出國報告（出國類別：開會）

參加 2017 年
第 77 屆世界藥學會
(FIP World Congress)

服務機關：衛生福利部食品藥物管理署

姓名職稱：戴雪詠組長

派赴國家：韓國

出國期間：106 年 9 月 9 日-13 日

報告日期：106 年 9 月 25 日

摘要

2017 年世界藥學會(FIP World Congress)於 9 月 10-14 日於首爾舉行，今年主軸為「藥師魂，超越藥品之外」(The soul of pharmacy，Medicines and Beyond)，會議重點如下：

一、藥師除了關注藥品調劑及研發外，應該做到病人為中心(patient focused)之全人藥事照護，並延伸到以社區人群為主的公共衛生推展。

二、基因學的發展帶動藥物基因學(pharmacogenomics) 及精準醫療(precision medicine)，由基因檢測可配對找到適合病人的藥品，更可藉此調整病人適合的劑量及預測嚴重副作用的發生，這種個人化、客製化醫療(personalized medicine)更需要未來世代的藥師扮演更積極角色，包括能解讀檢測數據、病患諮詢及副作用監測，惟目前全球藥學教育可能都面臨缺乏適當師資及課程設計的問題。

三、今年由台灣臨床藥學會及台灣藥學會聯合主辦 Taiwan Night 活動，有 24 個國家及超過 280 人參與，FIP president Carmen Pena 也到場致詞，台灣是地主國韓國外，報名最多的國家，有 110 多人參加，台北市及台中市分別與首爾及釜山締結為姐妹市，另韓國藥學會也在此次會議表達希望與台灣藥學會建立更密切之交流。

目錄

壹、目的

世界藥學會(International Pharmaceutical Federation，FIP)1912創立於荷蘭海牙，共有139個會員團體分佈於全球，包含約400萬名各國藥師或藥學相關學者，與國際護理學會(ICN)及世界醫師協會(WHA)，合組成國際衛生專業人員聯盟(WHPA)，為世界衛生組織WHO下三大非政府組織之一。

2017年FIP於9月10日至9月14日韓國，在首爾舉行年會，大會主題「Medicines and Beyond! The soul of Pharmacy」，討論議題包含藥學教育、藥事服務到藥學行政等，參加年會可得到藥事管理及風險控制之經驗交流及最新資訊，以提升藥物安全品質，另於會中與各國藥學專家學者，以積極拓展與國際藥事團體，加強與各非官方組織關係。

貳、過程

一、行程表

日期	9/9(六)	9/10(日)	9/11(一)	9/12(二)	9/13(三)
行程	抵達 台北→ 仁川機場	大會開幕 參與 FIP 會議	參與 FIP 會議 台灣迎賓會 Taiwan Night	參與 FIP 會議	返台 仁川機場 →台北

二、世界藥學會年會簡介

世界藥學會(FIP，International Pharmaceutical Federation)與世界醫師會(WMA，World Medical Association)及世界護理會(ICN，International Council of Nurses)是世界衛生組織下，鼎足而立的三個醫療專業團體，2017 年年會於 9 月 10 日-14 日於韓國首爾召開。

今年的主軸為「藥師魂，超越藥品之外」(The soul of pharmacy，Medicines and Beyond)主要在提醒藥師們因應超高齡社會的來臨及光速變化的科技發展，如何發揮藥師的專業及服務病人的心，將藥事服務範疇由藥品管理、研發、擴及病人全人照護，到更廣闊的社區人群關懷。

整個大會研討主題分成五大部分，A、豐富藥師核心(由教育、倫理及道德)，B、精準醫療，C、藥事服務（安全，依順性），D、智慧藥局、E 其他有趣領域。

三、FIP 主席致詞

2017 年年會有來自全球超過 2700 名藥師與會，FIP 主席 Carman Pena 在致詞時指出 FIP 的願景，即是如何透過全面拓展衛生服務，達到全球健康的終極目標(One Health for One World)，藥師必須要有改變的決心及態度，才能真正轉型，藥師也必須以研究數據來證明及凸顯藥師服務的成果及價值。

四、大會專題演講

引用 Dr.coslicrn Zellmer 所說，藥師要達到轉型(Transformation)必須在情感及心智上真正擁有幫助病患正確用藥的信念與決心。

全球發展藥物動力的泰斗，美國舊金山大學教授 Dr.Bennet 則指出，藥學由藥品劑型的研發，到藥品動力學開展、學名藥到生物相似藥品，以至基因學所帶動的精準醫療，即是讓藥品治療更須客製化，因應病人基因特殊調整劑量及選用藥品，將使未來藥師功能更加凸顯。

五、藥學教育

(一)藥學教育面臨下列挑戰：

- 科技改變教育及照護體系
- 新世代學習藥學教育的不同期待
- 社會期待更好照護，包括品質及可近性
- 老年人口改變所引發需求的增加

(二)未來的藥學教育：

- 必須奠定於有效數據基礎，能滿足需求及因地制宜
- 能符合社會照護系統及病人期待
- 能全盤考量藥事服務人力需求
- 藥學教育在不同國家或地區人力、環境及品質要求而有差異。

- 要能預備性培育人才符合未來需求

(三)精準醫療(Precision Medicine)

- 精準醫療指的是將病人基因、生活環境及生活型態列入治療考量，所以也稱個人化醫療。
- 精準藥物治療(Precision Pharmacotherapy)，以分子或細胞生物指標(biomarkers)客製化藥物治療，增加藥物治療效果。
- 精準醫療對病人之好處：
  - 可以較準確預防疾病
  - 更快速找到合適的藥物治療
  - 有效防範嚴重不良反應
  - 增進生活品質
  - 增加治療選擇

(四)藥物基因學(Pharmacogenomics)

- 透過基因差異的了解，可以運用於探知病人對藥物代謝反應及毒性作用。
- 運用基因學去選擇適切藥物及最適劑量，及最大化藥物治療效果及最小副作用。
- 藥師了解藥物基因學對於藥事服務有下列助益：
  - 可建議適切的藥物基因檢測，以幫助藥物選擇及劑量調整
  - 依病人基因 profile 客製化病人藥物治療計畫
  - 可以為治療的醫療團隊及病人做適切的諮詢服務。

(五)何謂第五世代的藥師?

- 了解個人化醫療
- 提供藥物基因的諮詢
- 在社區藥局提供藥物基因檢測
- 藥品及基因配藥排序做判斷

六、偽禁藥防治

(一)由於各國藥於偽禁藥定義分歧導致錯誤認知，世界衛生組織重新定義下列名詞：

- Substandard drug(劣藥)：指的是獲官方核准的藥品，但未能符合品質標準或規格。
- Unregistered/unlicensed drug(未經核准藥品)：沒有經過官方機構核准的藥品
- Falsified drug (偽造藥品)蓄意假造或仿製他人產品、產地來源。

根據 Globe Pharm 公司推估，美國約有 10%藥品為偽藥，開發中國家約 25%(含劣藥)，網站所售藥品則有 50%為偽藥。已開發國偽藥品項多為 life style drug 例如性功能障礙藥品、steroids 或昂貴之治療藥品，而開發中國家則多為必需性藥品如抗瘧藥、抗生素及 HIV/AIDS 藥品。

(二)產品辨識

美國 2013 年實施藥品供應鏈安全法案(Drug Supply Chain Security Act 2013) 先是要求製造廠，而後是要求包裝廠，在某些藥品包裝上要標貼產品辨識條碼(Product Identifier)且要能追蹤到產品出廠的序號(Serial Number)亦即除了知道每一批次號之外，還要能追到每一個別出廠藥品。

歐洲 EDQM 也提出建立 UMI(Unique Medicine Identifier)的建議，規劃藥品出廠時都標貼 UMI 條碼，如此藥品由藥廠中間販賣供應商到藥局時，都能層層追溯追蹤，避免有偽裝藥趁虛而入。

(三)如何發掘偽禁藥警訊，WHO 提出下列辨識方法：

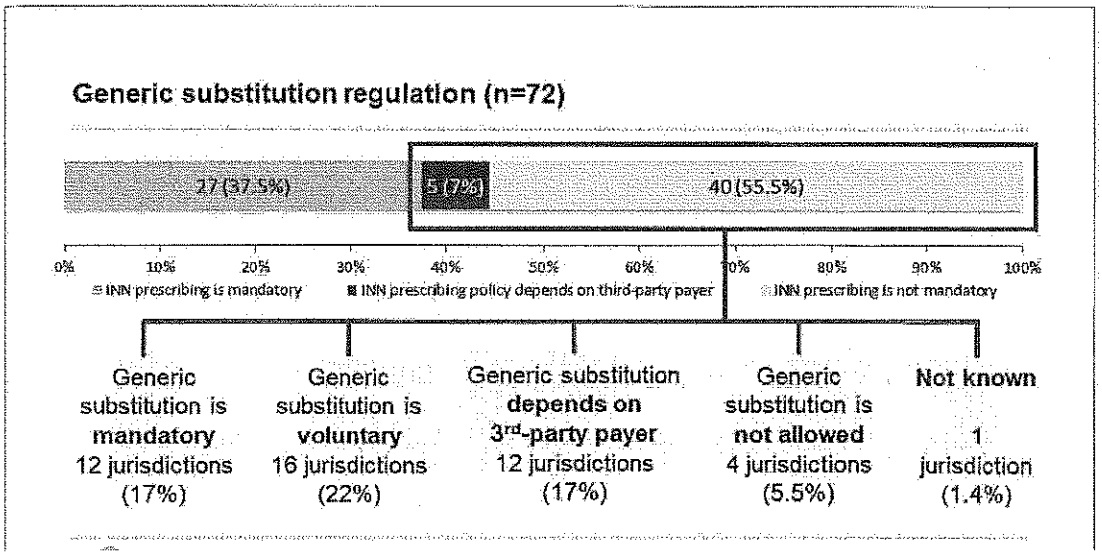
- 藥效：發現病人抱怨藥效不如以往，或出現未預期之副作用。
- 外包裝：印製粗糙，製造廠不清楚，文字拼音不對，或文法不對，批號或有效期限似乎被更改過。

- 內包裝：批號或有效期限、與外包裝不同，或仿單所用文字與外包裝不同。
- 來源：藥品來源、價格、供應讓人存疑，例如本來缺貨的藥品忽然大量供應。
- 其他：外觀、氣味或口味很奇怪，或包裝出現空包、分離或沒有適當儲存。

七、學名藥替代

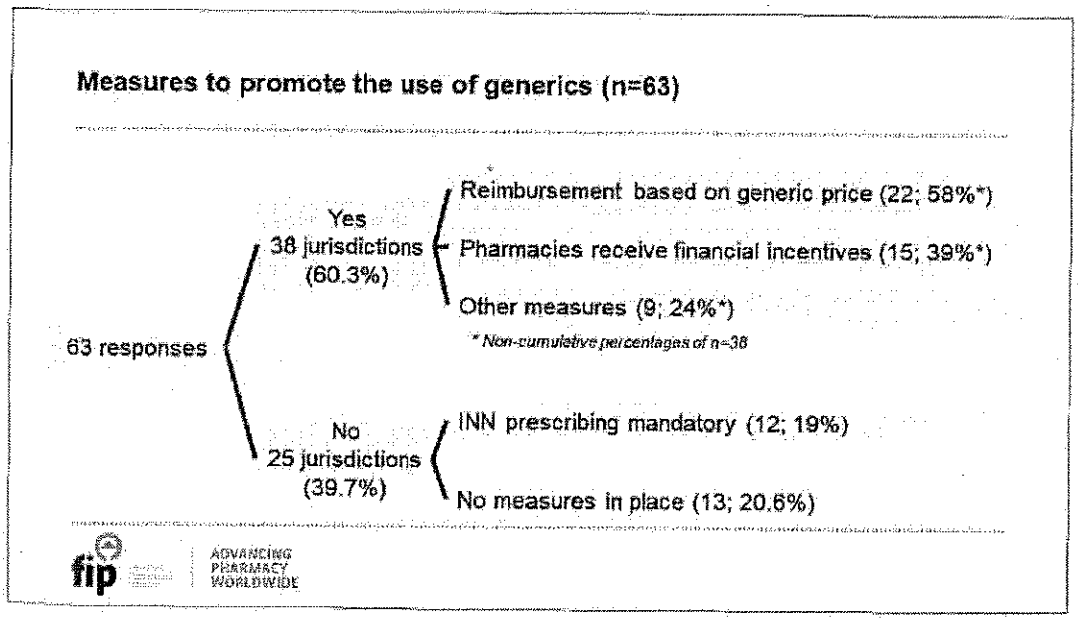
(一)FIP 立場：

- FIP 認為如果該國法律或醫師允許學名藥替代，則藥師以病人及付費者之價值考量適宜之學名藥替代，是藥師責無旁貸的責任。
- 2017 年 FIP 針對 72 個會員國調查發現，強制要求學名藥替代的國家佔 17%，自願性替代國家佔 22%，由保險人決定者佔 17%，不允許藥品替代之國家佔 5.5%(有 4 國，包括印度、香港、英國及克羅埃西亞)，如圖一。



圖一、學名藥替代不同措施之國家比例

- 各國鼓勵學名藥替代措施 63 個國家調查結果，有採取鼓勵措施者佔 60%，依次採取：依學名藥品價格給付、藥師替代給予財務誘因等，如圖二。

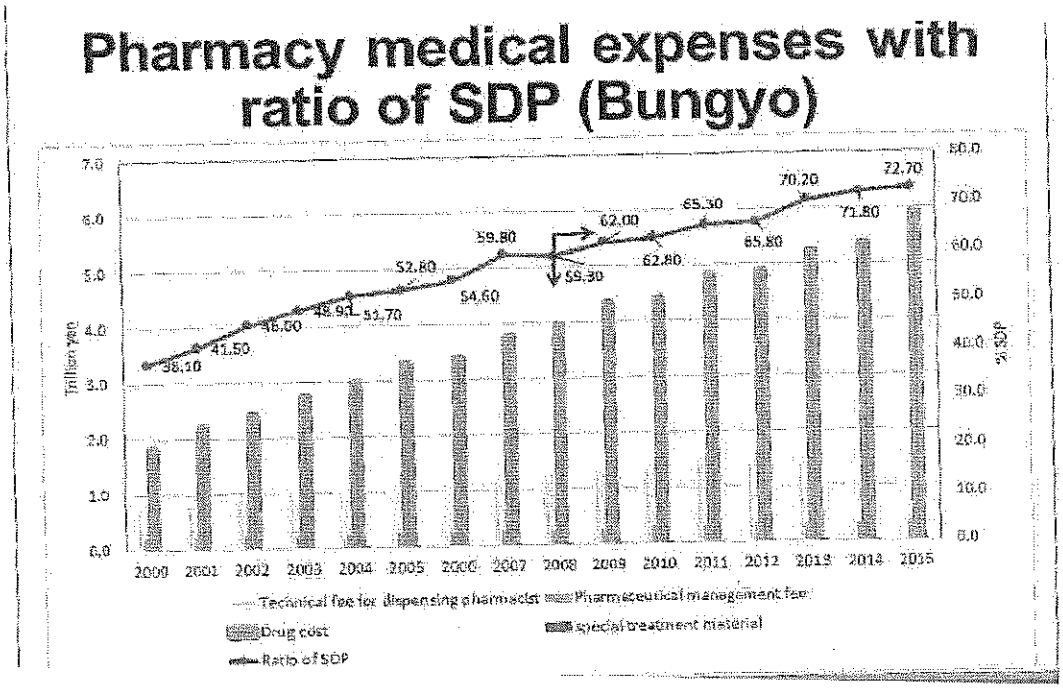


圖二、調查各國鼓勵學名藥替代措施結果

- 其他則包括下列鼓勵措施：
  - 降低藥廠品牌藥(branded product)的給付
  - 給予開立學名藥醫師財務誘因
  - 使用學名藥的病患無須另外付費

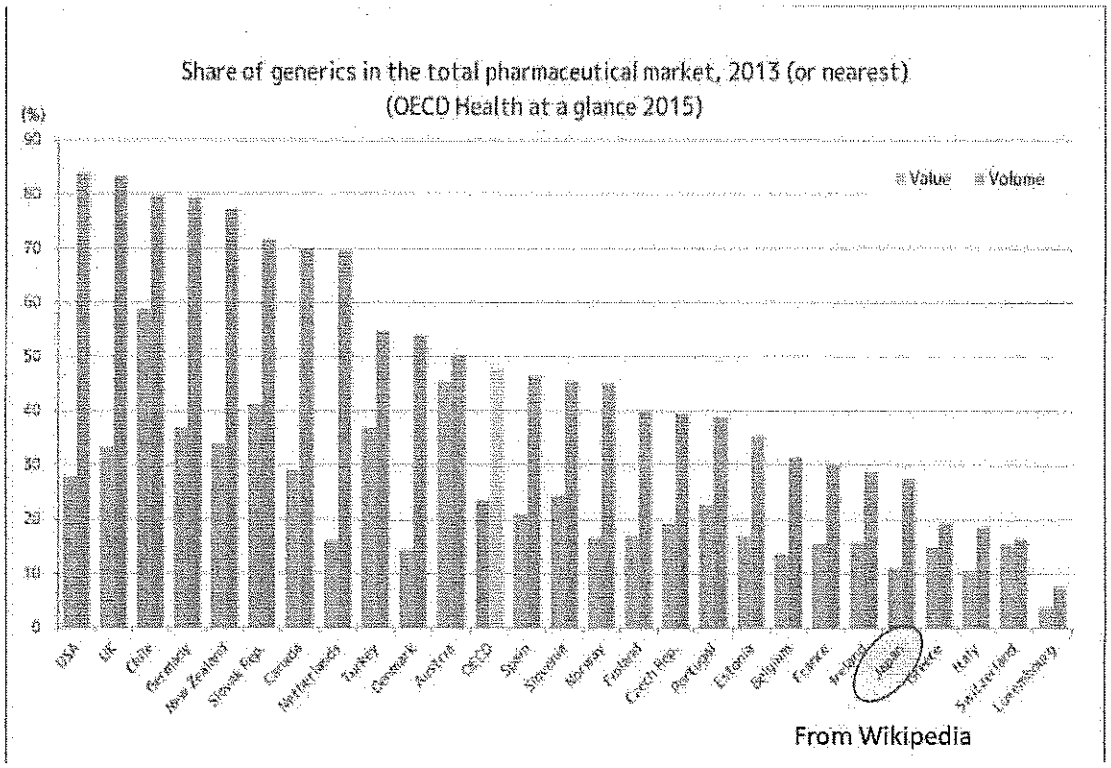
(二)日本經驗

- 日本大於 65 歲以上老年人口，預計至 2020 年約占全人口 28.9%，老年人口療支出及藥費支出急遽上升。日本政府採取醫藥分業及鼓勵名藥替代兩項措施，來降低藥費支出。
- 日本為了鼓勵醫藥分業，採取縮小藥價差策略，讓醫療機構及醫師開立處方時不受價差誘因干擾，故可見醫藥分業比率由 2000 年 38.1%，至 2015 年已提高至 72.7%，如圖三。



圖三、日本醫藥分業比率

- 日本與歐美先進國家相比，學名藥之使用量(volume)及金額(value)都非常低。由圖四可見美國學名藥用量百分比/金額百分比為 83%/28%，但日本則僅 28%/12%。



圖四、各國學名藥使用量(volume)及金額(value)

- 為了鼓勵醫師開立及藥師替代學名藥，日本自 2002 年給予醫師、藥師較高之處方費及調劑費，2006 年在醫師處方單上增列一個可替代學名藥品之空格，讓醫師可以勾選。至 2008 年則進一步放寬，除非醫師事先註明不可替代，否則藥師可直接替代學名藥。

Change in prescription form

Year	Change in prescription form
2002	Incentives introduced for doctors and pharmacists Introduction of additional fees for prescriptions with generic drugs Introduction of generics information fees and generic drug dispensing fees
2006	A box for 'generic substitution allowable'. If physicians would authorize pharmacists to switch to available generics from the prescribed branded drugs
2008	Allow generic substitution by pharmacies unless prescribers expressly forbid it.
2012	MHLW made recommendation to the physicians to prescribe medicine by International Nonproprietary Name (INN) and offered

圖五、日本鼓勵醫師開立及藥師替代學名藥措施

- 日本學名藥市場使用量佔有率由 2005 年 32.5%，10 年後至 2015 年已提高為 56.2%。日本厚生省預計在 2018 年至 2020 年間達到 80%之目標。

八、台灣之夜

- 由台灣藥學會及台灣臨床藥學會聯合主辦之台灣之夜，共 24 國參加，簽到人數超過 280 人，FIP 主席 Carmen Peña 亦親自到場致詞。
- 我國是本屆大會除地主國韓國外出席人數最多之國家，有超過 110 人報名參加，包括台北市、台中市等縣市公會及醫院代表如榮總、新光、慈濟、壢新等醫院。

圖六、台灣之夜合影

圖七、台灣之夜場內互動

參、心得及建議

一、心得

(一)

今年 FIP 主軸揭示了藥師未來應由病人全人照護(patient focused)，進一步擴展到社區人群之公共衛生參與，因為社區藥局是病人最容易接近的醫藥人員服務點。台灣的藥師公會全聯會在健保試辦的高診次病人用藥照護計畫中展現具體成效，包括在減少就醫用藥費用平均降低 9.2 百分點，社區藥局的藥師也積極參與減重、戒菸及糖尿病人衛教等公共衛生計畫，可說是充分體現了今年 FIP 的大會主題精神。

惟仍需建立居家藥事照護的其他品質指標，如減少重複用藥、藥物交互作用，以及照護流程(SOP)都需要再細緻精確才能，具體呼應 FIP 今年大會所提出的 evidence based 的主張。

(二)

為了避免外界對偽藥定義的混淆，WHO 認為 falsified drug(故意偽造)及 unlicensed drug (未經核准)兩個藥品定義，來描述不法藥品的兩種違法狀態惟依我國藥事法第 20 條，偽藥定義則包括第 1 款未經核准擅自製造及第 2 款所含成分與核准不符，第 3 款抽換、摻雜等，藥事法第 22 條禁藥第 1 項第 2 款則為未經核准擅自輸入。亦即在我國偽禁藥定義，同時包括了 WHO 定義的 falsified drug 及 unlicensed drug，故未來我國在飲用 WHO 不法藥品相關統計數據時，必須格外小心基本定義不同，以免外界誤解。

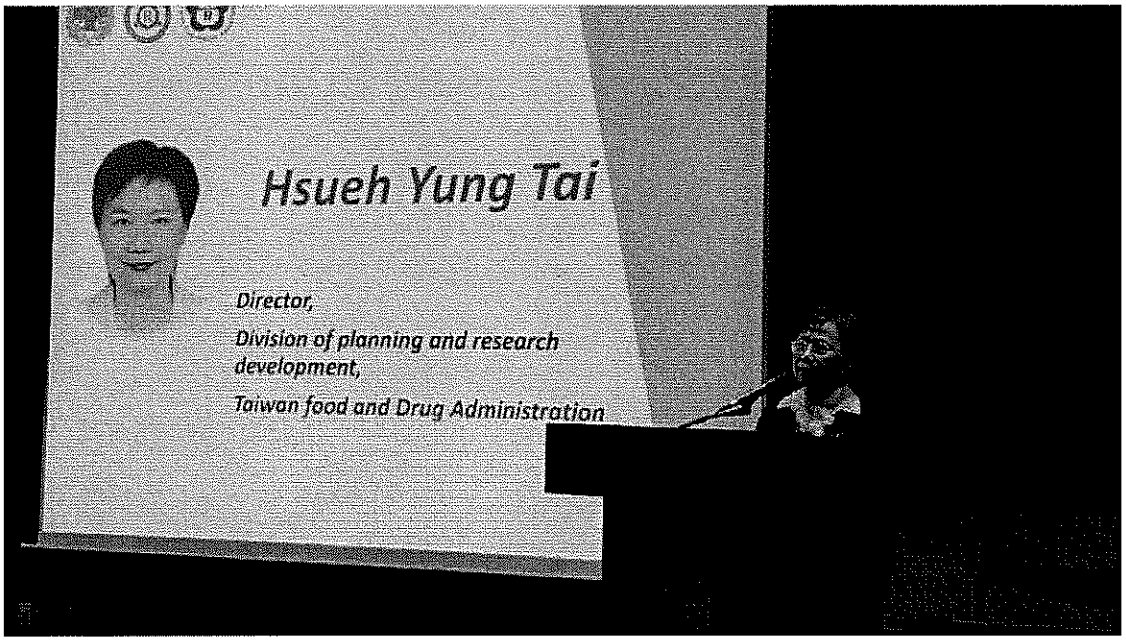
(三)

基因學的發展帶動藥物基因學(pharmacogenomics) 及精準醫療(precision medicine)，由基因檢測可配對找到適合病人的藥品，更可藉此調整病人適合的劑量及預測嚴重副作用的發生，這種個人化、客製化醫療(personalized medicine)更需要未來世代的藥師扮演更積極角色，包括能

解讀檢測數據、病患諮詢及副作用監測，惟目前全球藥學教育可能都面臨缺乏適當師資及課程設計的問題。台灣藥學教育應妥善因應，才能讓藥師之養成能跟上醫療科技進展的腳步。

(四)

職於台灣之夜致詞時，於國際藥界菁英面前，特別提到台灣社區藥局藥師過去幾年全新參與健保的居家藥事照護計畫，有效降低藥品不當使用及不需要的藥費支出，更積極推動戒菸減害等公共務生計畫。正因為民眾對藥師貢獻深有所感，所以在民意調查中，藥師是民眾最信賴之專業人員的第二名。讓在場國外友人印象深刻，還問我國是如何做到的。顯示台灣經驗值得與國際醫藥團體分享。



圖八、台灣之夜致詞

二、建議

(一)建立國際藥事照護交流平台，學習先進國家病人用藥風險管控機制：

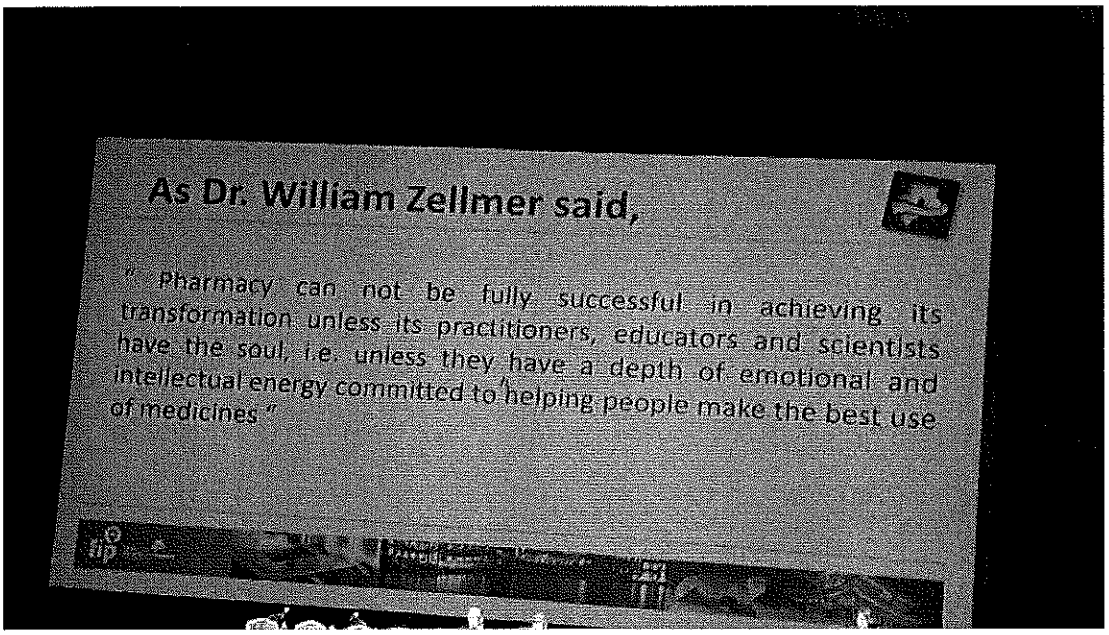
世界藥學會(FIP)為國際間最大藥師執業團體，其中社區藥局執業藥師又佔大宗，可邀請 FIP 主席或副主席或東北亞日本、韓國等民情相近國家的藥事團體領袖至我國參訪，以分享彼此藥品使用風險管控機制，如不良反應通報等智慧外，更可將台灣經驗向國際展示及推廣。

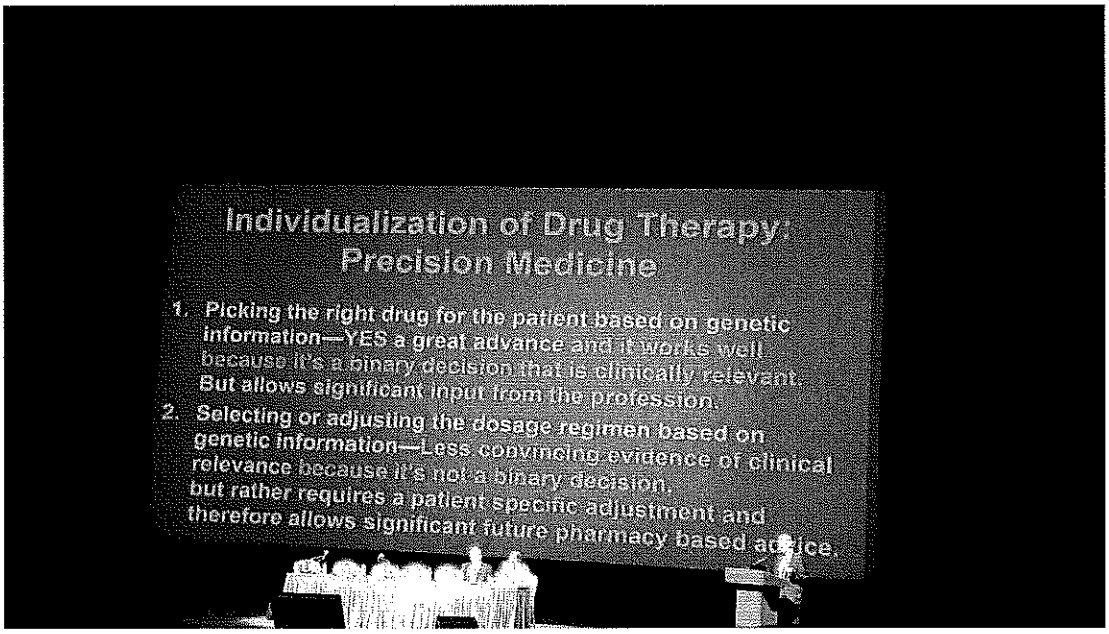
(二)建立醫院轉介社區藥局之照護機制，降低重症病人出院後用藥風險：

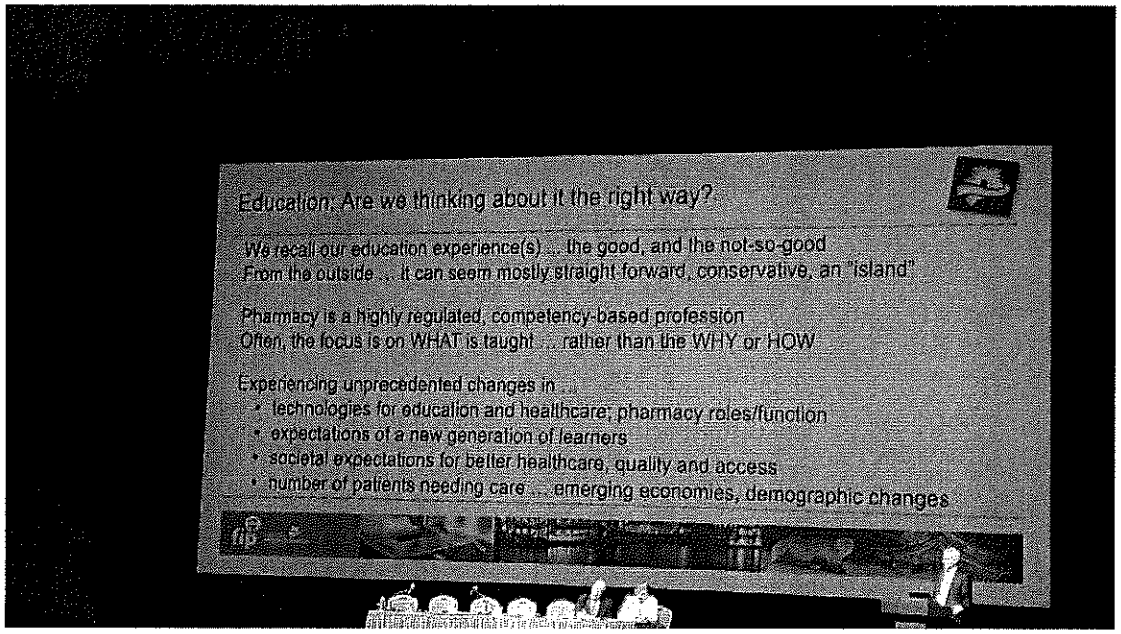
全球老年人口急劇增加，不僅大幅提高了醫藥費用，也改變了藥事照護的型態，依我國健保署資料顯示，近五成的藥費用於慢性病，三成的藥費用於重大傷病，而重大傷病的藥費成長率最高。

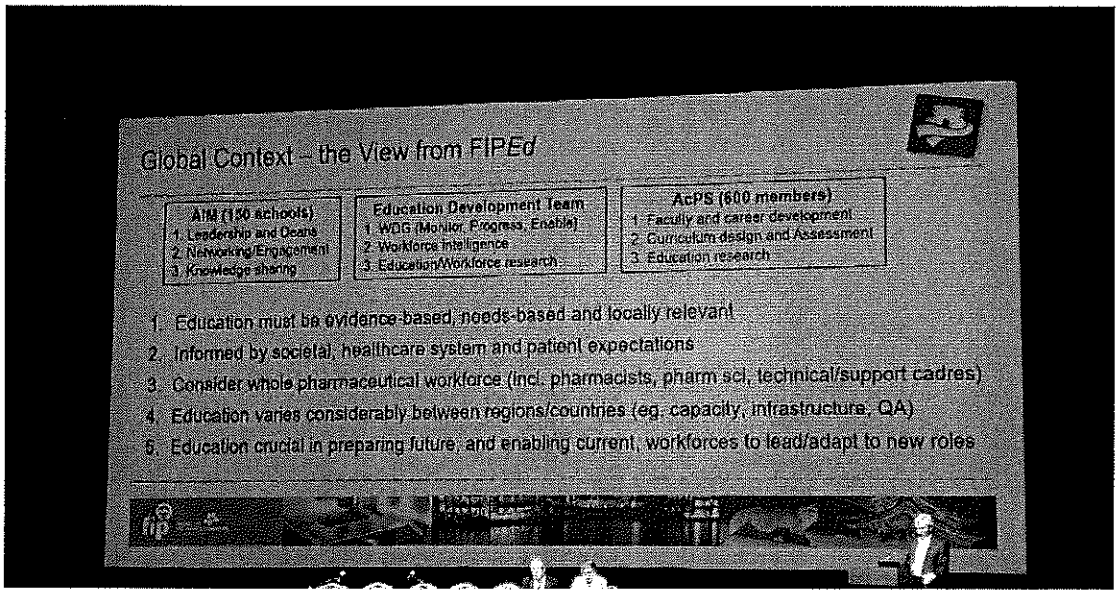
建立醫院轉介藥局之藥事照護機制包含設計評估轉介 SOP 及表單，強化社區藥局藥師訓練，以讓醫院重症病人於社區藥師接手照顧後，進一步確保重症病人正確用藥及避免往後可能發生之跨院就診之重複用藥風險。

附件


As Dr. William Zellmer said,
" Pharmacy can not be fully successful in achieving its transformation unless its practitioners, educators and scientists have the soul, i.e. unless they have a depth of emotional and intellectual energy committed to helping people make the best use of medicines "


Individualization of Drug Therapy: Precision Medicine
1. Picking the right drug for the patient based on genetic information—YES a great advance and it works well because it's a binary decision that is clinically relevant. But allows significant input from the profession.
2. Selecting or adjusting the dosage regimen based on genetic information—Less convincing evidence of clinical relevance because it's not a binary decision, but rather requires a patient specific adjustment and therefore allows significant future pharmacy based advice.


Education: Are we thinking about it the right way?
We recall our education experience(s) ... the good, and the not-so-good
From the outside ... it can seem mostly straight-forward, conservative, an 'island'
Pharmacy is a highly regulated, competency-based profession
Often, the focus is on WHAT is taught ... rather than the WHY or HOW
Experiencing unprecedented changes in ...
• technologies for education and healthcare; pharmacy roles/function
• expectations of a new generation of learners
• societal expectations for better healthcare, quality and access
• number of patients needing care ... emerging economies, demographic changes


Global Context – the View from FIP*Ed*
AIHI (150 schools)
1. Leadership and Deans
2. Networking/Engagement
3. Knowledge sharing
Education Development Team
1. WDG (Monitor, Progress, Enable)
2. Workforce Intelligence
3. Education/Workforce research
AcPS (600 members)
1. Faculty and career development
2. Curriculum design and Assessment
3. Education research
1. Education must be evidence-based, needs-based and locally relevant
2. Informed by societal, healthcare system and patient expectations
3. Consider whole pharmaceutical workforce (incl. pharmacists, pharm sci, technical/support cadres)
4. Education varies considerably between regions/countries (*eg*. capacity, infrastructure, QA)
5. Education crucial in preparing future, and enabling current, workforces to lead/adapt to new roles

We are in an Era of Precision Medicine

- **Precision Medicine:** An approach to disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. Also known as, "Personalized Medicine" or "Precision Health."
- Precision medicine approaches may lead to non-personalized interventions that can be used population-wide.
- **Precision Pharmacotherapy:** Customize medications to subgroups of patients, categorized by shared molecular and cellular biomarkers, to improve treatment outcomes.

Pharmacogenomics

- **Component of precision and personalized medicine**
- Understand how genetic variation contributes to variability in drug disposition, response, and toxicity
- Use genetic information to guide drug selection and dosing to maximize efficacy and minimize adverse effects

Examples of Clinical Pharmacogenomic Resources

Pharmacogenomics Knowledge Base (PharmGKB)

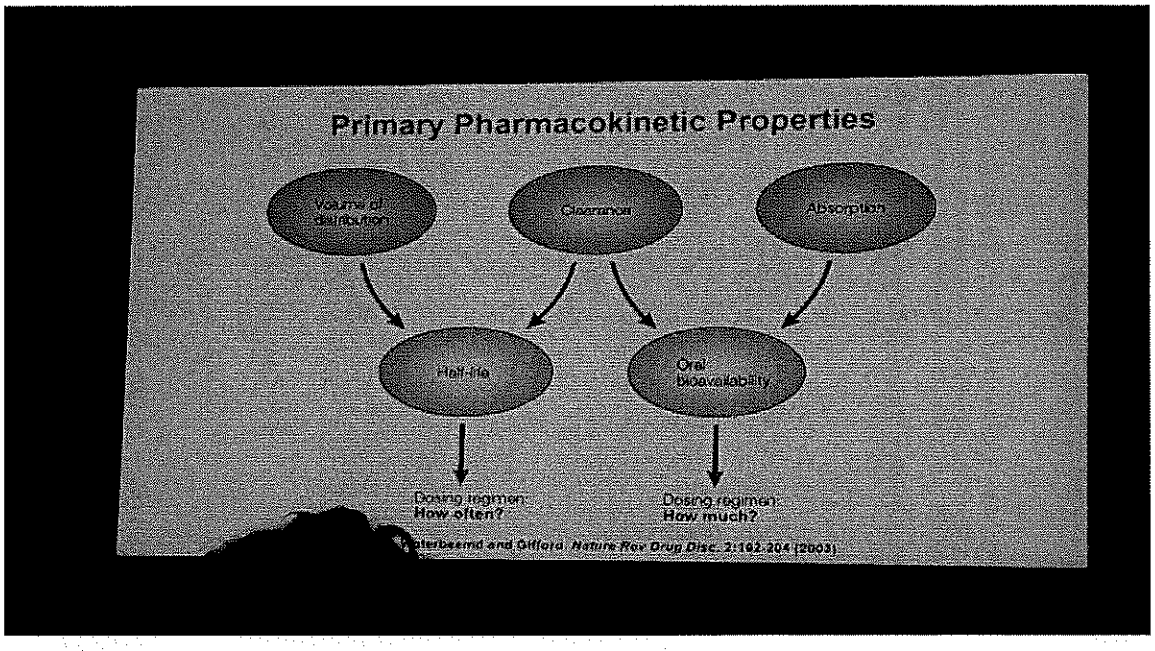
- Collects, curates, and disseminates knowledge about the impact of human genetic variation on drug responses.
- www.pharmgkb.org

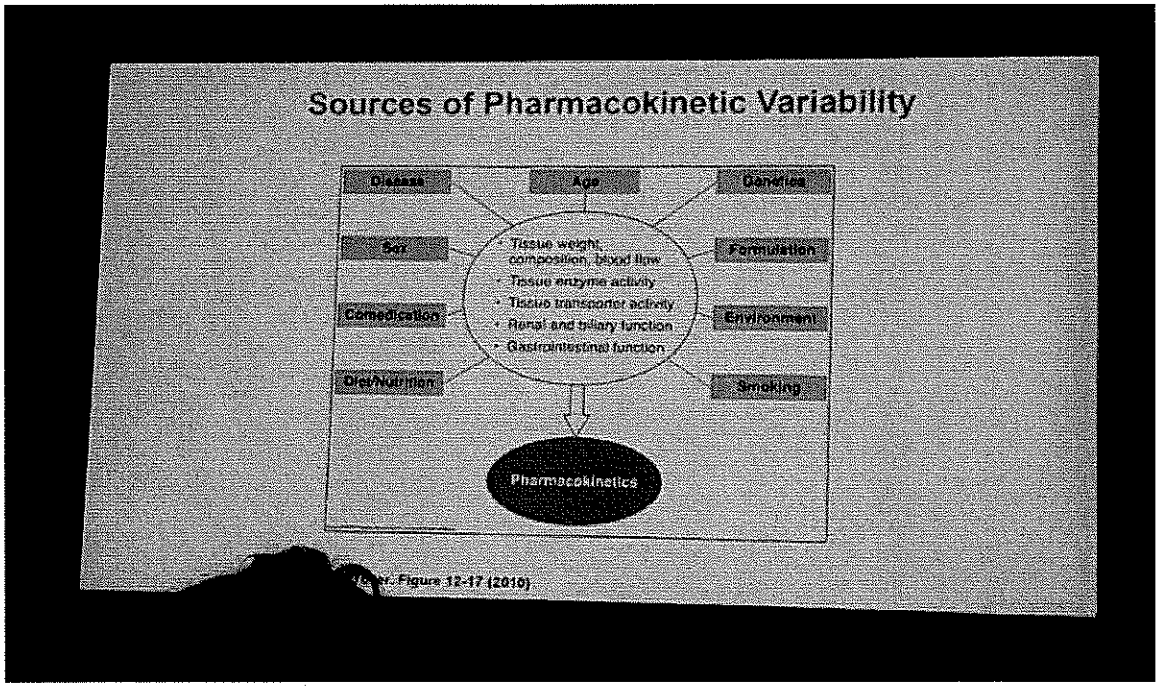
Clinical Pharmacogenetics Implementation Consortium (CPIC)

- Evidence-based, peer-reviewed guidelines for select drug-gene pairs.
- Provide guidelines to instruct clinicians on how to modify drug therapy based on genetic information.
- https://cpicpgx.org/

Pharmacogenetics (PGx)

- **The study of the role of genetic variations in determining the inter-individual variability in drug response in terms of efficacy and safety;**
- **Several robusts, well replicated PGx associations exist:**
  - ***HLA-B*57:01* with abacavir hypersensitivity;**
  - ***HLA-B*15:02* with carbamazepine-induced SJS/TEN;**
  - ***VCORC1* and *CYP2C9* with warfarin dosing**


Primary Pharmacokinetic Properties
Volume of distribution
Clearance
Absorption
Half-life
Oral bioavailability
Dosing regimen: How often?
Dosing regimen: How much?


Sources of Pharmacokinetic Variability
Disease
Age
Genetics
Sex
Formulation
Comedication
Environment
Diet/Nutrition
Smoking
• Tissue weight, composition, blood flow
• Tissue enzyme activity
• Tissue transporter activity
• Renal and biliary function
• Gastrointestinal function
Pharmacokinetics

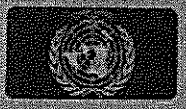
Traditional Pharmacies

- Pharmacist and technician are in the same location
- Prescription arrives in person, electronically, or via phone*
- Technician types prescription into patient's profile and a label is produced
- Technician fills prescription, labels it, and moves it to the pharmacist for checking and verification
- Pharmacist compares the labeled medication to the physical or electronic prescription and checks that there aren't any contraindications to other meds the patient is taking or disease states the patient has, then verifies the prescription
- The prescription is sold to the patient and the pharmacist provides face to face consultation on the medication, if it is a new or changed prescription.

Complex/Confusing Terminologies

Counterfeit Drug

Falsified Medicine



Substandard, Spurious, Falsely Labeled, Falsified and Counterfeit Medicines

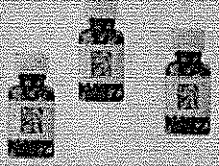
Definitions

WHO 2017

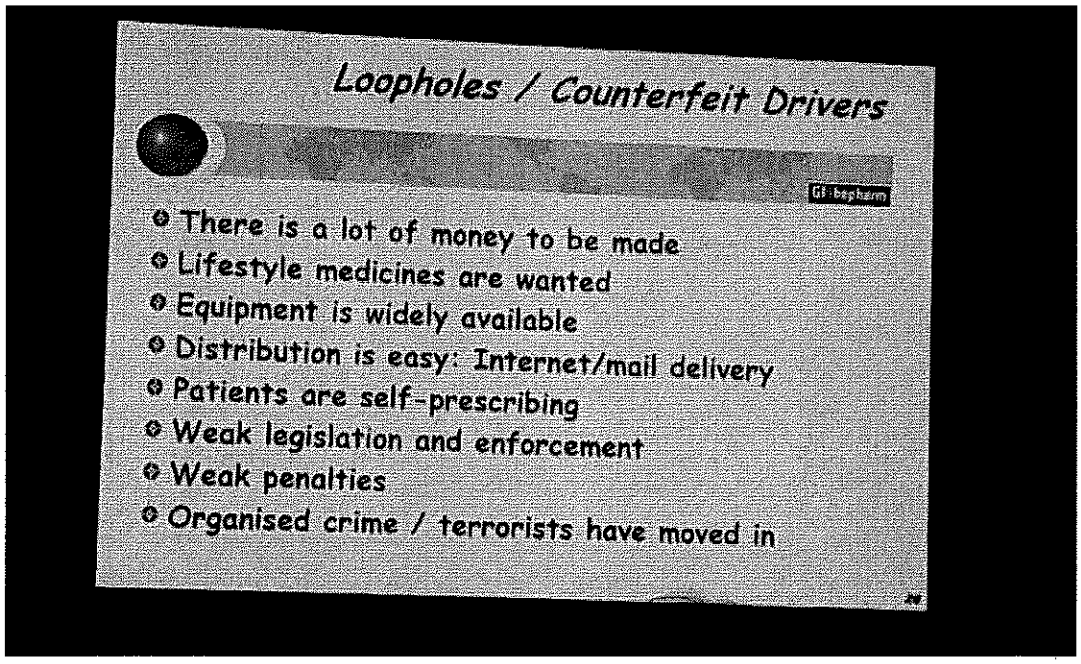
- Substandard:
  Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both.
- Unregistered/unlicensed:
  Medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority (NRRA) for the market in which they are marketed / distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Product Identification (Serialization)

- Beginning 4 years (11/27/2017), manufacturers, followed by repackagers (11/27/2018) shall place a unique product identifier on certain prescription drug packages
  - 2D bar code




Track and Trace - GS1 Standard


Loopholes / Counterfeit Drivers
There is a lot of money to be made
Lifestyle medicines are wanted
Equipment is widely available
Distribution is easy: Internet/mail delivery
Patients are self-prescribing
Weak legislation and enforcement
Weak penalties
Organised crime / terrorists have moved in

Good Distribution Practices

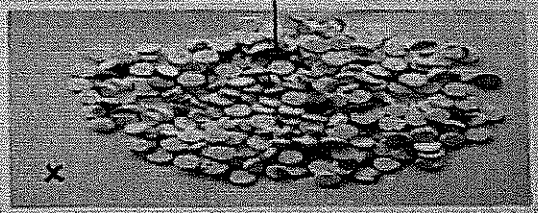
- World Health Organization
- European Union
- Pharmaceutical Inspection Cooperation Scheme
- FDA Drug Supply Chain Security Act 2013
- United States Pharmacopoeia ‹1083›
- California - Pharmaceutical Pedigree Act

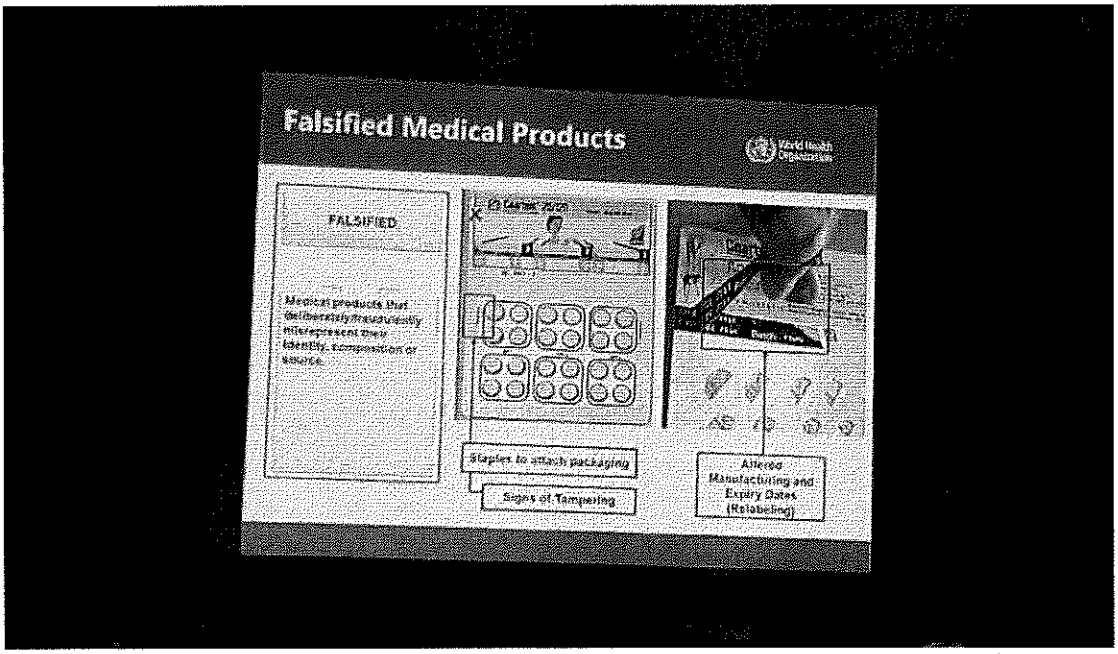
Substandard Medical Products

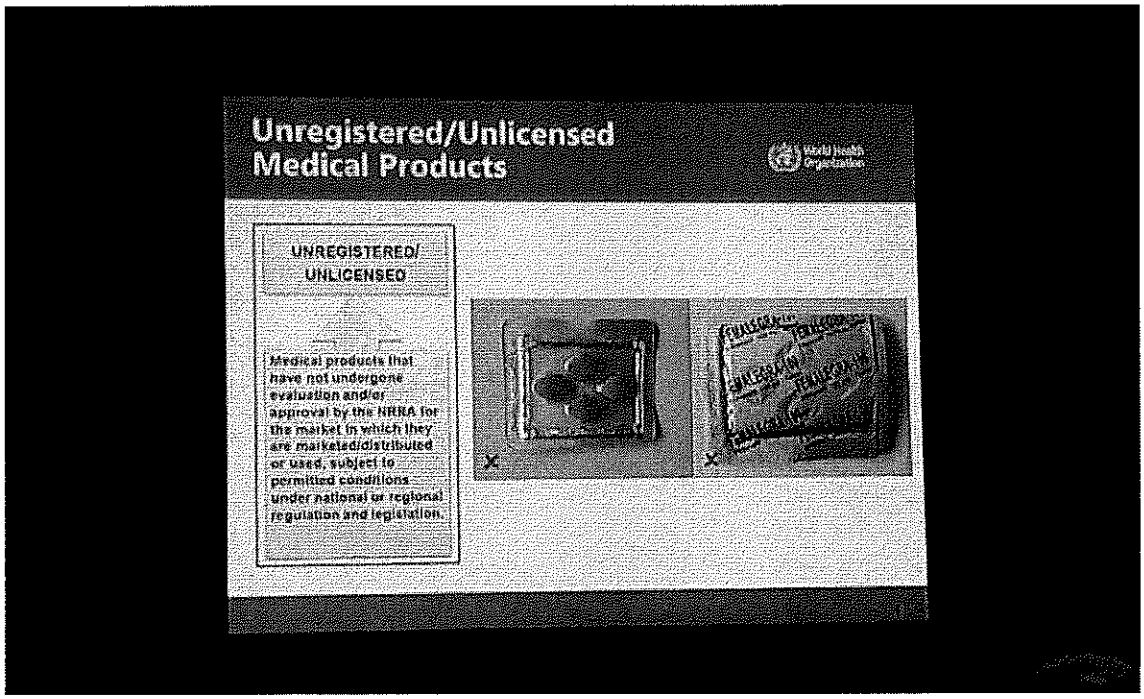
SUBSTANDARD

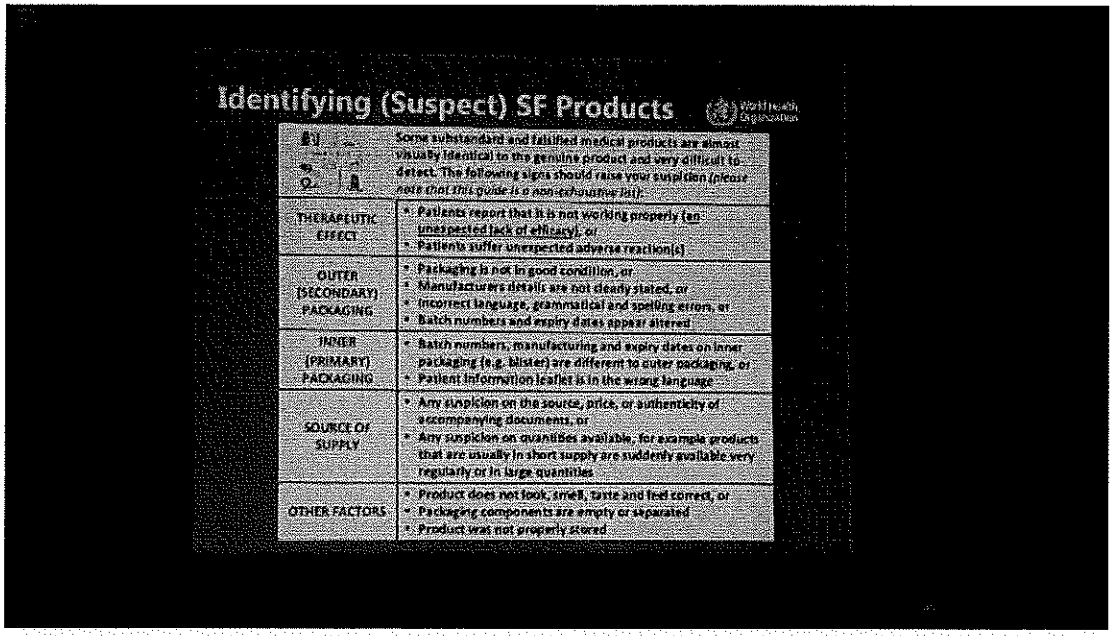
Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both.

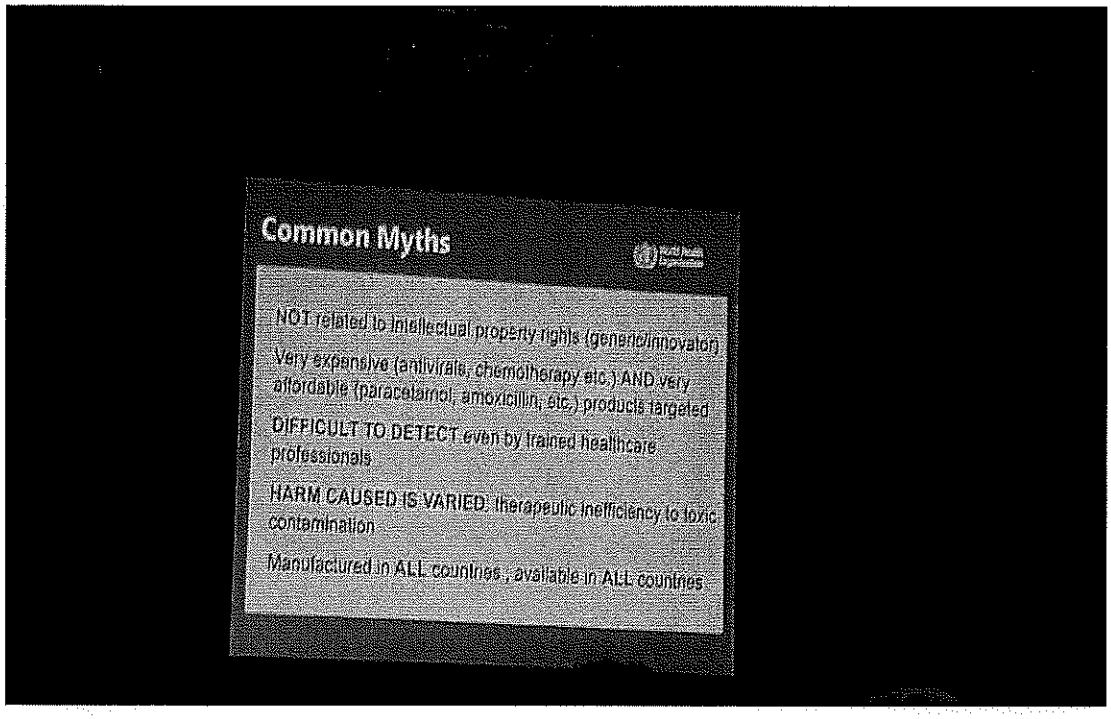
Discoloured




Falsified Medical Products
World Health Organization
FALSIFIED
Medical products that deliberately/fraudulently misrepresent their identity, composition or source.
Staples to attach packaging
Signs of Tampering
Altered Manufacturing and Expiry Dates (Relabeling)


Unregistered/Unlicensed Medical Products
World Health Organization
UNREGISTERED/ UNLICENSED
Medical products that have not undergone evaluation and/or approval by the NRRA for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.


Identifying (Suspect) SF Products
Some substandard and falsified medical products are almost visually identical to the genuine product and very difficult to detect. The following signs should raise your suspicion (please note that this guide is a non-exhaustive list):
THERAPEUTIC EFFECT
• Patients report that it is not working properly (an unexpected lack of efficacy), or
• Patients suffer unexpected adverse reaction(s)
OUTER (SECONDARY) PACKAGING
• Packaging is not in good condition, or
• Manufacturers details are not clearly stated, or
• Incorrect language, grammatical and spelling errors, or
• Batch numbers and expiry dates appear altered
INNER (PRIMARY) PACKAGING
• Batch numbers, manufacturing and expiry dates on inner packaging (e.g. blister) are different to outer packaging, or
• Patient information leaflet is in the wrong language
SOURCE OF SUPPLY
• Any suspicion on the source, price, or authenticity of accompanying documents, or
• Any suspicion on quantities available, for example products that are usually in short supply are suddenly available very regularly or in large quantities
OTHER FACTORS
• Product does not look, smell, taste and feel correct, or
• Packaging components are empty or separated
• Product was not properly stored

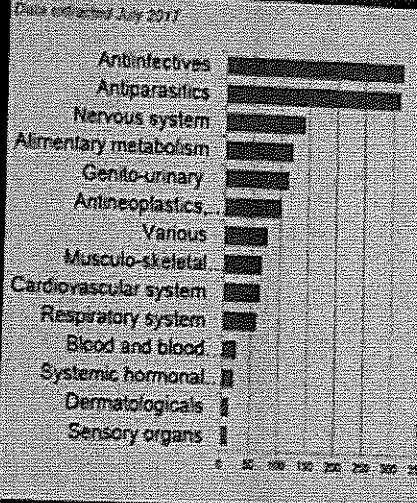

Common Myths
NOT related to intellectual property rights (generic/innovator)
Very expensive (antivirals, chemotherapy etc.) AND very affordable (paracetamol, amoxicillin, etc.) products targeted
DIFFICULT TO DETECT even by trained healthcare professionals
HARM CAUSED IS VARIED: therapeutic inefficiency to toxic contamination
Manufactured in ALL countries , available in ALL countries

MS Mechanism Published Documents

- Activities relating to SF medical products
- Treaty instrument
- Authorization permissions
- Global focal point network
- Definitions
- Publishing SF medical products
- Reporting re SF medical products
- Developing National Strategies

Visit our website for all documents:
http://www.who.int/medicines/regulation/ssffc/mechanism/en/

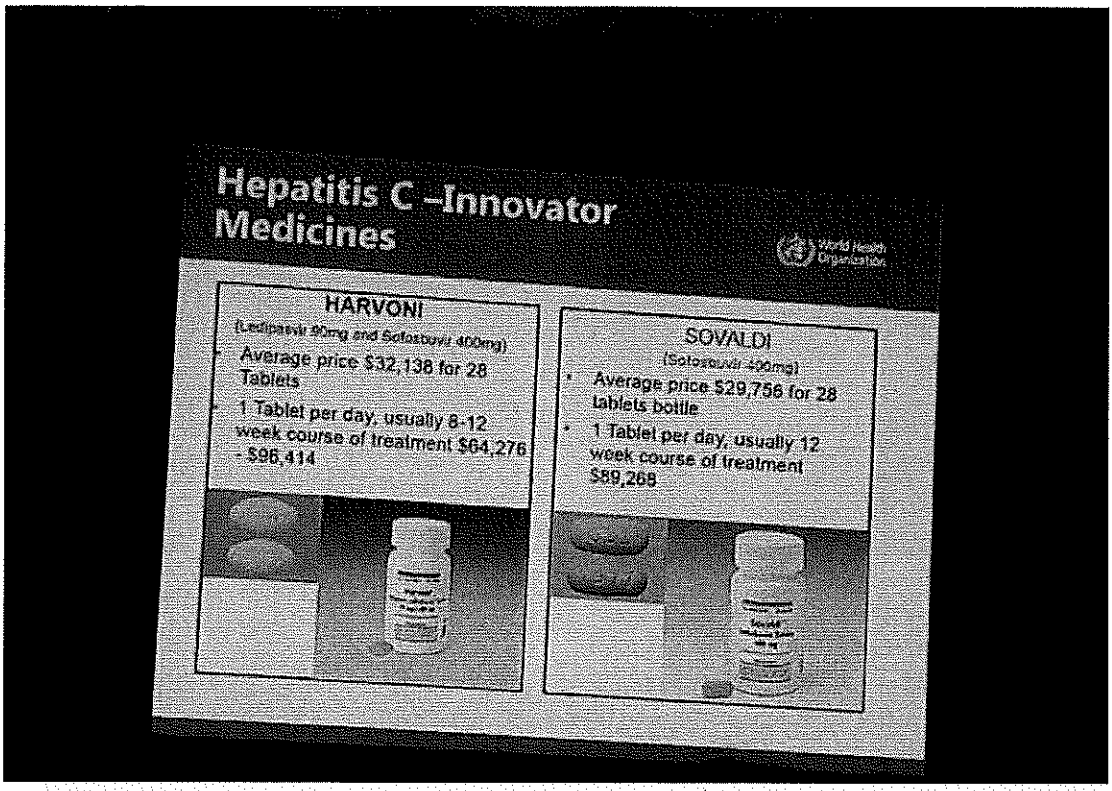
All products in all regions are targeted

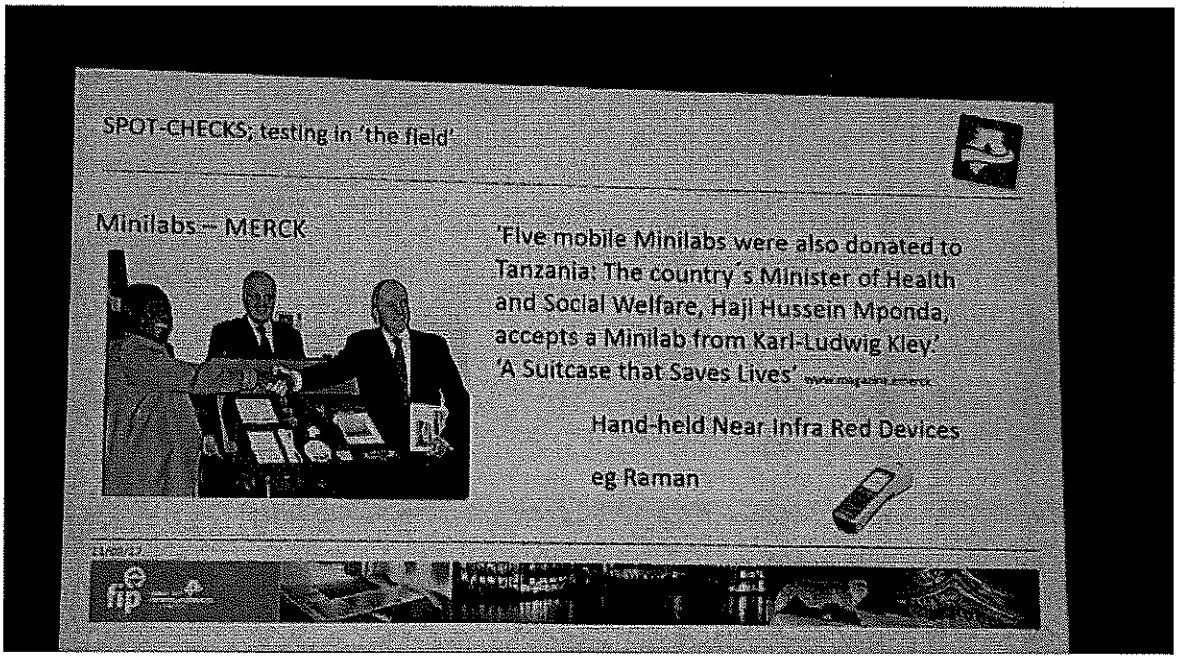


Approx.1500 products in the database, covering ALL therapeutic categories

Antimicrobials ≈ **half GSMS database** , reported from all regions

AMR Threat: reported AM are either critical or highly important


Hepatitis C –Innovator Medicines
World Health Organization
HARVONI
(Ledipasvir 90mg and Sofosbuvir 400mg)
Average price $32,138 for 28 Tablets
1 Tablet per day, usually 8-12 week course of treatment $64,276 - $96,414
SOVALDI
(Sofosbuvir 400mg)
Average price $29,756 for 28 tablets bottle
1 Tablet per day, usually 12 week course of treatment $59,268


SPOT-CHECKS; testing in 'the field'
Minilabs – MERCK
'Five mobile Minilabs were also donated to Tanzania: The country´s Minister of Health and Social Welfare, Haji Hussein Mponda, accepts a Minilab from Karl-Ludwig Kley.'
'A Suitcase that Saves Lives'
Hand-held Near Infra Red Devices
eg Raman

MINILABS

2 'family-sized suitcases' = 40kg

Comparison samples contained in 57 tubes

Drinking water can be used; no external power source required.

Bunsen burners and a small iron provide heating and drying as required

Funnels and batteries are also provided

Designed by Global Pharma Health Fund 1998; over 500 bought and distributed by Merck.

Hand-held NIR testing

Differentiates between counterfeit and genuine based on spectra of originator product compared to products with different excipients.

Can be screened while still packaged - NO PRODUCT DESTRUCTION or preparation required. Limited use in liquids

Further analysis in a laboratory would usually be required for prosecution.

Examples Nigeria and China country programmes

UK Regulatory and Customs Agencies particularly Viagra imports