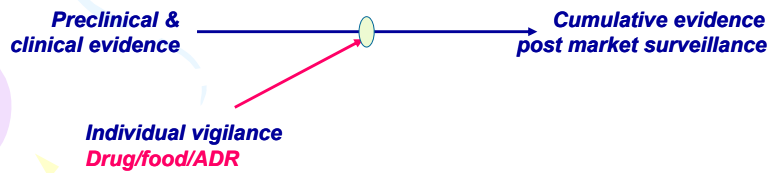


*Cumulative evidence
post market surveillance*

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看不見的知識的管理

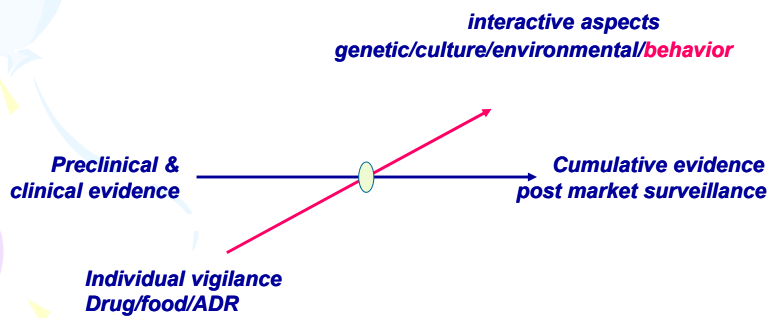
Pharmacovigilance **Specification** (risk monitoring)



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看不見的知識的管理及累積

ICH E2E (2005): PV Planning (risk minimization) **Evidence-based medicine** → **Pharmacoepidemiology**



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看不見的危險最危險

PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 2007; 16: 86–95
Published online 28 September 2006 in Wiley InterScience (www.interscience.wiley.com) DOI: 10.1002/pds.1324

ORIGINAL REPORT

Usage of the claim database of national health insurance programme for analysis of cisapride-erythromycin co-medication in Taiwan[†]

Churn-Shiow Gau PhD¹, I-Shou Chang PhD², Fe-Lin Lin Wu PhD¹, Hui-Tzu Yu MSc³, Yu-Wen Huang MSc⁴, Cheng-I Jang Chi MSc³, Su-Yu Chien MSc⁵, Keh-Ming Lin MD, PhD⁶, Ming-Ying Liu MSc² and Hui-Po Wang PhD^{3*}

SUMMARY

Purpose: This study aimed to use the National Health Insurance Research Database, Taiwan for risk analysis of concomitant use of cisapride and erythromycin.

Methods: The sample consisted of subjects identified in the Outpatient Sampling Database (OSD) and Longitudinal Health Insurance Database 2000 (LHID 2000), derived from the original claim data of the National Health Insurance Research Database, Taiwan.

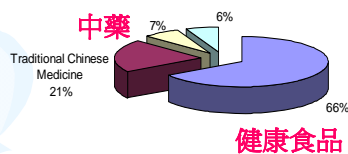
Results: According to the LHID 2000, a total of 464 individuals experienced 685 episodes of cisapride-erythromycin co-medication prescribed by 295 physicians, revealing a prevalence of 4.5% concomitant use, with higher prevalence in clinics (9.2%) than in other medical institutes (3.7–5.4%). Among the co-medication episodes, 81.9% and 61.2% were prescribed from the same health institutes and by the same physicians, respectively. No medical record of cardiac arrhythmias was found among these patients in 2001 and 2002, probably due to the fact that 78.9% of the 464 individuals were under age 16, 84.0% had short exposure duration (1–4 days) and 98.0% of the episodes were prescribed with a cisapride dose of less than 0.8 mg/kg/day.

Conclusions: Findings from this study suggest that there exists an urgent need for accreditation in terms of pharmacovigilance of clinical sites and their practicing physicians for the prevention of irrational concomitant prescription in Taiwan. Our findings also indicate that it is necessary to investigate other possible conditions of potentially dangerous co-medication in Taiwan and other developing countries. Copyright © 2006 John Wiley & Sons, Ltd.

看不見的危險最危險

托爾斯泰：上天有眼，暫時不語

疑似違規廣告(2004): 94.1%



年度	血液腹膜透析	洗腎人口比例
1997	20,697	1/1051
2000	29,937	1/744
2001	33,317	1/672
2004	42,550	1/533
2005	45,718	1/498

勇敢的台灣人邏輯不通!

1. 中藥+西藥 ⇒ 不良反應 (*Lancet* 2000)
2. 中藥廠: 中藥+西藥 ⇒ 犯法 ⇒ 十年苦牢!
3. 西藥廠: 西藥+中藥 ⇒ 犯法 ⇒ 十年苦牢!
4. 民眾: 一口中藥+一口西藥 ⇒ GMP? ⇒ 不犯法? ⇒ 造病 ⇒ 健保照顧!

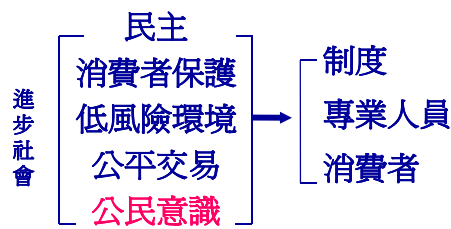
看不見的危險最危險

*From Pharmacovigilance to Pharmacovigilance Planning,
The System Building For Safe Medication
HUI-PO WANG et al, Review article, JFDA 2007*

As **xenobiotics** are subjected to biological processing of **ADME**, identification of the sites and the mechanisms of interactions between **xenobiotics** becomes important for the assessment of drug toxicity and its efficacy.⁽²⁷⁻³⁵⁾ With the emerging evidence from system-based research, the disclosure of the profiles on **transporters** and **metabolic enzymes** provides information regarding to the sites and the mechanisms of ADME processing of the **xenobiotics**. Reports demonstrated that transporters in the intestine for absorption and in the kidney for excretion showed characteristics of **broad substrate specificity**, indicating the possibility of drug interactions.⁽³⁶⁻⁴²⁾ As the metabolic systems process the biotransformation of **xenobiotics**.⁽⁴³⁻⁵⁴⁾ reports indicated that hepatotoxicity⁽⁵⁵⁻⁶³⁾ and renal toxicity⁽⁶⁴⁻⁷⁰⁾ relates to the formation of reactive metabolites no matter it is from **synthetic or herbal** resources.

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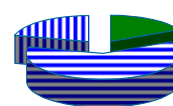
專業人與消費者在知識不對等的交易中如何公平交易？



陳文成林孝信1977-1981

切割式的思維
→ 不符合程序正義的民主
→ 遲早會被社會挑戰及拋棄

醫院 診所
醫師 藥師
進口藥 國產藥
中藥 西藥



消費者
Majority minority₆

Dvorak– From the New World



THANK YOU