Medicines policy in the era of neoliberal globalisation

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October 2017

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Purpose and outline

- Review the main policy challenges associated with the development, production, distribution and use of pharmaceuticals
- Review some background necessary to analysing these main policy problems
- Locate the politics of medicines policy within the broader context of neoliberal globalisation
- Explore policy directions for medicines policy reform
  - industry specific institutional reform
  - broader global governance reforms addressing the broader contextual issues

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Achievements

- Development (innovation, evaluation, prioritised)
  - antivirals
  - anticancer
  - biologicals
  - molecular drug design
  - genomics
- Production & distribution (quality, safety and efficacy)
  - high level marketing approval regulation (rich world)
  - effective regulation of substandard medicines (rich world)
  - speed of translation
- Affordable access (procurement, price, supply)
  - universal health cover (for some)
  - generic manufacturing
  - use of TRIPS flexibilities
- Quality use (information, promotion, prescribing, utilisation, review, feedback)
  - evidence based clinical guidelines
  - public agencies for professional and consumer education

3

Continuing problems

- Price barriers to access
- Procurement / distribution barriers to access
- Falsified and substandard medicines
- Post-approval emergence of safety issues
- Inappropriate use
- Skewed R&D investment

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Price barriers to accessing medicines (and health care)

- Impact
  - egregious prices
  - systemic failure to access care
  - catastrophic health care expenditure
- Causes
  - real costs of drug development and production
  - poverty / income inequality
  - weak or absent social protection
  - price gouging associated with IP monopoly
  - structured dependence on drug sales to support providers (China)
- Necessary background
  - drug development
  - intellectual property and medicines
  - financing access to medicines

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Table 2. Mean Incidence of Non-access to Prescribed Medicines and Catastrophic Expenditure for Medicines (Figures in %). Jung & Kwon(2015)

	Access to medicines	Catastrophic expenditure (threshold)		
Country	Nonaccess	-15%	-25%	-40%
Burkina Faso	7.6	69.5	55.9	41.7
Bangladesh	11.3	69.9	52.5	34.7
Brazil	12.6	52.9	33.4	16.8
China	1.8	52.9	34.5	19.8
Congo	23.5	67.4	48.3	30.6
Dominican Rep	15.9	69.9	53.8	36.5
Ecuador	15.5	73.3	54.6	32.3
Ethiopia	12.2	63.8	40.5	22.6
Ghana	6.6	50.2	33.9	19.3
Guatemala	7.4	76.9	61.1	43.5
India	9.8	64.5	46	31.4
Kenya	15.3	45.1	30.3	18.6
Sri Lanka	5.4	58.5	33.7	18.9
Morocco	10.6	54.4	34.3	16.5
Mexico	3.9	76.8	60.6	42.3
Mali	6.2	69.8	62.2	53.6
Mauritania	8.5	69	56.3	46.7
Mauritius	0.9	31.2	12.9	4.7

	Access to medicines	Catastrophic expenditure (threshold)		
Country	Nonaccess	-15%	-25%	-40%
Malawi	9.8	45.6	30.1	20
Malaysia	2.3	19.9	9	4.3
Nepal	2.8	66.7	48.4	32.1
Pakistan	9.2	69.4	48.6	29.8
Philippines	18.9	57.5	39	23.1
Paraguay	5.6	54.4	38.3	24.6
Russia	26.7	47.5	31.2	18.5
Senegal	14.8	60.1	42	27.2
Swaziland	6.7	28.6	18.1	11.8
Chad	25	68.6	53.7	40.4
Tunisia	15.3	64.1	41.8	23.4
Ukraine	28.7	56.3	36.9	21.6
Uruguay	5.4	29.2	12.5	5.4
Viet Nam	5.5	49	28.3	14.8
South Africa	13.3	41.2	26	20.3
Zambia	17.5	37.3	25.4	17.9
Zimbabwe	12.9	44.9	31.5	19.4
Total	9.2	60.1	42.6	27.5

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Treatment Action Campaign in South Africa

- 1997 South Africa passes a new law for the procurement of medicines; sourcing brand name drugs internationally through cheapest supplier (parallel importation)
- Feb 18, 1998 39 drug makers sued South Africa arguing that the law contravened international trade agreements
- 1997-1999. Continuing pressure from US Govt on SA Govt
- 1999. ACT UP dogs Gore campaign over access and IP (and pressure on SA); September 1999 US Govt starts to back off
- 2001 Medicins Sans Frontiers petition against the lawsuit collects 250,000 signatures
- March 6, 2001 TAC granted 'friend of court' status
- April 18, Pharma seeks adjournment (need to do more work)
- April 19, 2001 companies withdraw their lawsuit and agreed to pay the government's legal costs
- April 2001: WHO meeting on Access: differential pricing
- Dec 2001: WTO at Doha reaffirms legitimacy of compulsory licensing

Prices of AIDS medicines depend on whether national patent laws facilitate entry of generic manufacturers

- Efavirenz 600mg (innovator, 2007)
  - Guatemala (LMIC, 0.8%): **$237** per PY
  - El Salvador (LMIC, 0.8%): **$665**
- Lopinavir/ritonavir 133/33mg (innovator, 2007)
  - Burundi (LIC, 2.0%): **$504** per PY
  - Benin (LIC, 1.5%): **$1,051** per PY
- Lamivudine/zidovudine 150/300mg (generic, 2007)
  - Congo (LMIC, 3.5%): **$99** per PY
  - Cameroon (LMIC, 5.1%): **$210** per PY

Wirtz et al 2009

Country (company)	Active Pharmaceutical Ingredient (dosage)	Medical use	Price per Unit (in Jordanian dinars at prevailing exchange rate)	Jordan price compared to Egyptian price
Egypt (local generics manufacturer)	Metformin (850 mg)	Anti-diabetic	.02	800%
Jordan (Merck)	Metformin (500 mg)		.16	
Egypt (local generics manufacturer)	Atenolol (100 mg)	Anti-hypertensive	.03	367%
Jordan (Kleva)	Atenolol (100 mg)		.11	
Egypt (local generics manufacturer)	Rosiglitazone maleate (4 mg)	Anti-diabetic	.40	167%
Jordan (Glaxo SmithKline)	Rosiglitazone maleate (2 mg)		.67	
Egypt (local generics manufacturer)	Simvastatin (20 mg)	Anti-hyperlipidemic	.452	498%
Jordan (Merck)	Simvastatin (20 mg)		2.25	
Egypt (local generics manufacturer)	Ramipril	Anti-hypertensive	.14	557%
Jordan (Sanofi-Aventis)	Ramipril		.78	

Source: Jordan and Egypt Ministries of Health (2006)

Relative prices between medicines with no generic competition in Jordan (due to enforcement of data exclusivity) and the price of the lowest-priced generic equivalent in Egypt

Oxfam International 2007

Procurement / distribution barriers to access

- Impact
  - stock outs
  - essential medicines unavailable (injectables, paediatrics, chemotherapeutics)
  - vaccine shortages
- Causes
  - unprofitable lines (price control, competing drugs more profitable, low volumes)
  - chaotic procurement systems (including corruption)
  - costs of development and limits on production (esp vaccines)
- Necessary background
  - industry structure
  - financing access to medicines

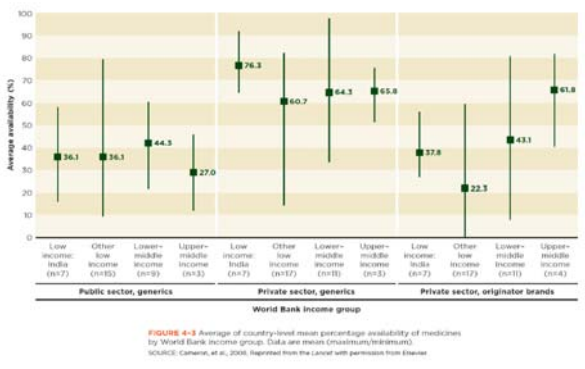


FIGURE 4-3 Average of country-level mean percentage availability of medicines by World Bank income group. Data are mean (maximum/minimum).

SOURCE: Cameron, et al., 2008. Reprinted from the Lancet with permission from Elsevier.

WHO (2015)

- … medicines likely to be in short supply are products that are mostly old, off-patent, difficult to formulate, have a tightly-defined shelf life or few manufacturers.
- reasons for shortages in production … include: difficulties in acquiring raw materials, manufacturing problems and fragmented markets.
- supply systems … poor availability and quality of data on actual demand; inadequate management practices in procurement and the supply chain, … large tender contracts that do not sufficiently define quality standards but whose sole emphasis is on obtaining the lowest prices; and too small profit margins for manufacturers
- Benzathine penicillin, for example, has been in chronic short supply for several years because of problems with manufacturing and thus the quality of the product, lack of consistent demand, and a decrease in indications for its use and a relatively low price.

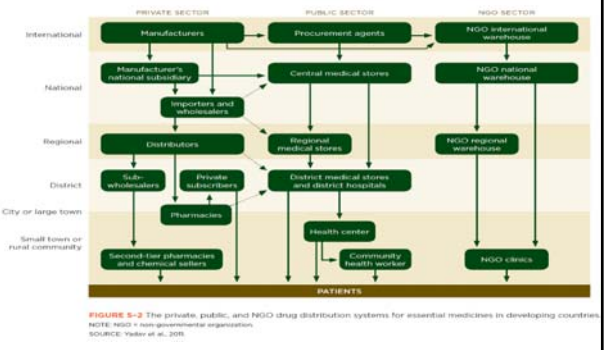


FIGURE 5–2 The private, public, and NGO drug distribution systems for essential medicines in developing countries.
NOTE: NGO = non-governmental organization.
SOURCE: Yadav et al., 2011.

Falsified and substandard medicines

- Impact
  - treatment failure
  - consumer fraud
- Causes
  - high prices for real drugs
  - access barriers to decent health care
  - weak regulation
- Necessary background
  - drug development
  - marketing approval
  - struggles over medicines regulation

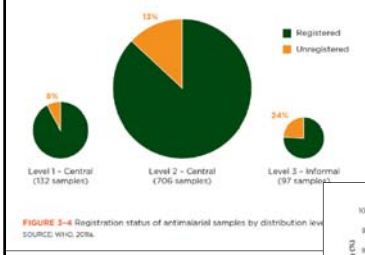
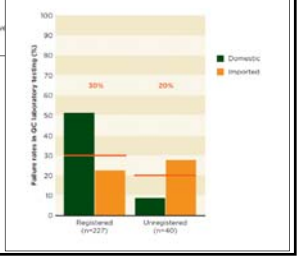


FIGURE 3–4 Registration status of antimalarial samples by distribution level.
SOURCE: WHO, 2008a.

Antimalarial drug samples collected (from central stores, licensed outlets, and unlicensed markets) by MRAs in six African countries (Cameroon, Ethiopia, Ghana, Kenya, Nigeria, and Tanzania). WHO 2008



WHO (2017)

"50% of all reports of substandard and falsified medicines received by the WHO Global Alert system are from Sub-Saharan Africa, and 80% of these are for essential medicines like anti-malarials and antibiotics."

Pharmaceutical Security Institute (OSI) Ranking of seizures or detections by country 2011

Country	Incidents
1 China	279
2 United States	141
3 Japan	79
4 Germany	62
5 Pakistan	61
5 Peru	61
7 Colombia	59
8 United Kingdom	56
9 South Korea	47
10 Brazil	45
10 Russia	45
12 Taiwan	44

From Kubic 2012, quoted in IOM (Buckley & Gostin) 2013. Reports from member corporations

TABLE 4–3 Top Countries for Arrests, 2011

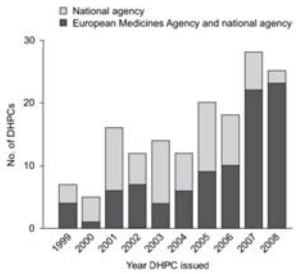
	Country	POS	Trans	Dist	Mfg	Theft	Unk	Total
1	China	74	3	92	120	0	110	**399**
2	Brazil	36	74	50	2	1	0	**163**
3	United States	47	1	62	0	1	1	**112**
4	Colombia	4	10	30	7	0	3	**54**
4	India	22	1	3	28	0	0	**54**
6	Pakistan	3	0	1	47	0	0	**51**
7	Thailand	37	0	3	10	0	0	**50**
8	South Korea	42	1	1	4	0	0	**48**
9	Israel	19	4	0	0	0	20	**43**
10	Poland	3	1	16	0	0	17	**37**
11	Spain	0	0	27	0	0	0	**27**

NOTES: Dist = distributing; Mfg = manufacturing; POS = point of sale; Trans = transporting; Unk = unknown
SOURCE: Kubic, 2012

Post-approval emergence of safety issues

- Impact
  - thalidomide and other disasters
- Causes
  - inadequate pre-marketing evaluation
  - weak post-approval monitoring
- Necessary background
  - marketing approval
  - post-approval pharmacovigilance

Safety events in Netherlands 1999-2009



- 157 DHPCs
- 112 active substances
- most within 3 years
- in 10 cases drug withdrawn (cardiotoxicity most common cause)

DHPC – direct health professional communication

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Inappropriate use

- Impact
  - over use
  - wrong treatment
  - inadequate treatment
- Causes
  - doctors' lack of information
  - doctors' lack of commitment to evidence based practice
  - aggressive marketing
  - weak regulation
  - consumer pressure
- Necessary background
  - medicines promotion; principles, precedents and politics
  - professional education
  - struggles over medicines regulation
  - community attitudes and expectations

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WHO (2002)

- Worldwide more than 50% of all medicines are prescribed, dispensed, or sold inappropriately, while 50% of patients fail to take them correctly.
- Common types of irrational medicine use are:
  - the use of too many medicines per patient (polypharmacy);
  - inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections;
  - over-use of injections when oral formulations would be more appropriate;
  - failure to prescribe in accordance with clinical guidelines;
  - inappropriate self-medication, often of prescription only medicines.

WHO (2002). Promoting Rational Use of Medicines: Core Components. WHO Policy Perspectives on Medicines. Geneva, World Health Organization

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Inappropriate prescribing for the elderly

- Brazil (60+ years, discharged from tertiary hospital)
  - 13.9% potentially inappropriate medications
  - 39.1% potential prescribing omissions
- Los Angeles (400 elderly African Americans)
  - 70% potentially inappropriate medications
  - 27% taking at least one medication classified as "Avoid"
- US Veterans Health Administration (older adults receiving OP care)
  - 12.3% potentially inappropriate prescriptions

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Inappropriate antibiotic use (WHO, 2005)

- In industrialized countries, around 80-90% of antibiotic use for humans occurs in the community
  - at least half of this is based on incorrect indications, mostly viral infections
  - contributing to widening threat of resistance
- Extensive use of antibiotics in livestock production contribute to spread of resistance
- Antimicrobial resistance plus reduced R&D threatens a 'post-antibiotic era'

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R&D investment distortions

- Impact
  - *lack of research* on antibiotics and 'neglected diseases'
  - *innovation focus* on 'block busters' for chronic disease
- Causes
  - R&D investment driven solely by expectations of profit
- Necessary background
  - drug development
  - regulatory standards and harmonisation

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Antibiotic development: the empty pipeline

- Antimicrobial resistance plus reduced investment threatens 'post-antibiotic era'
- Investments in antibiotics compete with drugs for musculoskeletal and neurological diseases with 10 or 15 times greater 'net present value' (the present value of future revenues)
- By 1991, most large pharmaceutical companies were reducing the funding of antibiotic research programmes because of the unfavourable financial prospects

WHO (2005)

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Lack of investment in drugs for neglected diseases

- Pedrique et al. (2013) "The drug and vaccine landscape for neglected diseases (2000-11): a systematic assessment."
  - 850 new therapeutic products registered in 2000—11,
  - 37 (4%) were indicated for neglected diseases (25 products with a new indication or formulation and eight vaccines or biological products)
  - only four new chemical entities were approved for neglected diseases (three for malaria, one for diarrhoeal disease)
    - 1% of the 336 new chemical entities approved during the study period.
  - Of 148,445 clinical trials registered in Dec 31, 2011, only 2016 (1%) were for neglected diseases.
- Pécoul et al (1999)
  - Of 1,233 new drugs that reached the market between 1975 and 1997 only 13 products were approved specifically for tropical diseases

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TABLE 1.4 WORLD PHARMACEUTICAL MARKET BY REGION (US$ BILLION, EX-MANUFACTURER PRICES)

REGION	2004	2005	GLOBAL SHARE OF SALES 2005 (%)
North America	249.0	268.8	44.4
Europe	169.2	180.4	29.8
Japan	66.1	69.3	11.4
Oceania	7.1	7.7	1.3
CIS[a]	4.2	5.0	0.8
South-east Asia	25.3	28.8	4.6
Latin America	24.4	26.6	4.4
Indian subcontinent	6.6	7.2	1.2
Africa	6.3	6.7	1.1
Middle East	4.7	4.9	0.8
Total world market	**562.9**	**605.4**	**100.0**

[a] Commonwealth of Independent States.

Source: reference *(43)*.

85%

WHO Commission on IP, Innovation and Public Health (2006)

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Necessary background

- Industry structure
  - corporate structures
  - value chains, business strategy
  - national interest
  - politics and debates
- Drug development
  - academia, companies & countries
  - costs of drug development
  - sources and sinks; patterns and trends
  - politics and debates
- Marketing approval
  - regulatory standards (and harmonisation)
  - pre-approval evaluation
  - post-approval pharmacovigilance
  - politics and debates
- Medicines promotion
  - corporate practice
  - community attitudes and expectations regarding medicines
  - regulation: principles and precedents
  - politics and debates
- Financing access to medicines
  - medicines access financing: principles and precedents
  - bulk purchasing, procurement, 'community service obligation'
  - politics and debates
- Intellectual property and medicines
  - investment, prices, access
  - regulatory structures: national legislation and trade agreements
  - politics and debates
    - IMPACT and the 'counterfeit' saga

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Industry structure

- Size, wealth, power now
- History
- Corporate structures
- Value chains and business strategy
- Complex engagements with governments
- Politics and debates

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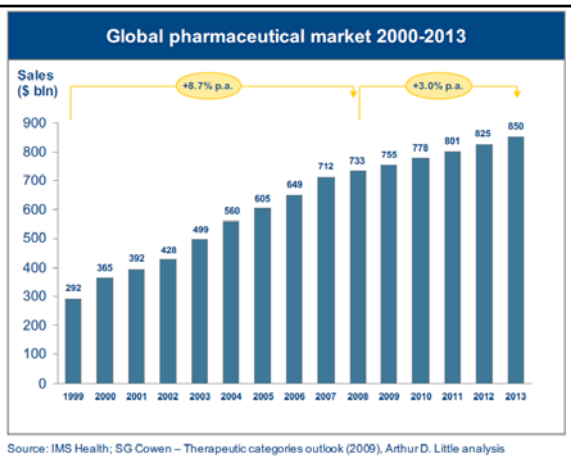

Source: IMS Health; SG Cowen – Therapeutic categories outlook (2009), Arthur D. Little analysis

Revenues, costs and profit

Sales	100%
Inputs	20-25%
Marketing & sales	25-35%
R&D	20-25%
Admin	8-10%
Finance	2-3%
Profit	20-27%

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Evolution of pharmaceutical industry

- Formative (1880s – 1940s)
  - emergence from chemical industry
  - 'proprietary' medicines
- Golden age (1940s-1970s)
  - rapid development of medical research
  - increasing number of NCEs (random screening)
  - expansion of marketing
- New partnerships (from 1970s)
  - emerging importance of biotechnology
  - targeted drug development
  - emerging generics industry
- Blockbusters (1990s – 2010)
  - rapid growth in sales (23%)
  - strengthened IP protection
  - expansion of social protection
- Uncertainty (2010 +)
  - expanded R&D but fewer approvals
  - social pooling monopsony power and cost-containment
  - resistance to further IP protection
  - tensions over investment priorities
  - big pharma engaging with emerging economies
  - promise of 'personalised medicine' and biologicals

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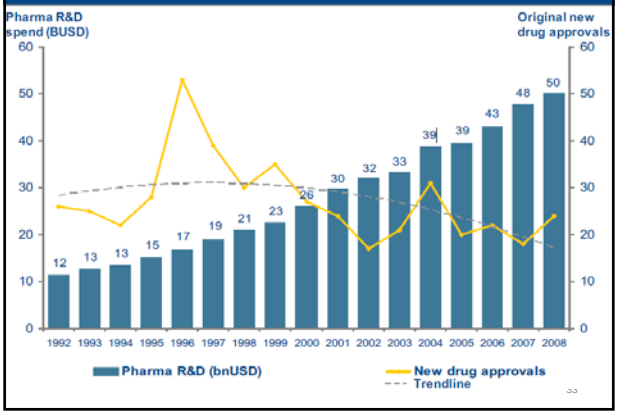
Pharma R&D spend and new drug approval 1992-2006



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Structural relationships and business models

- Changing structures and networks
  - academic spin-offs
  - role of venture capital and equity markets
  - mergers and acquisitions
  - research partnerships between large firms
  - emerging economies (India, Brazil, Thailand, China)
  - contract research organisations
- Business models
  - centralised R&D
  - contracting out API manufacturing
  - local finishing and packaging
  - role of generic manufacturing

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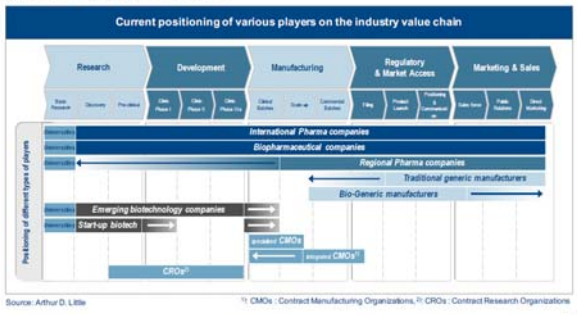
Arthur D Little

Changing business environment – Value chain

The pharmaceutical industry business models is increasingly modular : specialists capture some of the value



Source: Arthur D. Little

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Drug development

- Academia, companies & countries
- Costs of drug development
- Politics and debates

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Stages of drug development and marketing

- Research
  - basic research
  - discovery of new chemical entity (NCE)
  - pre-clinical studies (pharmacokinetics, efficacy, toxicity)
  - manufacturing
  - patenting
- Development: clinical trials
  - Phase 1 (safety)
  - Phase 2 (efficacy and side effects)
  - Phase 3 (therapeutic effectiveness, safety)
- Manufacturing
  - clinical batches
  - scale up
  - commercial batches
- Regulatory and market access
  - global strategy
  - regulatory filing
  - pricing and subsidies
  - launch
- Marketing and sales
  - sales force
  - public relations
  - direct marketing
- Post-approval surveillance (pharmacovigilance)

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Costs of drug development

- New cancer drug
  - DiMasi (2016)
    - $2.7b
  - Prasad and Mailankody (2017)
    - $800m
  - KEI (2017)
    - $40m
- Data on costs top secret
  - contribution of publicly funded research
  - tax expenditures
  - costs of clinical trials
- Development costs do not influence price
- Investment decisions
  - based on estimated revenues and
  - development costs
- Public debate re costs largely about IP protection

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Regulation

- International standards and norms
  - mutual recognition
  - International Conference of Medicines Regulatory Agencies
  - International Coordination and Harmonisation
  - International Nonproprietary Names
  - WHO guidelines and standards
- National
  - licensing of manufacturers and certification of foreign manufacture (GMP)
  - approval / notification of clinical trials
  - registration of medicines
    - pre-approval evaluation
    - post-approval pharmacovigilance
  - labelling and packaging
  - advertising and promotion
- Politics and debates
  - harmonisation

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Data for marketing approval

- Quality data
  - composition of the drug substance and the drug product
  - batch consistency
  - stability data
  - sterility data (if applicable)
  - the impurity content
- Nonclinical data
  - pharmacology data
  - toxicology data
- Clinical data
  - results of clinical trials
  - results of post-approval surveillance
- Risk management plan (pharmacovigilance)

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Pharmacovigilance

- Risk management plan
  - analysis (and review) of safety profile of drug
  - initial drug evaluation data for marketing approval
  - monitoring activities
    - routine
    - additional
  - risk minimisation activities
    - routine
    - additional

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Risk monitoring

- Routine
  - evaluation for approval
  - adverse event reporting
  - periodic update safety reports
  - identification and analysis of safety signals (eg WHO product alerts)
- Additional
  - clinical trials
  - post-authorisation safety studies
  - drug utilisation studies
  - patient registries
  - physician surveys
  - prescription event monitoring

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Risk minimisation

- Routine
  - product information
  - consumer medicine information
  - directions for use document
  - labelling, pack size and design
  - legal (prescription) status
- Additional
  - education programs
  - prescriber checklists
  - DHCP letters
  - controlled access programs
  - medical software alerts

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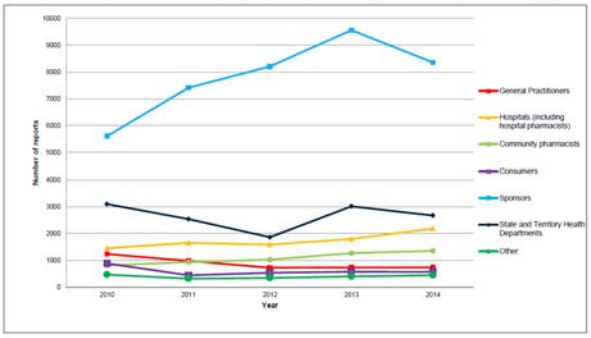
Volume of adverse event reports received by the TGA (2010-2014)



Pharmacovigilance - a regulator's perspective 30

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Example – lumiracoxib cancellation

- Lumiracoxib:
  - registered July 2004
  - COX-2 inhibitor, not the first in class
  - PBS subsidy August 2006
  - 60,000 users.
- Eight reports of serious hepatotoxicity, with two deaths and two transplants.
- Registration cancelled August 2007.
- Liver death (fatality or transplant) 1 in 15,000:
  - rule of 3: would need 45,000 in a trial
  - therefore, impossible to detect premarket
  - but a significant risk considering underlying disease, efficacy and availability of alternatives

Pharmacovigilance - a regulator's perspective 42

Medicines promotion

- Aggressive marketing of under-patent drugs standard practice
  - maximise revenues before patent expires
  - embed brand name familiarity to maintain price premium after patent expires
- Includes
  - public relations
  - advertising
  - direct marketing ('medical representatives')
- Spending 50-100% more than on R&D
- Benefits and risks
  - rapid translation of therapeutic advances into practice
  - encourages over-servicing and inappropriate prescribing
  - drives cost escalation
  - builds community expectations: 'a pill for every ill'
- WHO 'Ethical criteria'
- National regulatory norms
  - principles and precedents
- Politics and debates

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WHO: ethical criteria for drug promotion

- … claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste
- [promotional material] should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks
- The word "safe" should only be used if properly qualified. Comparison of products should be factual, fair and capable of substantiation.
- Promotional material should not be designed so as to disguise its real nature.
- Scientific and educational activities should not be deliberately used for promotional purposes.
- Advertisements to the general public … should not generally be permitted for prescription drugs or to promote drugs for certain serious conditions that can be treated only by qualified health practitioners.

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Common practices

- Advertising
- Public relations
- Medical detailing
- Advertisements within prescribing software
- Gifts (equipment, travel, accommodation, etc)
- Sponsored dinners, recreational events
- Conference sponsorship
- Journal support through advertising
- Sponsored research
- Sponsored clinical guidelines
- Consultancies and advisory boards
- Ghostwriting
- Support for patient associations
- Disease mongering (meetings, media, reports)

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Drug Promotion: Why the concern?

Drug giant forks out $65,000 on posh nosh for doctors
The Australian, July 21, 2006

- Pharmaceutical promotion selectively promotes the benefits of the latest and most expensive drugs.
- It provides minimal information about drug side-effects, contra-indications and opportunity costs.
- Cost-effective generic drugs and non-drug solutions are rarely promoted.

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BMJ 2003;326 (31 May)

"Pigs and reptiles"

- Some 80-95% of doctors regularly see drug reps despite evidence that their information is overly positive and prescribing habits are less appropriate as a result.
- Many doctors receive multiple gifts from drug companies every year, yet most doctors deny their influence despite considerable evidence to the contrary.

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However

- 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

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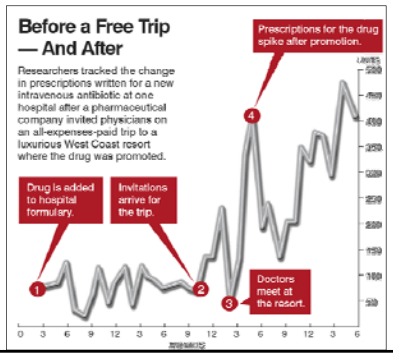
"Pigs and reptiles"



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Financing access to medicines

- Access to medicines: financing
  - commercial / social insurance
  - single payer public 'insurance'
  - subsidy programs
- Bundled care (medications as a cost) versus drug selling (medication profit as revenue stream)
- Value based pricing, price control, bulk purchasing, price auctions, 'community service obligation'
- Politics and debates

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Intellectual property and medicines

- Investment, prices, access
- History of IP and pharma
- Regulatory structures: national legislation and trade agreements
- Politics and debates
  - Trade agrements
  - TRIPS flexibilities and access to medicines
  - IMPACT and the 'counterfeit' saga
  - ACTA

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The politics of medicines in the context of neoliberal globalisation

- Global power and the transfer of value
  - transnational corporate power
  - international relations: imperial versus subaltern
  - race, gender, religion and class
- Corporate transnationalisation
  - mergers and aquisitions, concentration, monopoly
  - the global value chain
  - financialisation
    - banks & investment funds as beneficiaries from generous dividends
    - banks & investment funds supporting M&As
- The 1970s inflexion
  - threat of the NIEO and emerging economies
  - declining profits? Stagflation?
  - the focus on IP
- The corporate imperial complex globally
  - corporate engagement in policy making globally
  - multilateralism hobbled
    - WHO debates (TRIPS flexibilities, counterfeit and SFC)
    - ICH versus DRAs
    - ethical promotion
  - ambivalence regarding health care financing
    - yes to subsidies; no to restrictive regulation
  - the politics of 'trade' 'agreements'
    - loose IP standards and tight IP enforcement
    - investment protection
    - trade in services
- Corporate class alliances nationally
  - corporate engagement in policy making nationally
  - drug development, technology gifting and IP protection
  - regulatory capture / intimidation
    - ethical promotion
    - the counterfeit hare
  - impact on health care funding policies

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Global power and the transfer of value

- The corporate imperial complex
  - Pfizer and TRIPS
  - TRIPS plus in trade agreements
  - US Super 301
  - EU drug seizures
- The transfer of value
  - unconscionable prices for individuals and social pooling schemes
  - extreme global IP rules ensures tribute flows to a small number of net IP exporters, principally the US
  - barriers to technology transfer and local production, local research

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Corporate transnationalisation

- Mergers and acquisitions, partnerships, subcontracting
- The global value chain
  - R&D, clinical trials, API manufacture, local compounding and packaging, tax havens
- Financialisation
  - banks and investment funds supporting M&As and R&D
  - banks and investment funds as beneficiaries from generous dividends

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The 1970s inflexion

- Threat of the NIEO and emerging economies
  - the threat of the NIEO neutered by the rate hike of 1980, the debt trap and structural adjustment
- Threat to big pharma from Indian generics (and the 1970s patent law)
  - countered through TRIPS
- Developing country voices in WIPO and WHO leads to forum shifting … to GATT and trade
  - sanctions available under trade agreements linked to trade power

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The corporate imperial complex globally

- Corporate engagement in policy making globally; from international diplomacy to the 'multi-stakeholder partnership'
- Multilateralism hobbled
  - WHO debates (TRIPS flexibilities, counterfeit and SFC)
  - ICH versus ICDRAs
  - ethical promotion
- Corporate ambivalence regarding health care financing
  - yes to subsidies; no to cost control
- Corporate engagement in low tax extortion and tax avoidance / evasion
- The politics of 'trade' 'agreements'
  - loose IP standards and tight IP enforcement
  - investment protection and curtailing nation state sovereignty
  - trade in services (and the privatisation of health care and insurance)

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Corporate class alliances nationally

- Corporate engagement in policy making nationally (eg role of pharma in health care reform in the US)
- Public support for drug development linked to technology gifting and IP protection and open prices for drugs in health insurance (US)
- Regulatory capture / intimidation
  - ethical promotion
  - the counterfeit hare
  - lack of regulation of prescribing
- Corporate tax extortion

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Medicines policy reform: institutional reform

- Health systems strengthening
  - universal health cover including social pooling of the cost of real medicines (price barriers, falsified and substandard)
  - effective bulk purchasing, tight health system logistics, contract solutions to production and distribution shortfalls (procurement and distribution)
  - decent health care (inappr use, falsified and substandard)
- Delinking monopoly pricing and the funding of drug development; public funding of drug development (price barriers, falsified and substandard, skewed investment)
  - including as necessary, public funding of vaccine production, incl technology transfer (procurement and distribution)
- Strengthening national and regional medicines regulatory agencies (falsified and substandard)
  - Strengthened pharmacovigilance (late emergence)
  - Regulate and restrict corporate drug promotion incl (inappr use)
  - Closer monitoring of drug prescribing (inappr use)
- Invest in provision of independent advice; professionals (including clinical guidelines, academic detailing); consumers (including social marketing) (inappropriate use)

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Health systems strengthening

- Universal health cover including social pooling to cover the cost of medicines
- Effective bulk purchasing, tight health system logistics, contract solutions to production and distribution shortfalls
- Clinical governance including clinical guidelines and quality assurance

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Delinking and public funding of drug development

- Delinking monopoly pricing and the funding of drug development; public funding of drug development
  - including as necessary, public funding of vaccine production
  - including technology transfer
- Addressing the price barriers and investment distortion problems

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Strengthening medicines regulation

- Strengthening DRAs
  - strengthened pharmacovigilance
- Effective regulation of corporate drug promotion
- Closer monitoring of drug prescribing

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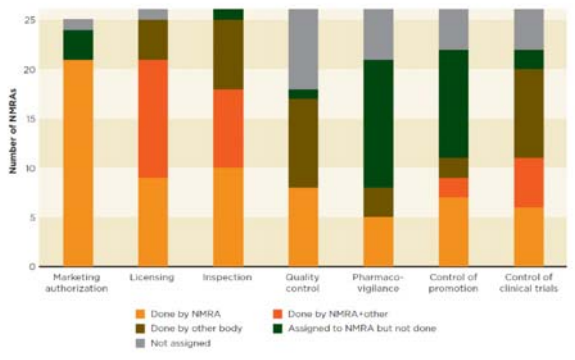

FIGURE 4-4 Number of sub-Saharan African countries out of 26 surveyed meeting the main functions of a regulatory authority.
NOTE: NMRA = National Medicines Regulatory Authority.
SOURCE: WHO, 2010a.

Independent advice

- Invest in provision of independent advice;
  - professionals (including clinical guidelines, academic detailing);
  - consumers (including social marketing) (inappropriate use)

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Independent information

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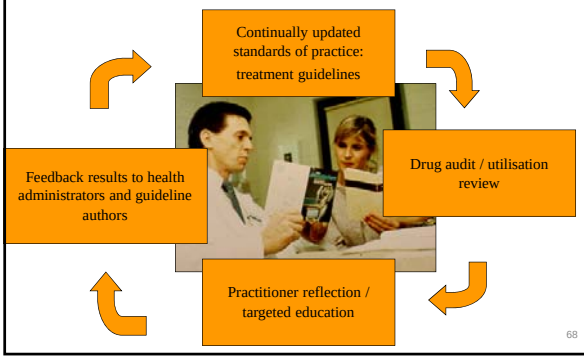
Quality Assurance Cycle



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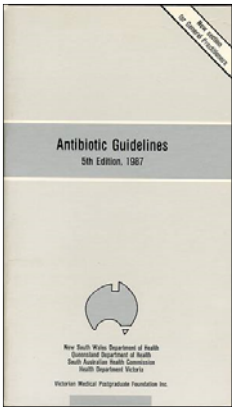
Antibiotic Guidelines



- Best practice recommendations concerning the treatment of choice for common clinical problems.
- Written by teams of national experts.
- Evidence based where possible.
- Regularly updated.
- Endorsed by Medical Associations, Colleges, etc.
- Used for medical education, problem look-up, drug audit and targeted educational campaigns.

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Guidelines evolution…

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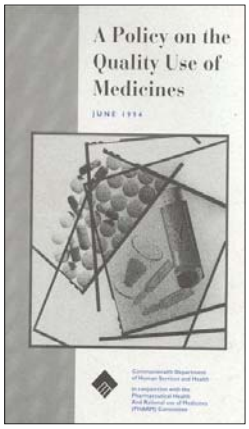
Quality Use of Medicines Policy



- Strategies
  - policy development and implementation
  - national facilitation and co-ordination (PHARM)
  - independent information
  - ethical promotion
  - education and training (NPS)
  - services and interventions (NPS)
  - evaluation

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Current challenge

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

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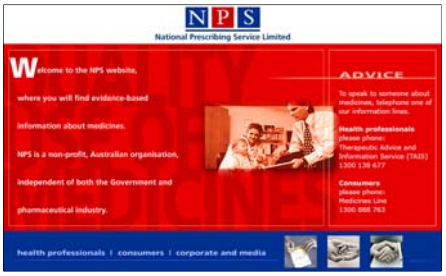
Ethical promotion

QUM: Services and interventions



- Core curriculum
- Academic detailing
- Campaigns
- Drug audits
- Case studies
- Advice and information
- Practice incentive payments

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

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NPS: Core curriculum

http://nps.unisa.edu.au/new/index.htm

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NPS: Academic detailing

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

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NPS: Consumer Campaigns

http://www.gottacold.com/

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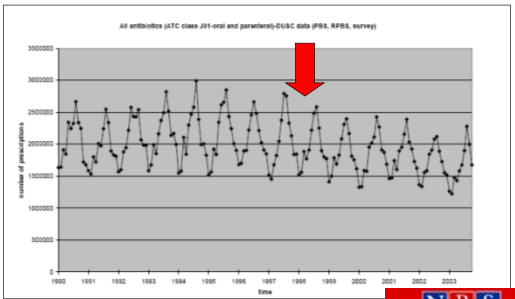
Results: antibiotics scripts 1990-2004



- The NPS initially received about $5 million per annum (for four years) in 1997/98.
- A evaluation of their first three years of operations suggested their activities achieved PBS savings of over $15 million per annum for a cost of $5 million per annum.
- Their budget has subsequently been increased and a consumer education moiety has been added.
- Spending money on RDU activities saves money by reducing inappropriate drug use.

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In hospitals: drug and therapeutics committees (DTCs)

- Select cost-effective drugs for the hospital formulary.
- Develop (or adapt) and implement standard treatment guidelines.
- Audit drug use to identify problems.
- Conduct interventions to improve drug use.
- Manage adverse drug reactions and medication errors.
- Educate staff about drug use issues, policies and decisions.

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Medicines policy in the era of neoliberal globalisation: addressing the institutional issues in ways which recognise and address the macro, global and longer term dynamics

- Mobilise for a fairer global trading and financial regime, including addressing tax avoidance by big pharma
- Engage with trade negotiations: resist extreme IP; defend the full use of TRIPS flexibilities; support for technology transfer and expansion of national drug manufacturing (addressing price barriers)
- Mobilise for national patent reform as appropriate (addressing price barriers)
- Mobilise for tighter regulation of TNCs
  - international (eg through HR treaty)
  - national (eg ETOs)
- Support multilateralism; democratise global health governance
  - support WHO in TRIPS flexibilities, strengthening OF DRAs, regulation of promotion
- Mobilise for health system strengthening (price barriers, falsified and substandard, procurement and distribution, inappropriate use)
- Reduce income inequality (part of addressing price barriers)

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