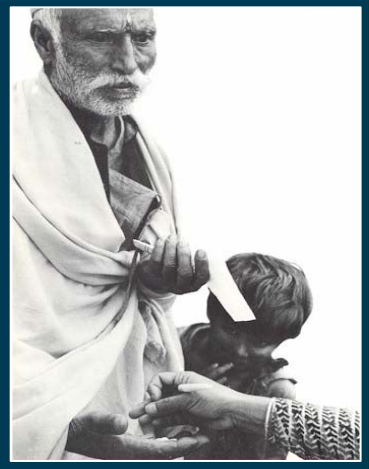


E-Health, patients and ethics

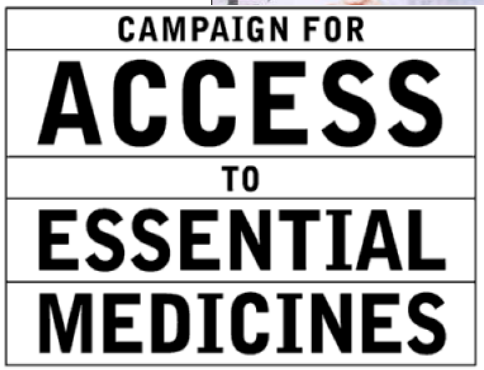
Dr. Ken Harvey MB BS, FRCPA

http://www.medreach.com.au

HIC08, Melbourne, September 1, 2008

LA TROBE UNIVERSITY AUSTRALIA

Disclosure of interests



- Health Action International Asia Pacific (HAIAP).
- Australian Consumers' Association.
- Public Health Association of Australia.
- Australian National Prescribing Service.

E-Health, patients and ethics

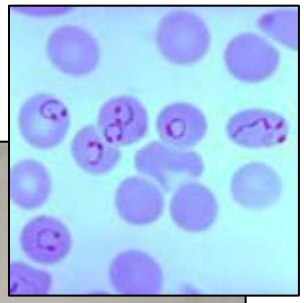
Parallels of medicines policy and E-Health

- Quality products.
- Equitable access.
- Rational use.
- Viable industry.

Case history

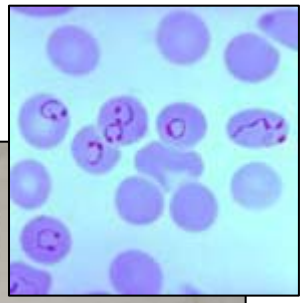
- A 23-year-old man presented with fever to a rural hospital in eastern Burma (Myanmar).
- He was diagnosed by microscopy as having falciparum malaria (4.2% infected red blood cells).

Case history



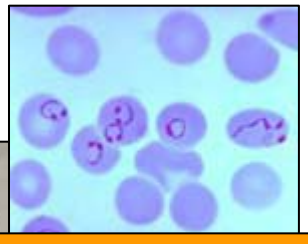
- He was treated with oral artesunate, labelled as made by Guilin Pharmaceutical (Guangxi, People's Republic of China), 4 mg/kg once a day, the treatment of choice in this area.
- Since artemisinin derivatives have been used in this area, not one of 600 patients prospectively studied with 4% parasitaemia has died.

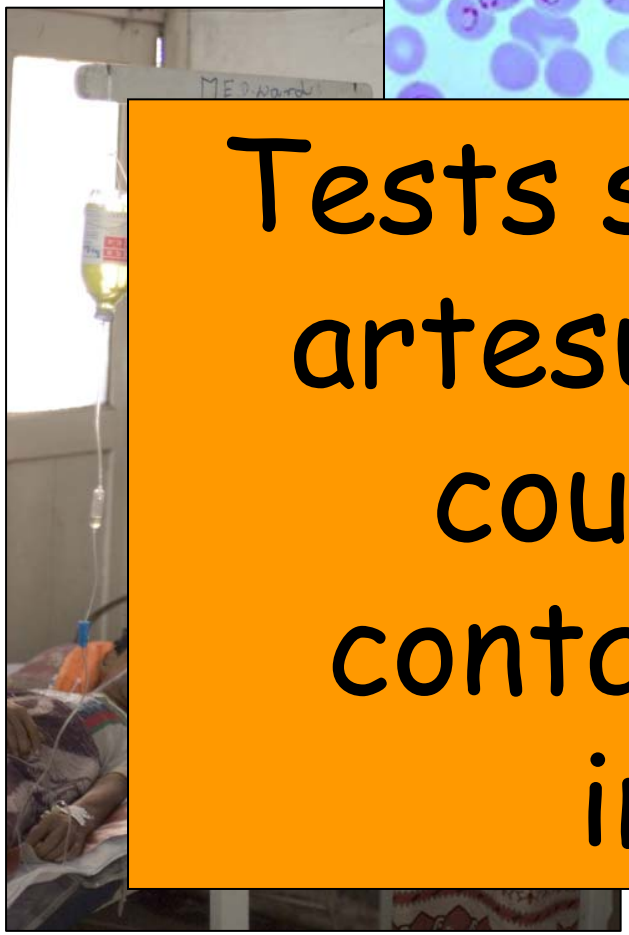
Case history



- However, on the third day the young man was found to be in a coma, with renal failure and increased parasitaemia (5.5% infected red blood cells).
- He was perfused with intravenous fluids and given intravenous artesunate but he died 12 hours later from cerebral malaria.

Case history





- However, on the third

Tests showed that the artesunate used was counterfeit and contained no active ingredient.

us
n
12
a.

Counterfeit artesunate in Asia

- The World Health Organization notes that between 38% and 52% of "artesunate" blister packs sampled in Asia contain no active ingredient.

Philippines Bureau of Food & Drugs

High quality products

- Australian Therapeutic Goods Administration (TGA)
  - Appropriate legislative framework.
  - Licensing of manufacturers (GMP inspection, product sampling, testing).
  - Product registration (drug evaluation for quality, safety and efficacy).
  - Post-marketing surveillance (monitoring adverse drug reactions, pharmaceutical promotion).

Relevance to E-Health

Australian Government
Department of Health and Ageing

ahic
Australian Health Information Council

nehta

EAN AUSTRALIA

HL7 AUSTRALIA

SNOMED INTERNATIONAL

Australian Healthcare Messaging Laboratory

- If industry is to play a responsible role:
  - government policy,
  - standards, and
  - tests of product compliance
- are all required.

Adverse drug reaction reporting

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Office use only

Report of suspected adverse reaction to medicines or vaccines

(See statement about the collection and use of personal information overleaf)
Please attach any additional data to this sheet

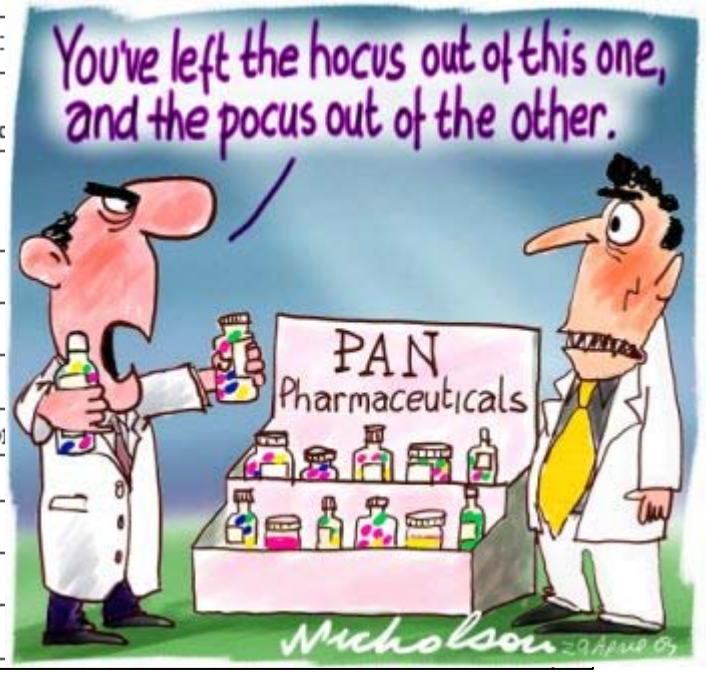
Patient initials or medical record number:	Sex: M ☐ F ☐	Date of birth or age:
	Weight (kg):	

Suspected medicine(s)/vaccine(s)
(please use trade names; include **AUST R or AUST L number** for non-prescriptio

Medicine/vaccine	Dosage (Dose number for vaccines eg 1st DTP)	Date begun

edicine(s)/vaccine(s) taken at the time of the reactio

e/vaccine	Dosage	Date begun



Adverse drug reaction reporting

Adverse Drug Reaction System - Mozilla Firefox

File Edit View Go Bookmarks Tools Help

https://www.tgasime.health.gov.au/SIME/ADRS/ADRSRepo.nsf/Lc

Go

Members Equity UniSuper Medreach Pty. Ltd. La Trobe University iiNet Toolbox iiFTP Downloads Currency Converter

TGA THERAPEUTIC GOODS ADMINISTRATION

Australian Adverse Drug Reaction Reporting System

Help

Registered Reporters

You will be prompted to enter a username and password. After logging in you will then be able to create, save and edit ADRS Notifications prior to lodging them with TGA. Logging in also allows you to view previously lodged notifications and request specific ADRS reports.

Registered Users Login

Unregistered Reporters

This option allows you to lodge a notification without having to register with ADRS. After the ADRS notification is completed and lodged, an acknowledgement receipt will be sent via email as confirmation.

This option is recommended if you only lodge Adverse Drug Reaction System notifications infrequently.

Alternatively you can register with the Adverse Drug Reaction System. Registering provides you with the benefits of registered users.

Lodge a Notification | Submit Supporting Documentation

Done www.tgasime.health.gov.au

Adverse drug reaction reporting

AUSTRALIAN DRUG EVALUATION COMMITTEE
ADVERSE DRUG REACTIONS ADVISORY COMMITTEE

AUSTRALIA

All correspondence to be addressed to **THE SECRETARY**

PO Box 100
WODEN ACT 2606
Enquiries: 1800 044114
Email: adrac@health.gov.au
Fax (02) 6232 8392

Successfully tested in 2003
Yet to be implemented!

Dear Doctor

I write to request your assistance with the testing of a new featur
number of desktop prescribing software packages (Locum, Medi
32). The Adverse Drug Reactions Advisory Committee (ADRA
Collaborating Centre for eHealth at the University of Ballarat in
electronic transmission of the "Report of Suspected Adverse Rea
Vaccines" (blue card). ADRAC has been collecting information
reactions from prescribers, pharmacists and other healthcare pro
for over 30 years. The current process requires a reporter to com
notification form.

ADRAC Notification

D.O.B.:	17/06/1943
Sex:	Male
Date of onset of reaction:	06- March -2
Drug name and form:	ZANTAC TABLET 150mg
Dose:	1- 2 times
Date started:	03/02/2000
Indication:	REFLUX OESOPHAGITIS
Reaction:	Worked too well
Description of Adverse Reaction:	Patient felt great
Treatment of reaction:	Advised to cease it
Severity:	Severe
Outcome:	Fully recovered (no sequelae)
Sequelae:	
Comments:	What a fab tool!

Append details | Print | Send | Cancel

e-denial

Acknowledgments to Andrew Magennis, Medical Director

Goals of medicinal drug policy

1. Medicines of high quality, safety and efficacy

2. Equitable access to necessary medicines

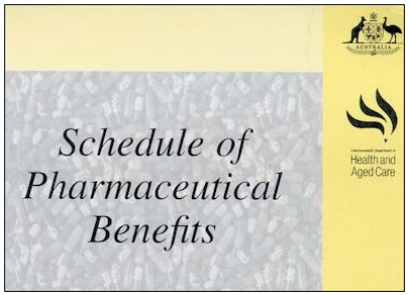
3. Quality use of medicines

4. A viable & responsible local pharmaceutical industry

Equitable access

- Two billion people (one third of the world's population) still lack regular access to essential medicines.
- Six million people in developing countries lack anti-retroviral drugs.
- Medicines are the largest health expense for poorer households and the second largest public health cost.
- The price of drugs in a free market bears no relation to the ability of people to pay.

Equitable access



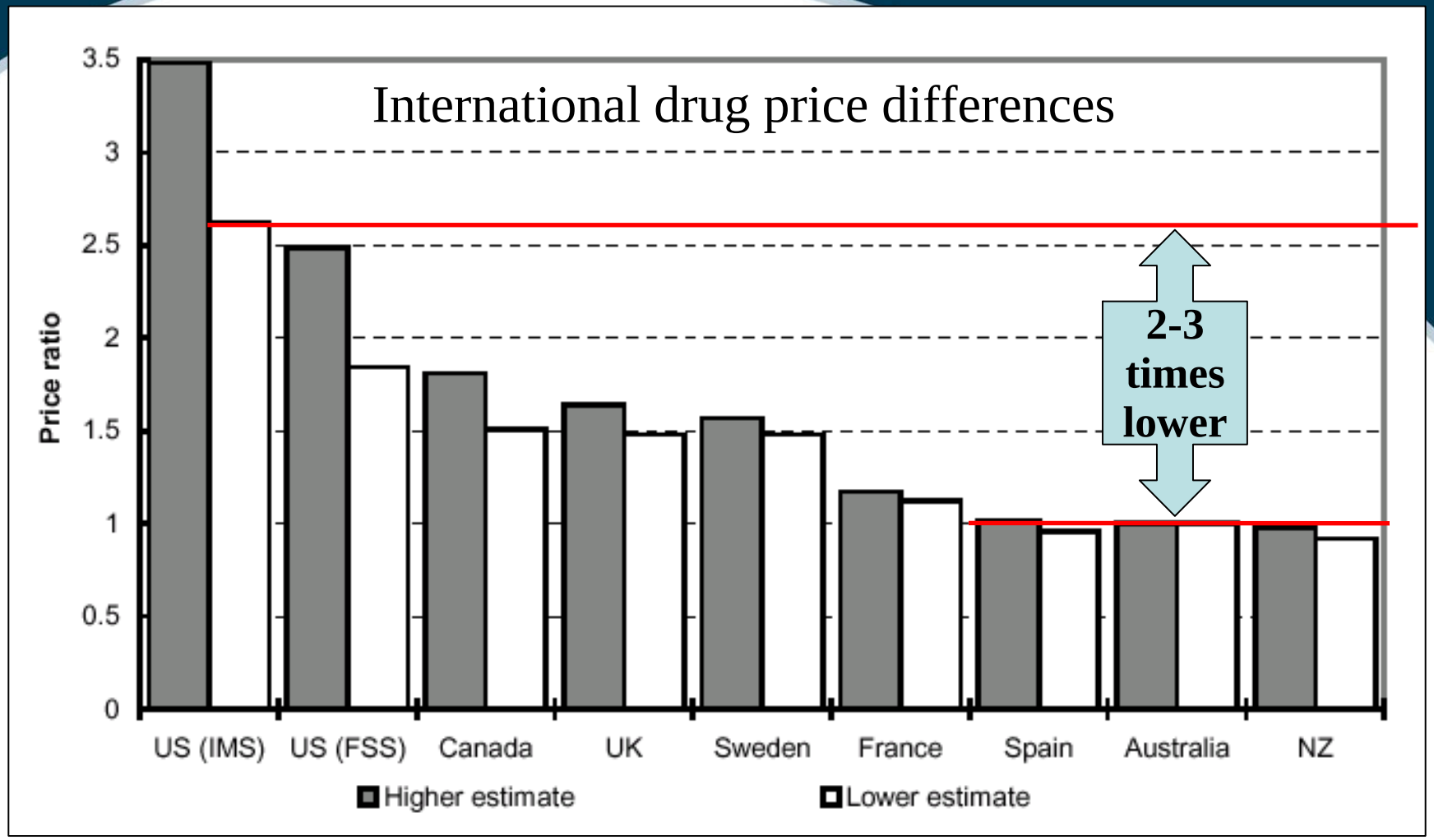
- Limited list of cost-effective, necessary drugs.
- Cost subsidised by national or private insurance schemes.
- Prices negotiated using:
  - Pharmacoeconomic analysis (pay only what the drug is worth)
  - Monopsony buying power (counters monopoly power of pharmaceutical companies during patent protection)
  - Reference pricing (subsidise only the lowest price product in a generic group and in some therapeutic classes)
  - Generic substitution by pharmacists for drugs of proven therapeutic equivalence .
- Local production (compulsory licensing).

Patents, prices & FTAs

PhRMA
New Medicines. New Hope.
1100 Fifteenth Street, NW Washington, DC 20005

- In January 2003, the Pharmaceutical Research Manufacturers of America (PhRMA) lobbied US trade negotiators to seek Australian government commitment to, “refrain from trade distorting, abusive, or discriminatory price controls found in the Pharmaceutical Benefits Scheme (PBS)”.
- In October 2003, President George Bush told Prime Minister John Howard that raising drug prices is a key goal for United States negotiators in any FTA deal. Mr Bush said his pharmaceutical industry believes some countries do not pay their share of the cost of research and development to create new medicines, making US consumers pay the bill.

Why doesn't Big Pharma like the PBS?



Productivity Commission Research Report, July 2001 (top 150 PBS drugs)

Are Australian drug prices too low?

- While drug prices in Australia are 2 to 3 times lower than those in similar countries price differences vary across different categories of pharmaceuticals:
  - prices for new innovative drugs are much closer to those in the other countries
  - largest price differences for ‘me-too’ pharmaceuticals (modified versions of older drugs similar in clinical value to drugs already available) and generics.

Are Australian drug prices too low?

- While dr

No!

much

es

e-too'

sions of

value to

ble) and generics.

US drug prices (and profits) are too high!

SAVEWITHCANADADRUGS.COM
ORDER PRESCRIPTIONS
CANADIAN PRICES
@ONLINE
START SAVING
CLICK HERE :·

Hence campaigns for equitable access

Parallels with the digital divide

- Negotiated prices
  - Affordable broadband
- Generic drugs
  - Low cost computers
  - Linux o/s; open office.
- Generic drug substitution
  - Offering a choice of more cost-effective open source software rather than embedding more expensive Microsoft products.

Goals of medicinal drug policy

1. Medicines of high quality, safety and efficacy

2. Equitable access to necessary medicines

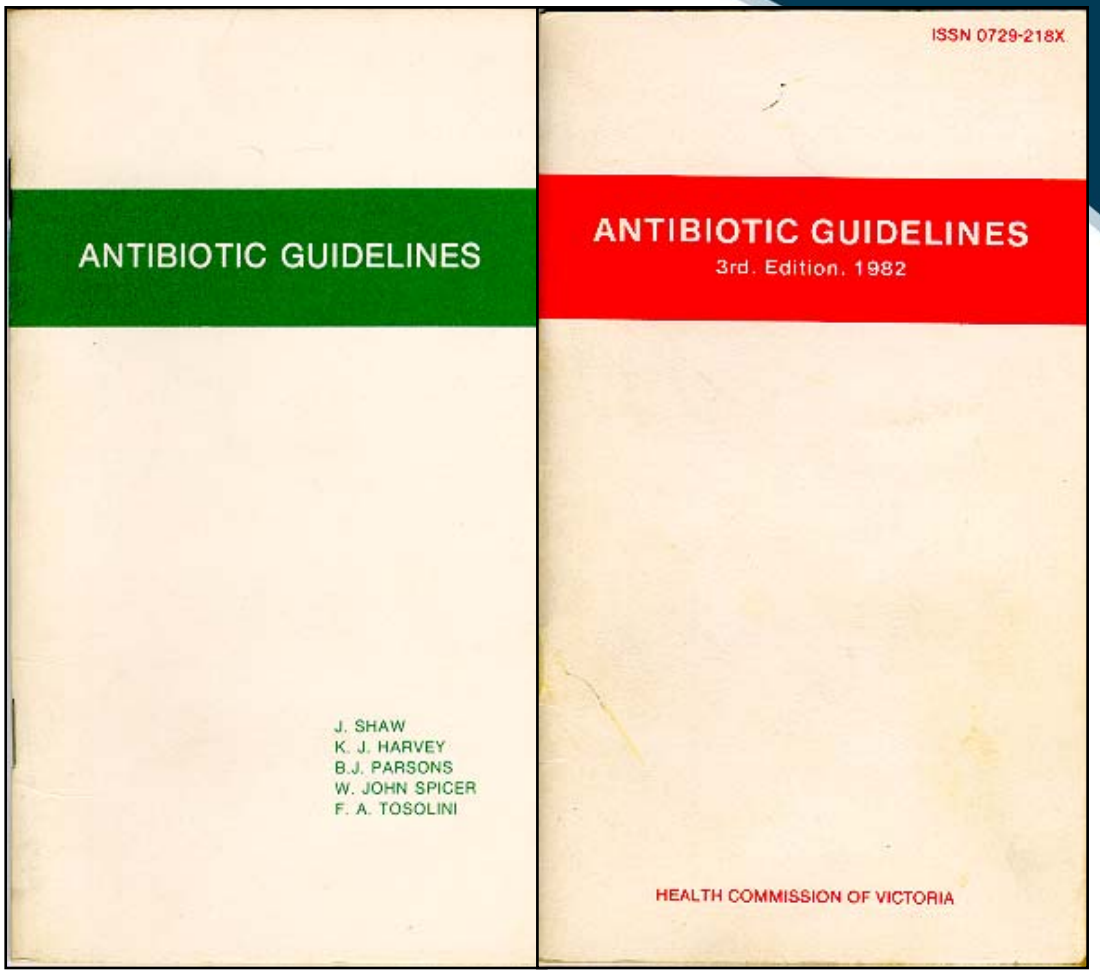
3. Quality use of medicines

4. A viable & responsible local pharmaceutical industry

My own interest started at the RMH

Hospital acquired infection with antibiotic-resistant microorganisms

The Royal Melbourne Hospital



Quality Assurance Cycle

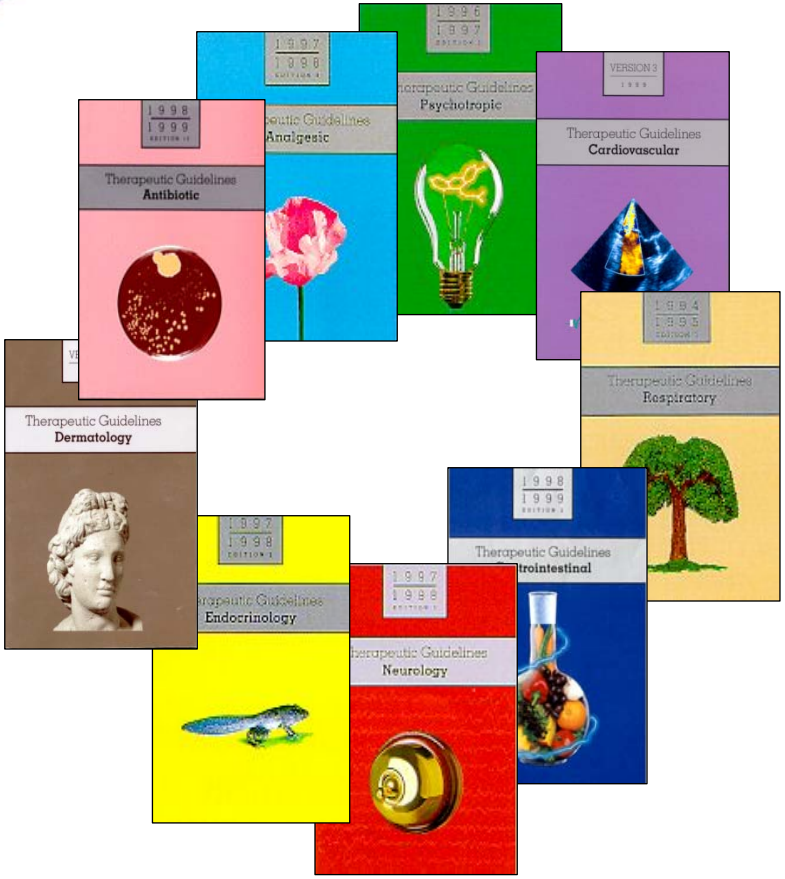
Continually updated standards of practice: treatment guidelines

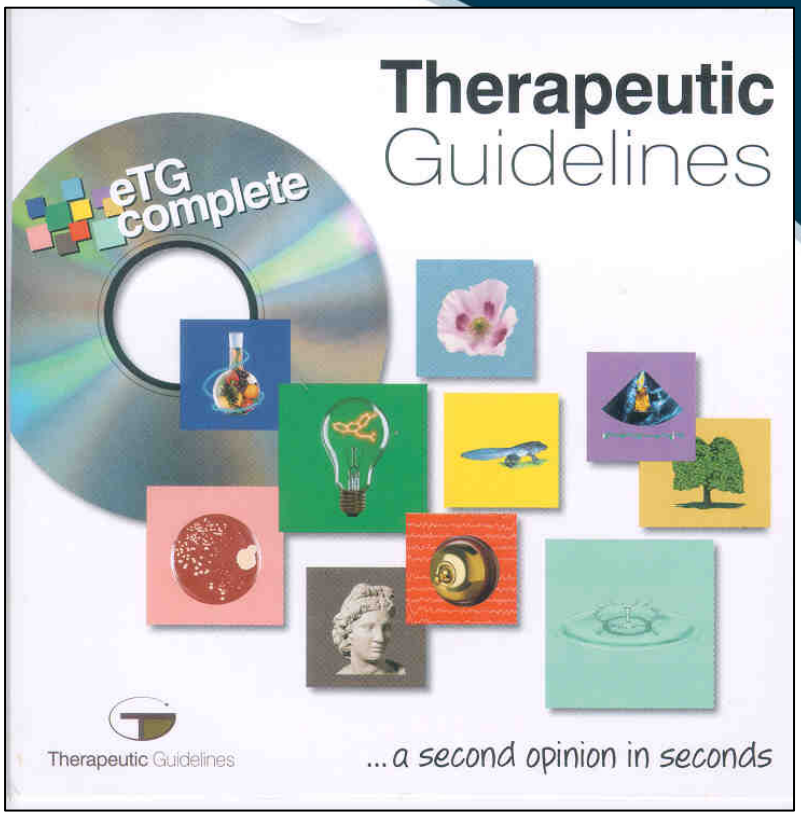
Drug audit / utilisation review

Practitioner reflection / targeted education

Feedback results to health administrators and guideline authors

Guidelines evolution...

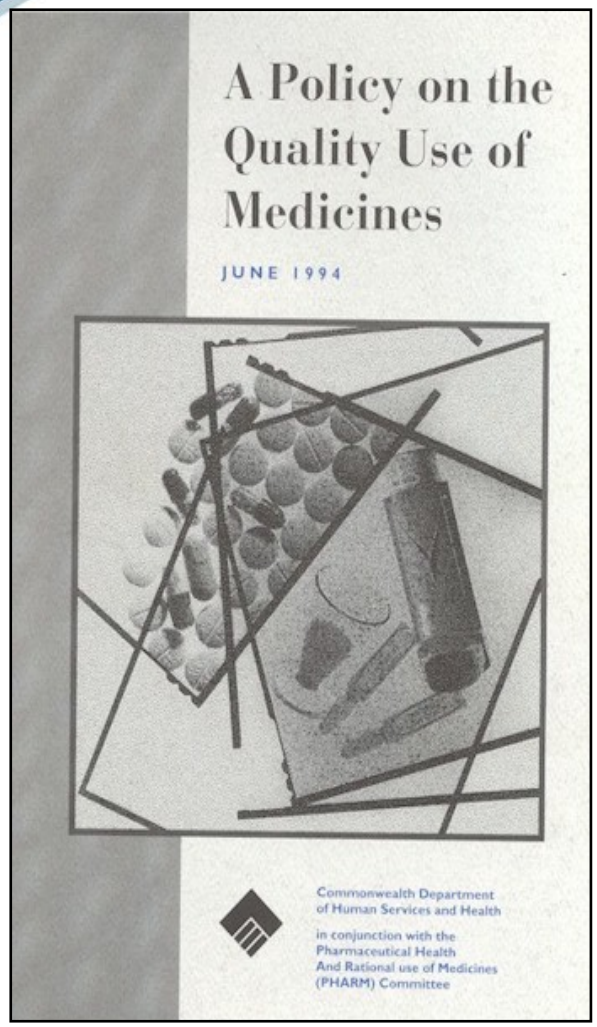




Scaling up nationally

Health Minister, Peter Sharples, with members of the PHARM Committee during the development of the Quality Use of Medicines Policy

Quality Use of Medicines Policy



Strategies

- Policy development and implementation.
- National facilitation and co-ordination.
- Independent information.
- Ethical promotion.
- Education and training.
- Services and interventions.
- Evaluation.

Independent information

NPS RADAR
Rational Assessment of Drugs and Research

AUSTRALIAN ADVERSE DRUG REACTIONS BULLETIN

TG Complete - Microsoft Internet Explorer

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Antibiotic, Version 11, 2000
Principles of antimicro
Getti to kn your
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eTG complete

April 2002

Quick Start
Click on the Ind
frame), and typ
condition or dru
click on index t
show associated

Therapeutic Guidelines Antibiotic

Therapeutic Guidelines Dermatology

Therapeutic Guidelines Endocrinology

Therapeutic Guidelines Analgesic

Schedule of Pharmaceutical Benefits

Health and Aged Care

australian prescriber
An Independent Review

AMH
AUSTRALIAN MEDICINES HANDBOOK ONLINE

Current challenge

To make best-practice Guidelines, medication review and other proven QUM techniques more accessible via physician's computers.

QUM^{IT}: The vision

Patient problem

Physician decision

Prescriptions, Investigations, Consumer information

Guidelines

Drug information

Drug-drug interaction

Dose calculators

Assisted by decision support software

ALERTS

Improve

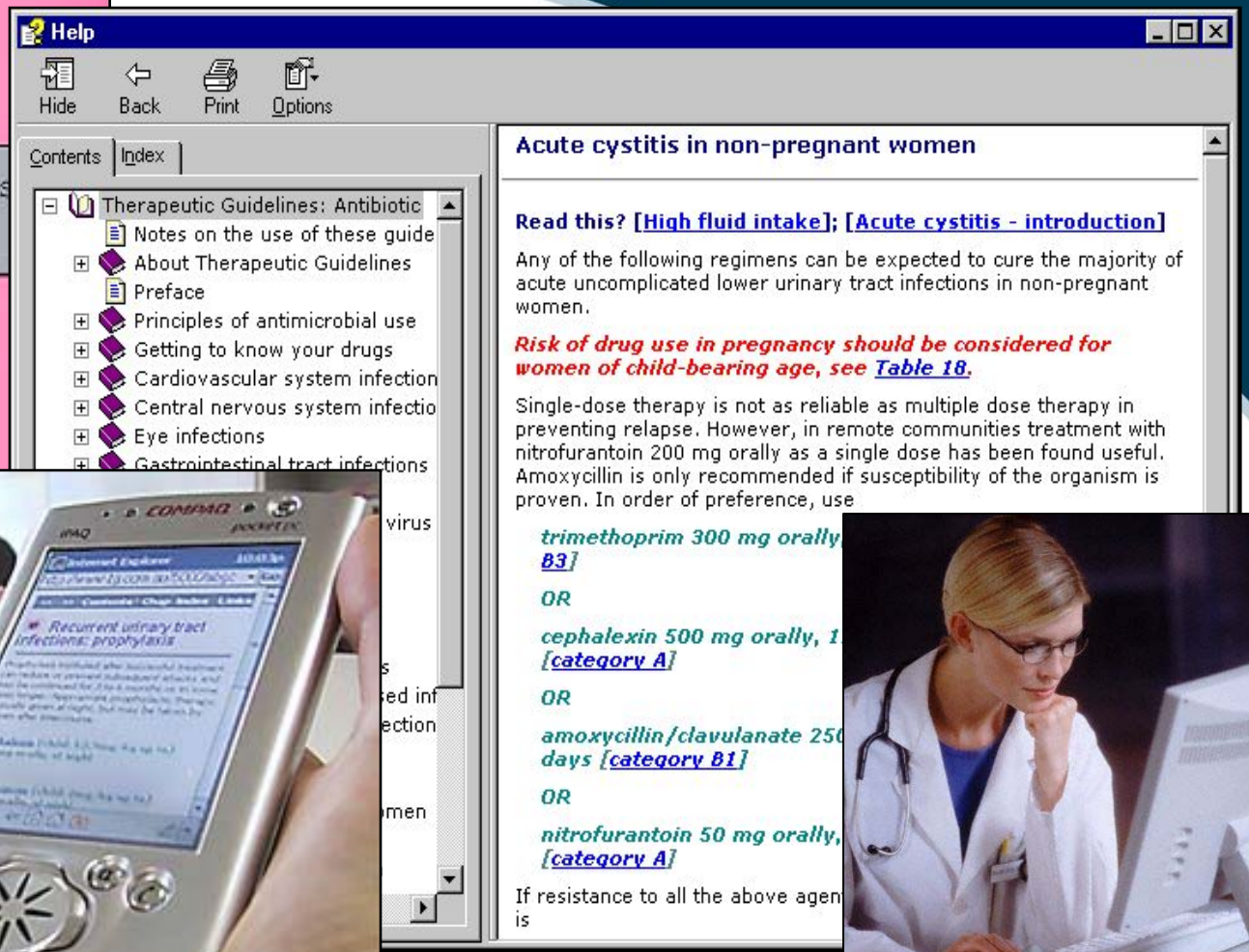
Outcome analysis

e-Patient record

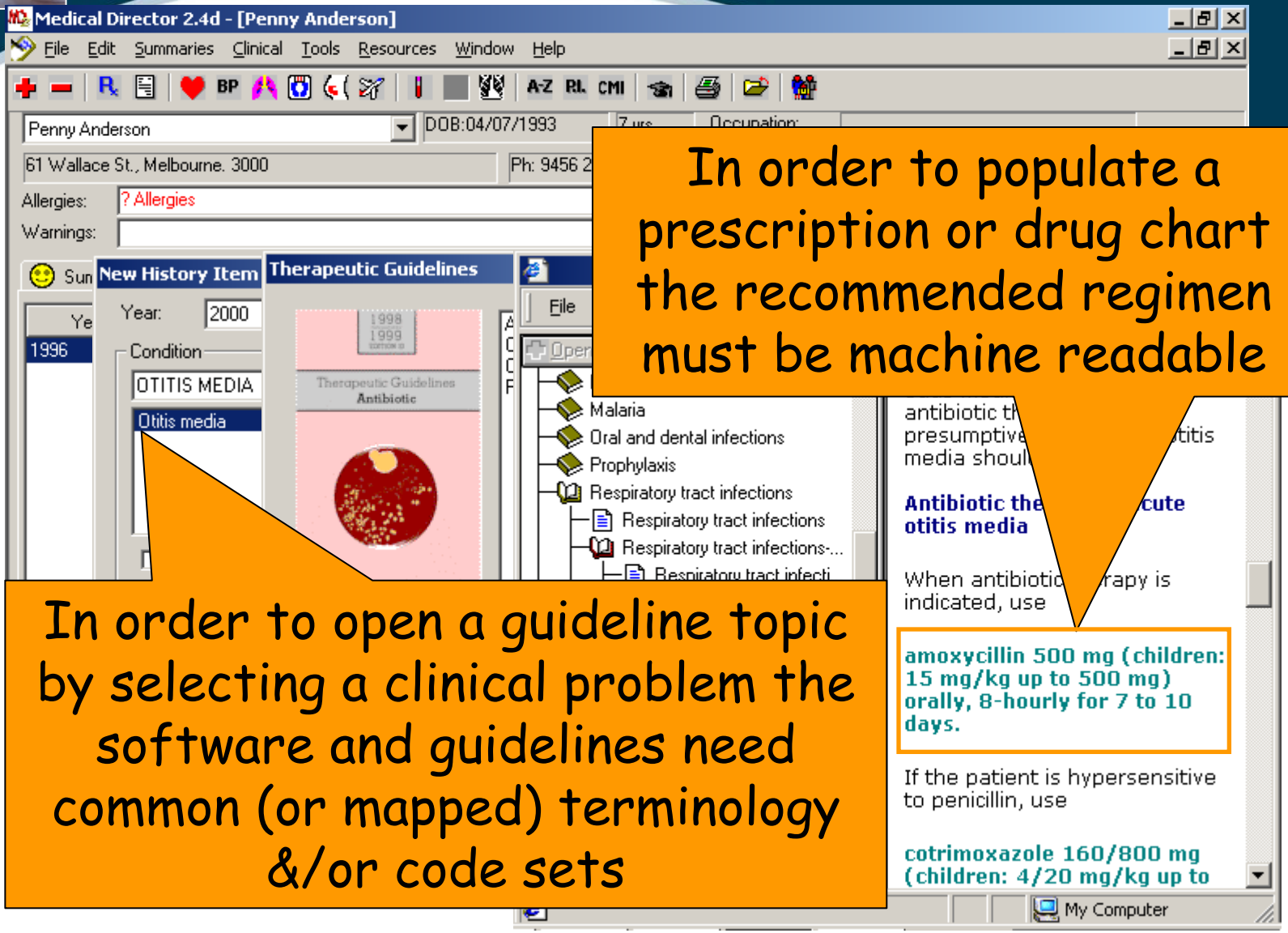
Health*Connect*
ADRAC

Lab results

Challenges: E-conversion



Challenges: E-integration



In order to populate a prescription or drug chart the recommended regimen must be machine readable

In order to open a guideline topic by selecting a clinical problem the software and guidelines need common (or mapped) terminology &/or code sets

Making guidelines machine readable

Guideline and formulary information can be atomized into machine readable components using XML tags (but displayed in HTML via XSL)

e.g. *amoxicillin (child 15 mg/kg up to) 500 mg, 8 hourly, orally* can be represented in machine readable form as:

```
<REGIMEN>
  <ATC>J01CA04</ATC>
  <DRUG>amoxicillin</DRUG>
  <DOSE>
    <CHILDREN>15<UNIT>mg/kg</UNIT></CHILDREN>
    <ADULT>500<UNIT>mg</UNIT></ADULT>
  </DOSE>
  <FREQ>8 hourly<FREQ>
  <ROUTE>oral</ROUTE>
</REGIMEN>
```

E-Guidelines: XML technologies

Well styled MS Word manuscript

Parsed by computer

Database application

TGDB

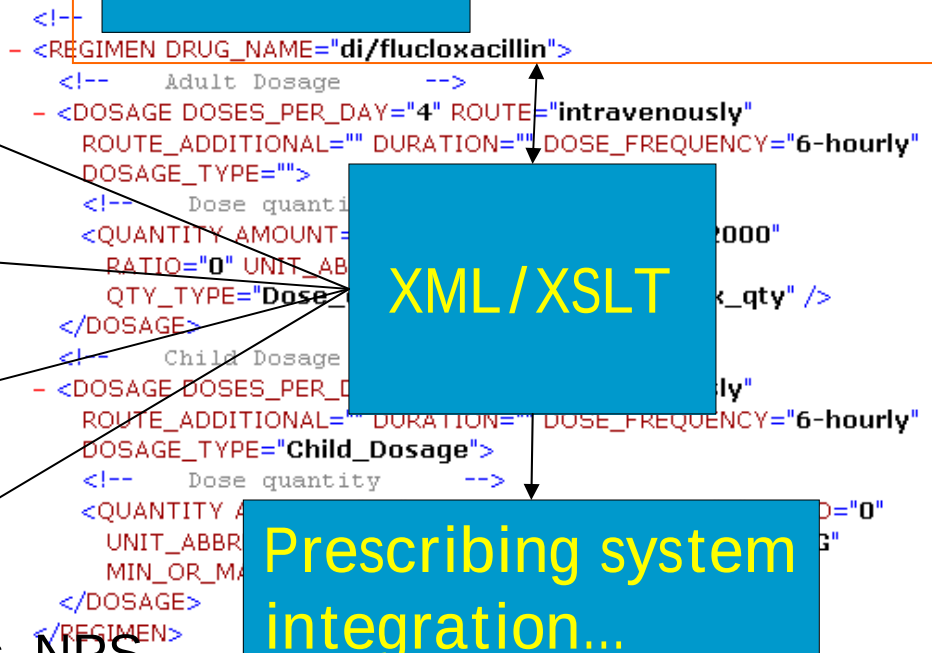
Print

CD-ROM

Intranet

PDA

XML/XSLT



Prescribing system integration…

Acknowledgments: Dr. Bryn Lewis, NPS

The need for standards

http://www.hl7.org.au/CDSS.htm

- Guideline representation
- Clinical terminology / Diagnostic coding
- Medicines terminology

e-denial

Drug promotion

AMA President,
Dr Mukesh Haikewal

Drug company dinners "oiled the wheels" of medical education and $200-a-head meals were appropriate, rather than doctors "slumming somewhere in a budget chain motel".

http://www.ama.com.au/web.nsf/doc/WEEN-6S3CAY

Drug promotion

AMA President,
Dr Mukesh Haikewal

"If doctors don't learn about new life-saving and health-enhancing drugs through seminars put on by the pharmaceutical companies then patients will not be prescribed the best possible drug for their condition – it's as simple as that."

http://www.ama.com.au/web.nsf/doc/WEEN-6S3CAY

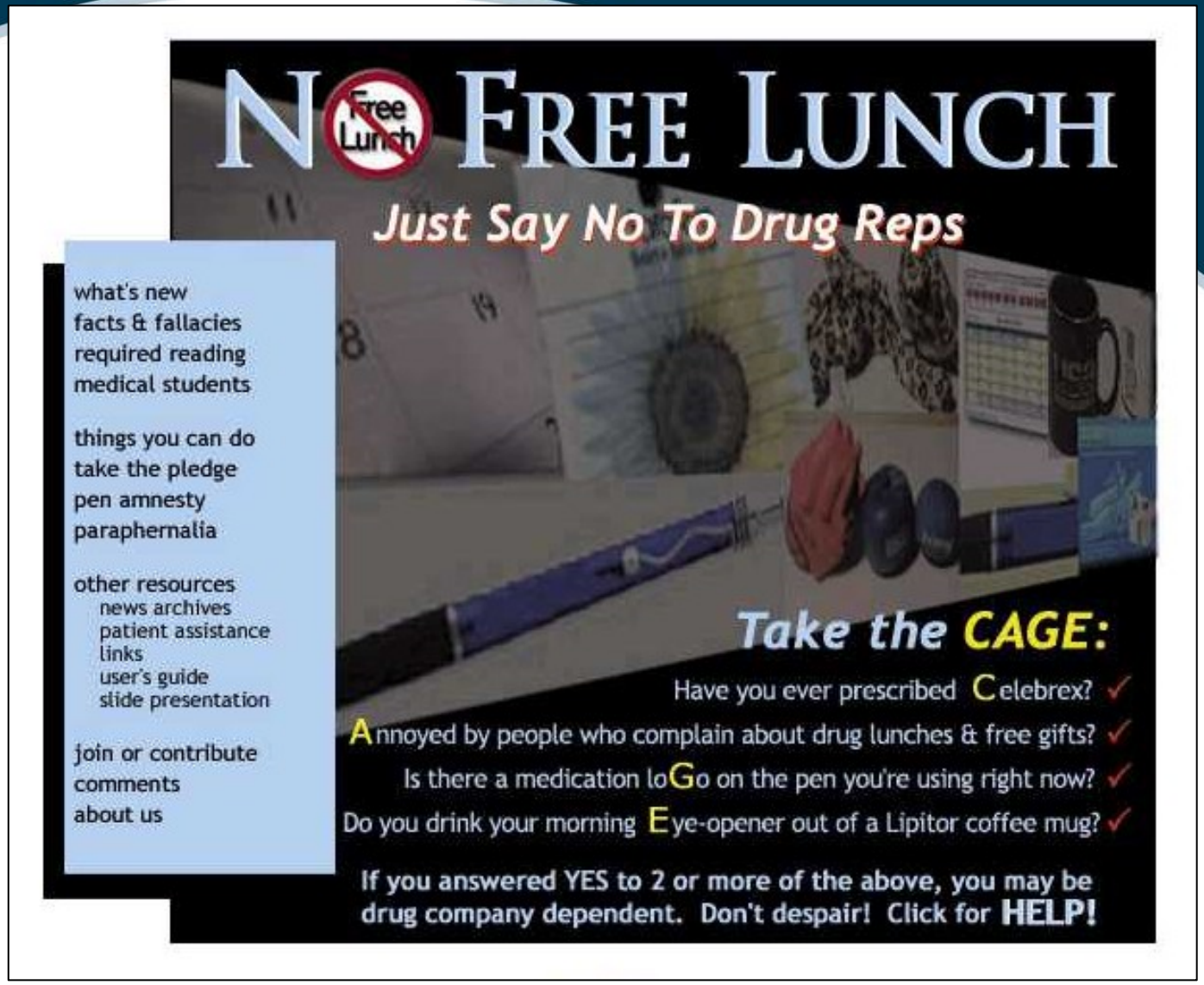
However

BMJ 2003;326 (31 May)

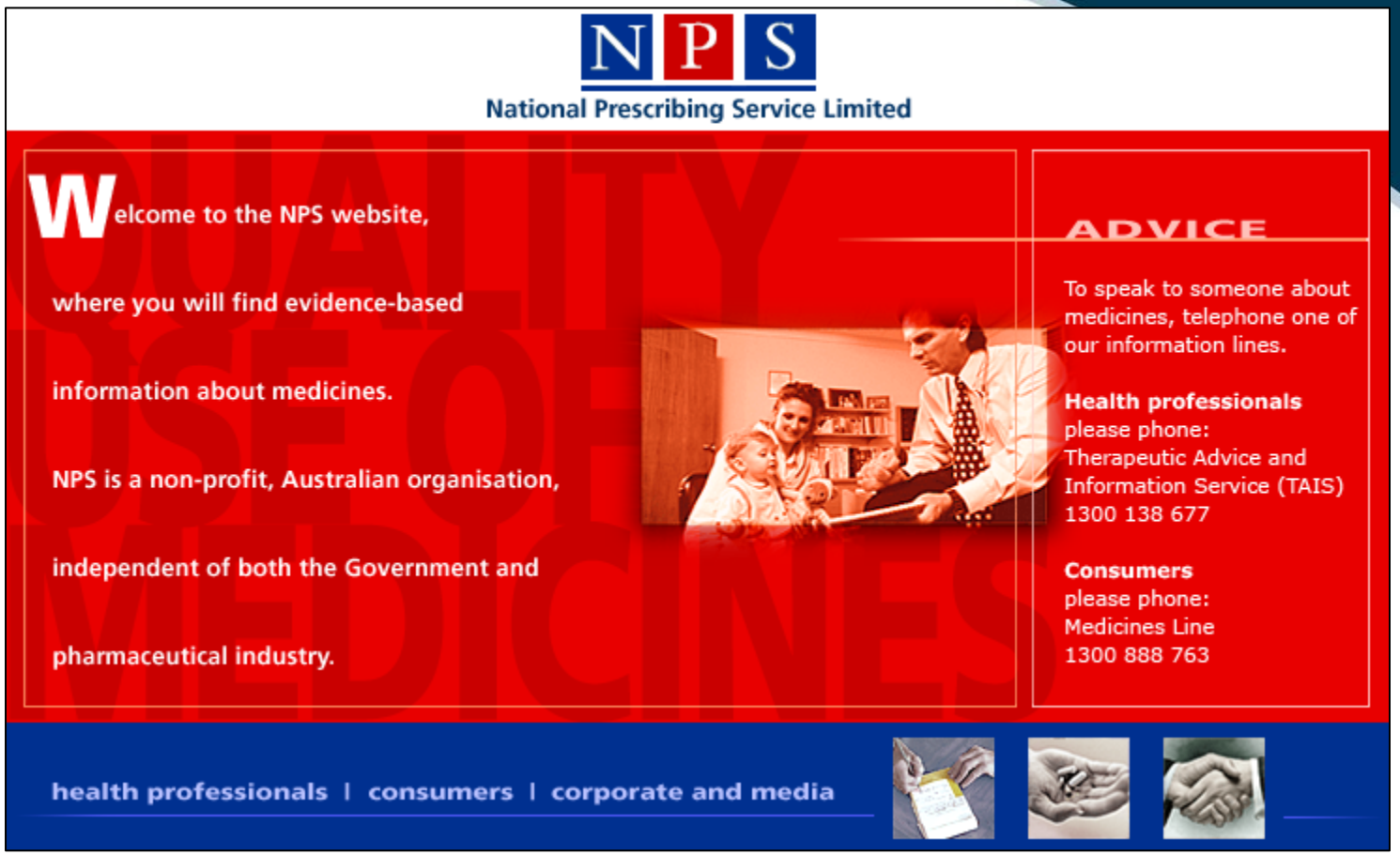
Industry-doctor interaction correlates with:

- Doctors' preferences for new products that hold no demonstrated advantage over existing ones.
- Decreased prescribing of generic drugs.
- A rise in both and irrational and incautious prescribing.
- Rising prescription expenditures.

Hence


NO FREE LUNCH
Free Lunch
Just Say No To Drug Reps
what's new
facts & fallacies
required reading
medical students
things you can do
take the pledge
pen amnesty
paraphernalia
other resources
news archives
patient assistance
links
user's guide
slide presentation
join or contribute
comments
about us
Take the CAGE:
Have you ever prescribed Celebrex? ✓
Annoyed by people who complain about drug lunches & free gifts? ✓
Is there a medication loGo on the pen you're using right now? ✓
Do you drink your morning Eye-opener out of a Lipitor coffee mug? ✓
If you answered YES to 2 or more of the above, you may be drug company dependent. Don't despair! Click for HELP!

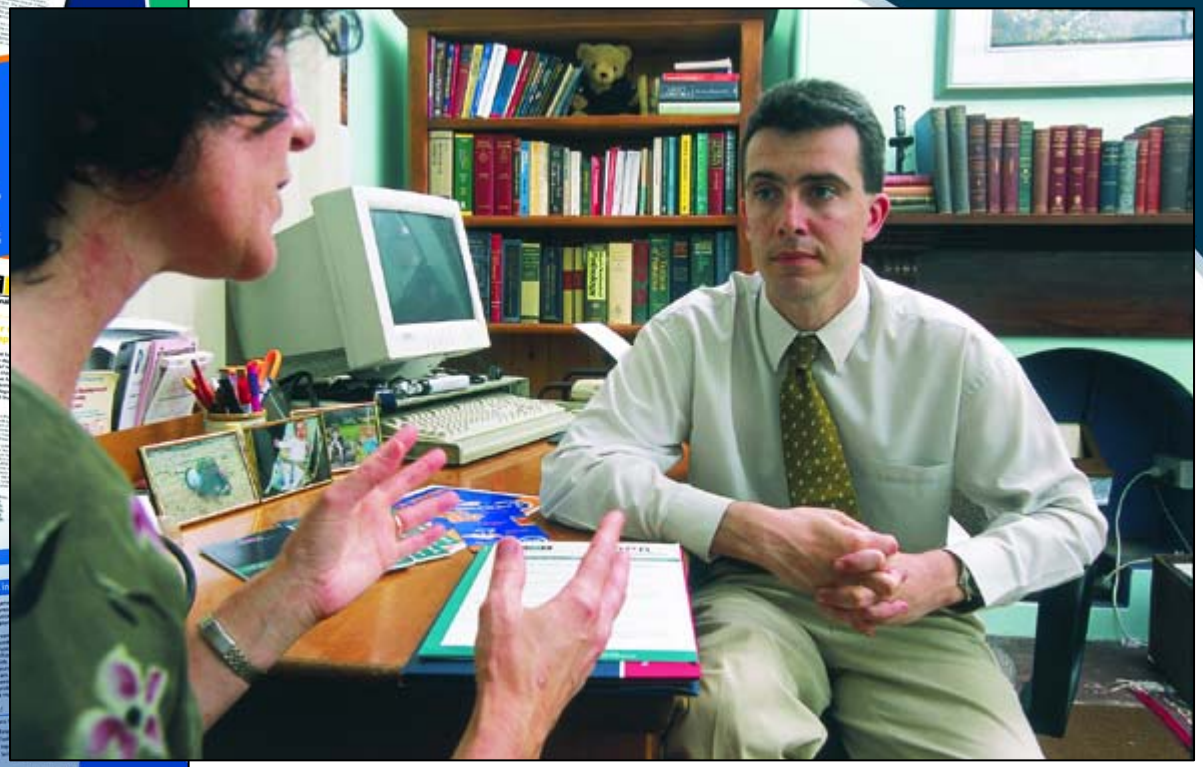
Hence



http://www.nps.org.au/

NPS: Academic detailing

Also: home medication review by pharmacists (Government-Guild agreement)



NPS: Campaigns

National Prescribing Service Limited

I'VE GOT A SORE THROAT: WILL AN ANTIBIOTIC MAKE ME BETTER?

Some information to help you in the next week or so

What is a "sore throat"?
Sore throat is a very common infection caused by bacteria or viruses. It is usually part of a simple illness such as the common cold but rarely may be a symptom of more severe illness such as glandular fever. The sore throat may be accompanied by sniffles, cough and generally feeling weak and feverish.

Bacteria and viruses infect the tissues at the back and sides of the throat. The body makes antibodies to the infection, and this may cause the glands (lymph nodes) in the neck to swell and become tender.

Most people (90%) are over their infection by one week. Half are better by about 3½ days.

Will antibiotics help a sore throat?
Traditionally doctors have prescribed antibiotics to kill any bacteria in the throat. However recent research has suggested that antibiotics do not make much difference to symptoms.

In fact they only shorten the time you are unwell by 16 hours overall. You have a 50% chance of being better in 3¾ days without antibiotics, and 2½ days with them. In either case – with or without antibiotics – you have a 90% chance of being better in 7 days.

There are some rare complications, however they are so rare that it is not necessary to use antibiotics routinely to prevent them unless you are in a special risk group (which your doctor can advise you about).

What are the disadvantages of antibiotics?
- Antibiotics can have unpleasant side effects (for example, thrush, rashes, tummy upsets and diarrhoea).
- Taking antibiotics when you don't need them isn't sensible.
- Overusing antibiotics produces resistant germs, which means the antibiotics may not work when they are really needed.

Your doctor has examined you during your visit to the surgery and, even though you feel unwell, he or she hasn't found any serious illness that definitely needs antibiotics today.

So, your sore throat will quite likely get better without antibiotics. However, your doctor may have given you a prescription to have available in case you do need antibiotics in the next few days. Follow your doctor's advice as to whether to get them; the prescription should only be used for this episode of illness.

When should I return to my doctor?
If you feel your illness is getting worse.
If you feel your sore throat is getting worse.
If you are not better in _____days / hours.

If you do use antibiotics, do take the FULL course.

Is there anything I should look out for?
Should you find that you develop any new or worrying symptoms, or if symptoms persist telephone the surgery and make an appointment for a further check-up.

Ways to help your sore throat

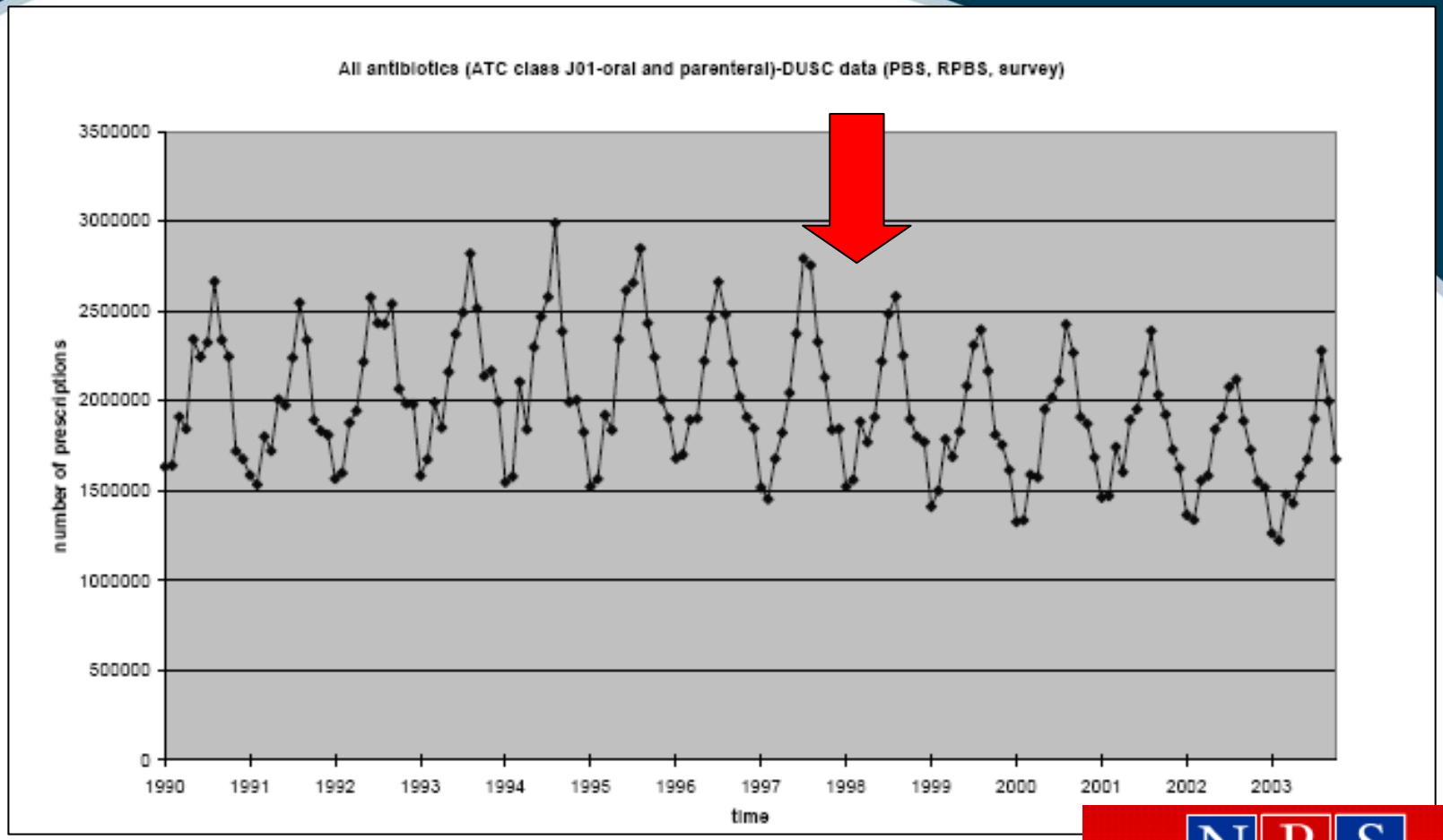
1. Pain relief may be the most effective thing to do. Take paracetamol or aspirin (for adults). Check the package for dosing instructions.
2. Some people find sucking a lozenge or ice is soothing.

Practice stamp

NPS
National Prescribing Service Limited
Level 7, 418A Elizabeth Street, Surry Hills 2010
Phone: 02 8217 8700

This information sheet may be copied for patient use.
Adapted with permission from Professor Chris Del Mar, University of Queensland. April 2002.

Evaluation: antibiotic use is slowly declining



National Prescribing Service Limited

Australia–China Export

中澳卫生与艾滋病项目

编号：CFHSS080049

中澳卫生与艾滋病项目（CAHHF）

项目活动意向申请表

申报日期：2008 年 1 月 30 日

1 拟申请项目名称		Establishment of the National Rational Drug Use Policy Implementing System in China						
2 申请单位	名称	DMA, MoH						
	地址	北京市西城区西直门外南路 1 号，100044，中国						
3 法人代表	姓名	王　羽	电话	010-68792204	传真	010-68792513	电邮	mohyzsylc@163.com
4 项目负责人	姓名	张宗久 赵明钢	电话	010-68792204 010-68792209	传真	010-68792513	电邮	mohyzsylc@163.com
5 拟合作的中外机构	Australia National Prescribing Service Limited (NPS), share experiences of NPS in promoting quality use of medicines, and implementing National Medicines Policy. WHO China Office, use the tools developed and advocated by WHO to p The MoH Hospital Management Institute will take care of the routine pr							
6 项目覆盖地区及时	Central level and some selected provinces； Time period: 2008-2009							

NPS
National Prescribing Service Limited

Relevance to E-Health

- Australian medicinal drug policy is highly regarded.
- We are actively exporting and localising these concepts internationally.
- If only we could get our E-Health act together we could also export and localise relevant software and services.

Goals of medicinal drug policy

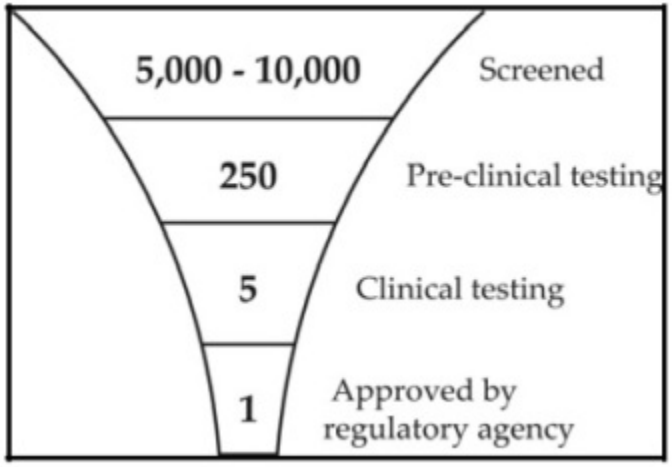
1. Medicines of high quality, safety and efficacy

2. Equitable access to necessary medicines

3. Quality use of medicines

4. A viable & responsible local pharmaceutical industry

Viable industry



Pharmacia&Upjohn

gsk GlaxoSmithKline

SB SmithKline Beecham

- Innovation has become more expensive, difficult and time-consuming.
- Drug evaluation and regulation has become more lengthy and more rigorous.
- Companies are merging in order to achieve critical research mass.

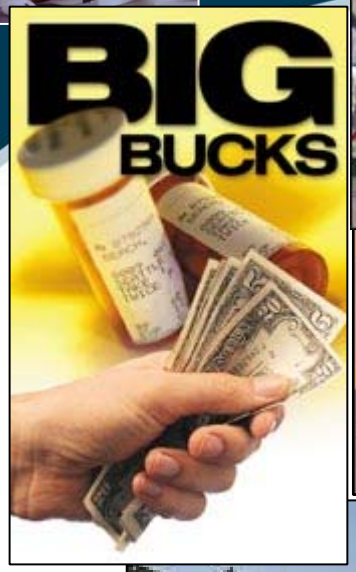
Viable industry requirements

- IP protection.
- Stable policy setting.
- Appropriate but not excessive regulation.
- Skilled health labour force.
- Incentives for appropriate research and development (e.g. Medical Innovation Prize Fund)
  - recognising that the profit motive will not produce research into neglected diseases in developing countries.

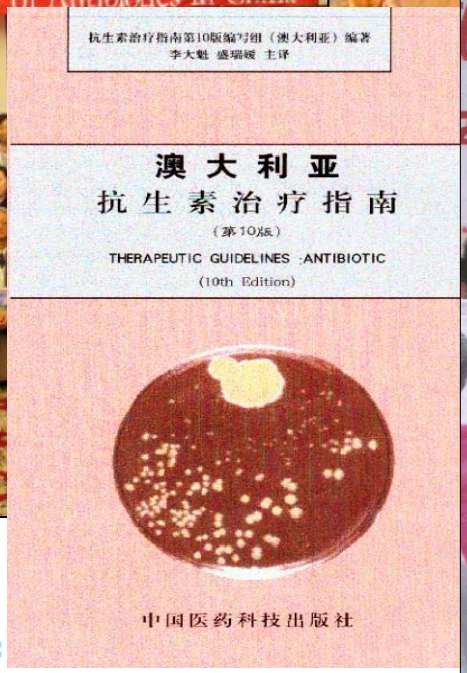
Conclusions

- Global economic growth is providing greater resources for the purchase of medicinal drugs (and other health services).
- However, market forces do not assure people affordable access to essential drugs of adequate quality nor do they guarantee that drugs are used wisely.
- As a consequence, there is much interest in innovative policy that make markets more responsive to health needs.
- There are many similarities between good medicines policy and E-Health policy.

All counties have the same problem



All are interested in solutions



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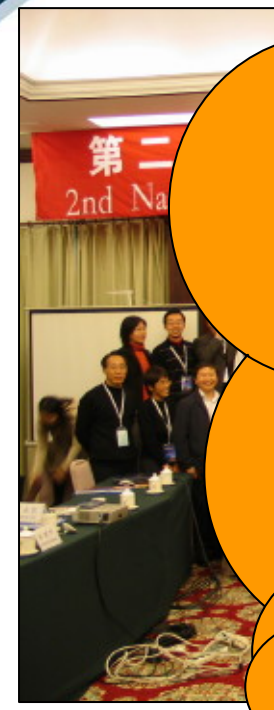
All can learn from each other!



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