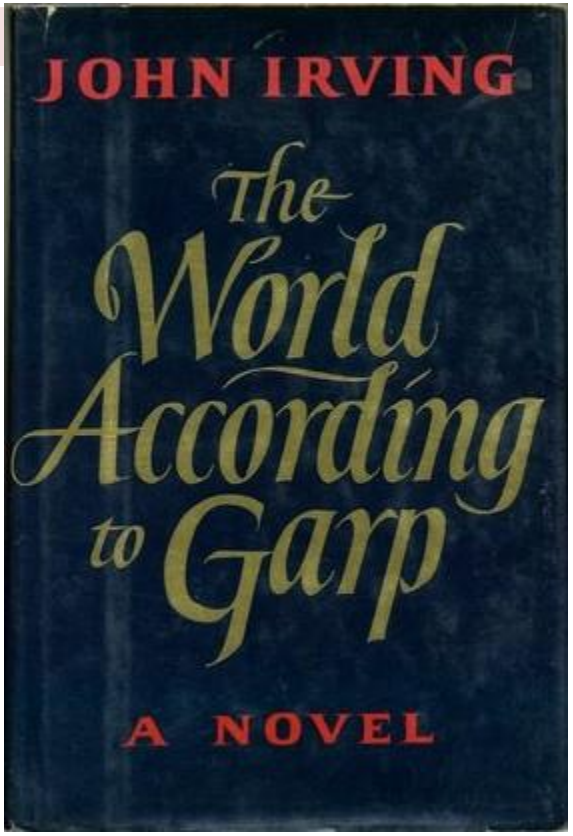
Pharmaceutical pricing and reimbursement policies: perspectives for the future

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

Andy Gray
Division of Pharmacology
Discipline of Pharmaceutical Sciences

Am I really here ….
at last?



Grillparzertorte

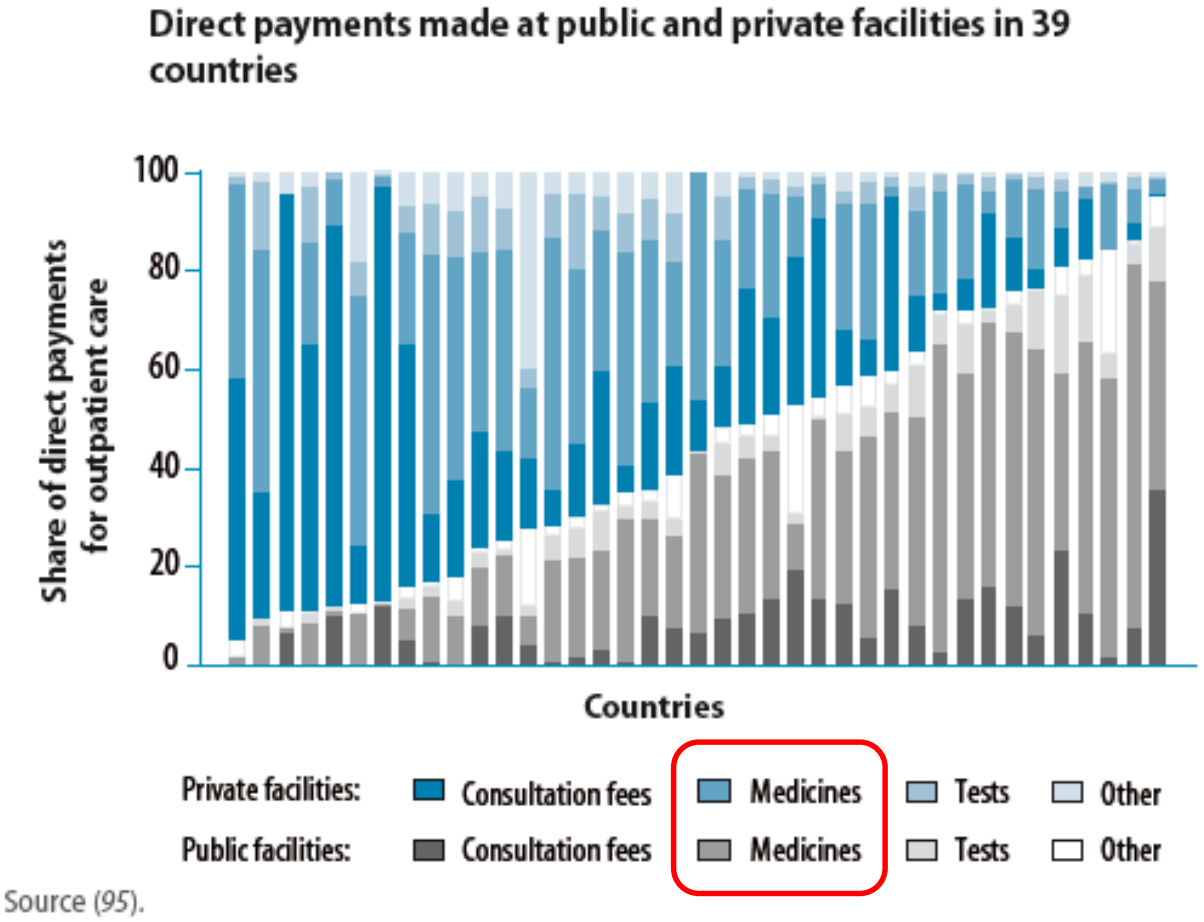
Outline

- Looking backwards – where have we come from, and why?
- The overwhelming demands of Universal Health Coverage (UHC) – all change
- South Africa as an exemplar
  - NDP 1996
  - Challenges, missteps and realignments
- The future – we're all in this together

Where have we come from, and why?

- Developing countries
  - Fragmented health systems
  - Public sector funded by the fiscus + donor + user fees
  - A national Essential Medicines List
  - Public sector procurement based on competitive bids (tender), largely of generics
  - Rational use assumed, based on guidelines
- Developed countries
  - National or social health insurance
  - Purchaser-provider split
  - Wide range of pricing interventions – generic policies, distribution chain price controls, co-pays (as a disincentive to overuse)
  - Reimbursement, perhaps informed by Health Technology Assessment (HTA)

But are we ignoring the similarities?



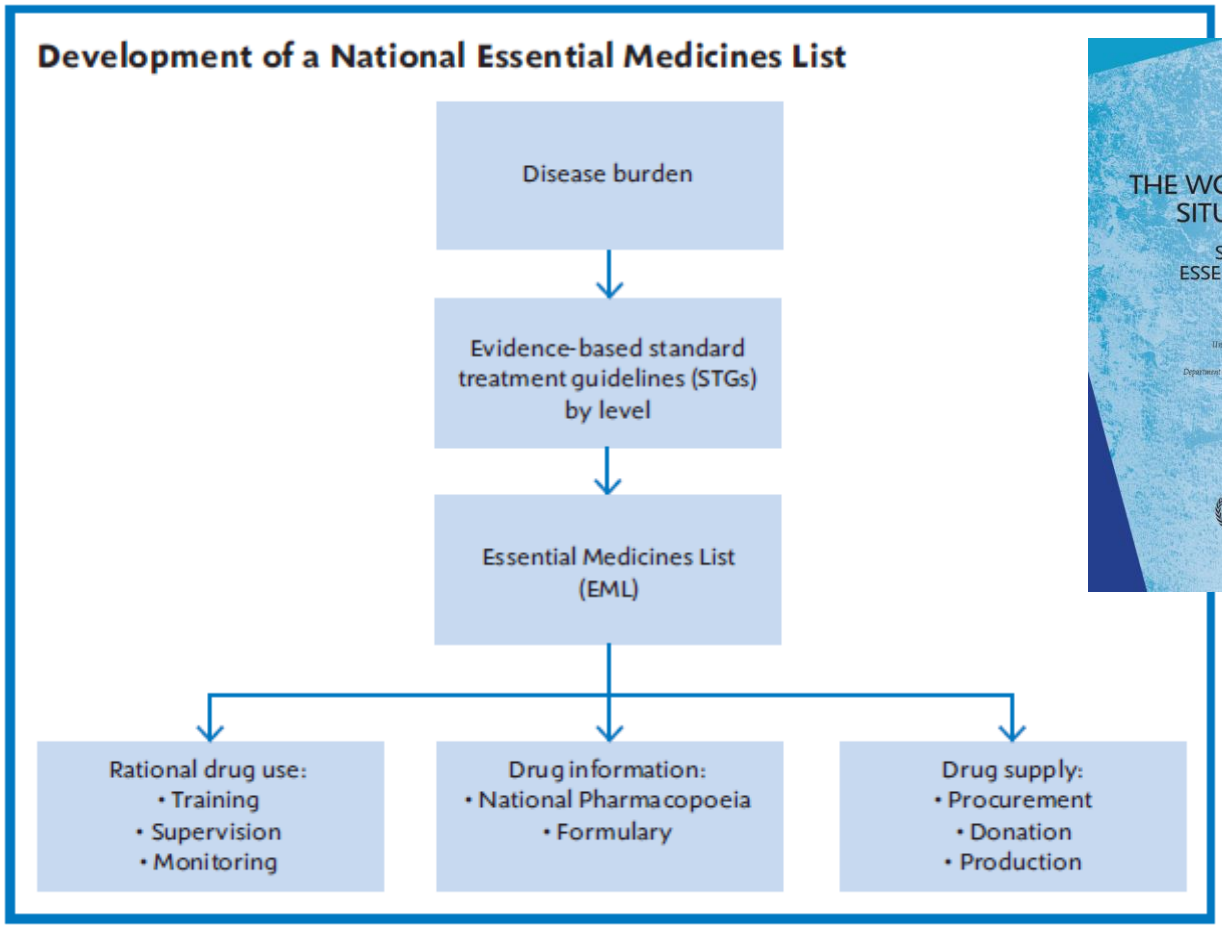
Source (*95*).

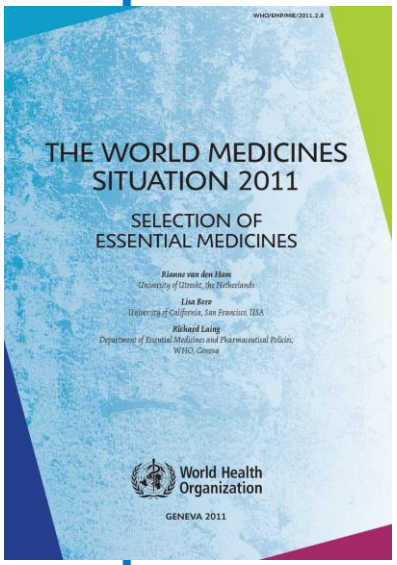
World Health Report 2010

And what of industrial policies…

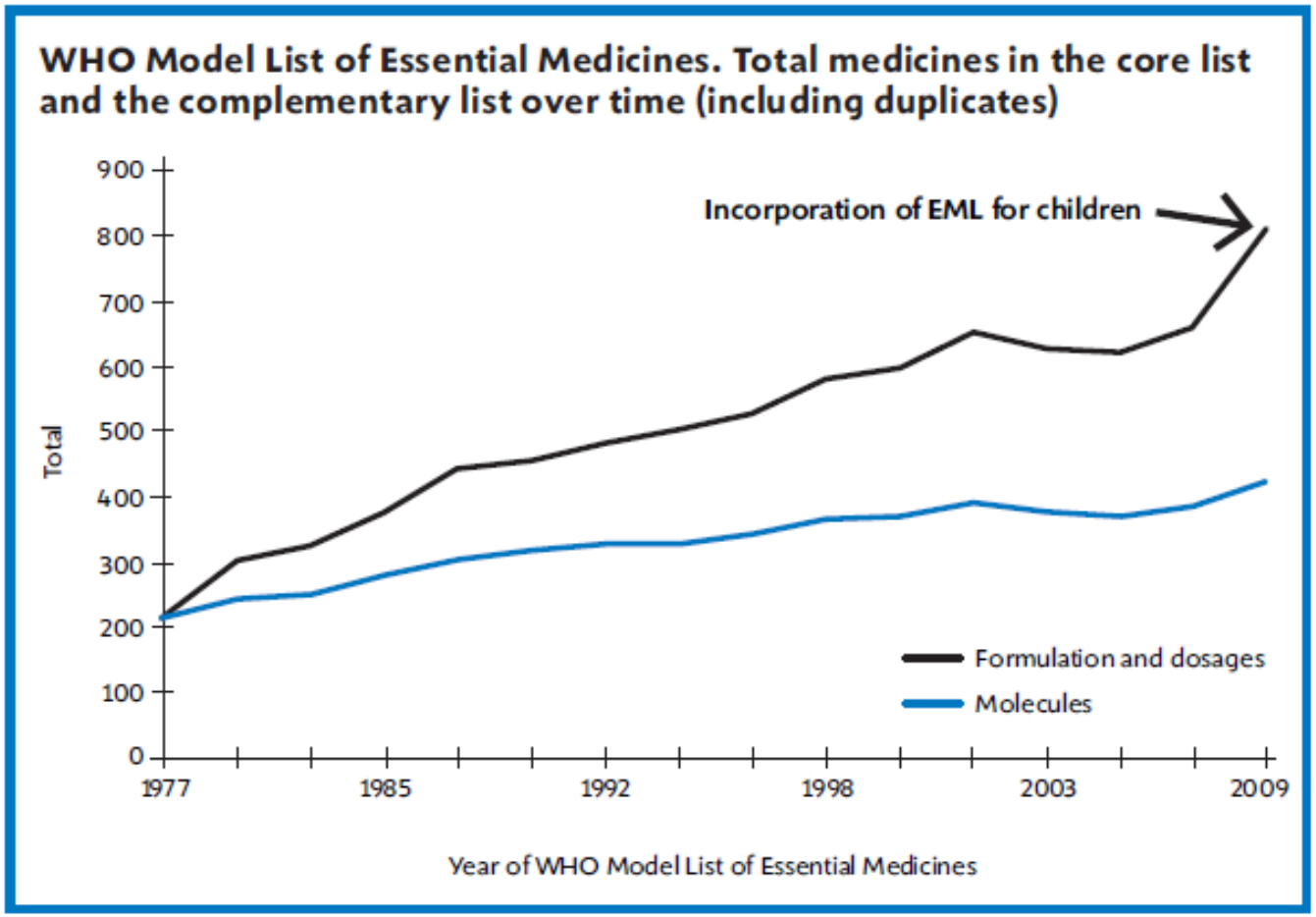
- Developing countries
  - Some nods to the need to stimulate local production capacity, but of subsidiary interest (or highly dependent on development partners)
  - Locally-relevant innovation delinked from pharmaceutical policies
- Developed countries
  - In some settings (but by no means all), a strong pro-industry stance
  - Innovation driven almost exclusively by the protection of intellectual property (IP)

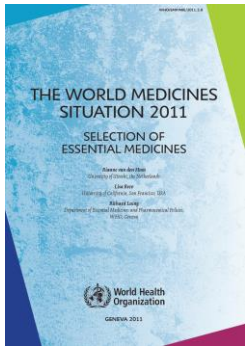
We all know this (in theory)





We have also watched this….





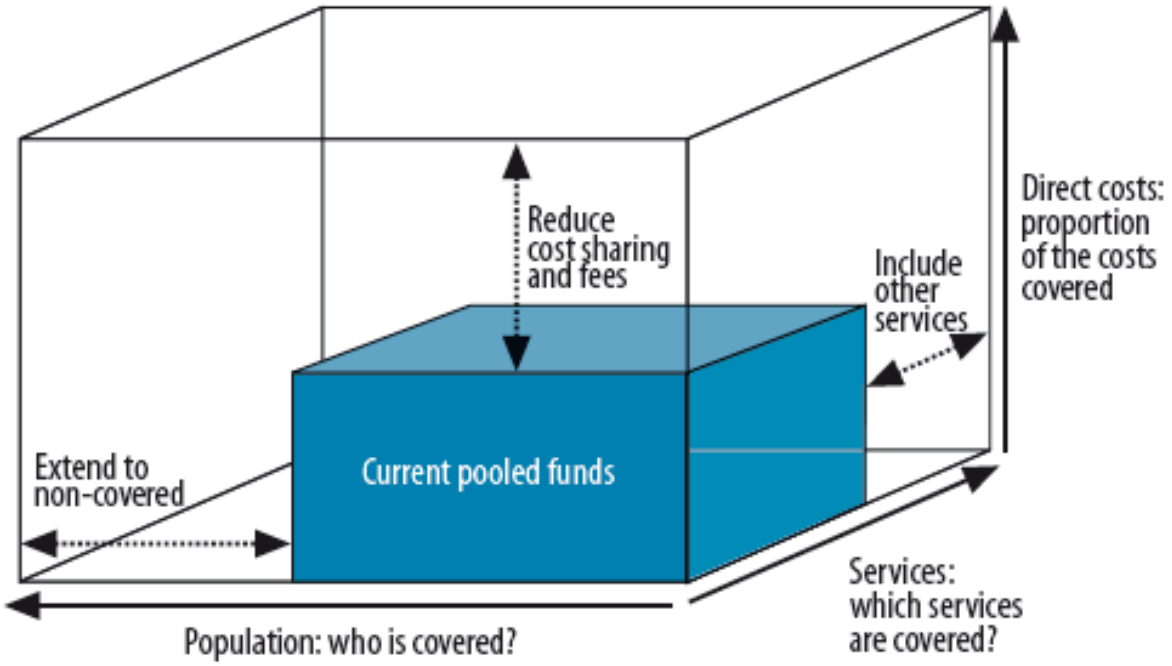
Details of national essential medicines lists by country income level

	Country income level[a]							
	Low (48)		Middle (73)		High (35)		Global (156)	
	yes/resp. countries	% yes	yes/resp. countries	% yes	yes/resp. countries	% yes	yes/resp. countries	% yes
Existence of national EML	48/48	100%	63/73	86%	23/34	68%	134/155	86%
Update of EML within last 5 years[b]	39/48	81%	54/73	74%	14/34	41%	107/155	69%
Use of EML in different sectors								
Public sector procurement	44/46	96%	59/65	91%	22/22[c]	100%	125/133	94%
Public insurance reimbursement[c]	14/40	35%	20/50[c]	40%	13/18[c]	72%	47/108[c]	44%
Private insurance reimbursement[c]	4/35	11%	6/49[c]	12%	2/8[c]	25%	12/92[c]	13%
Committee for EML medicines selection	38/44	86%	59/67	88%	19/19[c]	100%	116/130	89%
	Median [25th, 75th percentile]		Median [25th, 75th percentile]		Median [25th, 75th percentile]		Median [25th, 75th percentile]	
Number of medicines in EML	355		441		1706		397	
	[272,	384]	[350,	601]	[1143,	3272]	[334,	580]
	n=34		*n=52*		*n=8*[c]		*n=94*[c]	

[a] World Bank list

The challenge of UHC

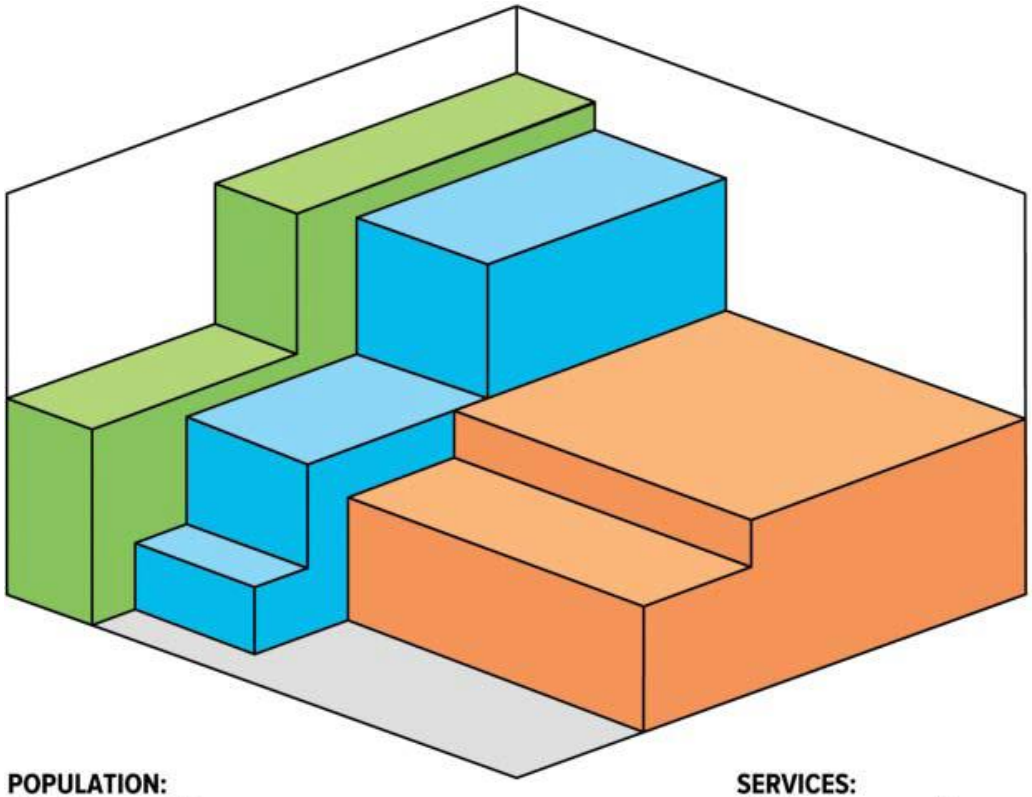
Three dimensions to consider when moving towards universal coverage



The World Health Report: health systems financing: the path to universal coverage. 2010

But don’t forget this …

Carefully….



Source: Authors

Health Systems & Reform, 1(1):22–27, 2015

ISSN: 2328-8604 print / 2328-8620 online
DOI: 10.1080/23288604.2014.995981

Taylor & Francis

Research Article

Disaggregating the Universal Coverage Cube: Putting Equity in the Picture

Marc J. Roberts[1,2], William C. Hsiao[1,2] and Michael R. Reich[1,*]
[1]Department of Global Health and Population; Harvard School of Public Health; Boston, MA USA
[2]Department of Health Policy and Management; Harvard School of Public Health; Boston, MA USA

Do we have the evidence?

Int J Clin Pharm
DOI 10.1007/s11096-015-0156-6

REVIEW ARTICLE

The relevance of systematic reviews on pharmaceutical policy to low- and middle-income countries

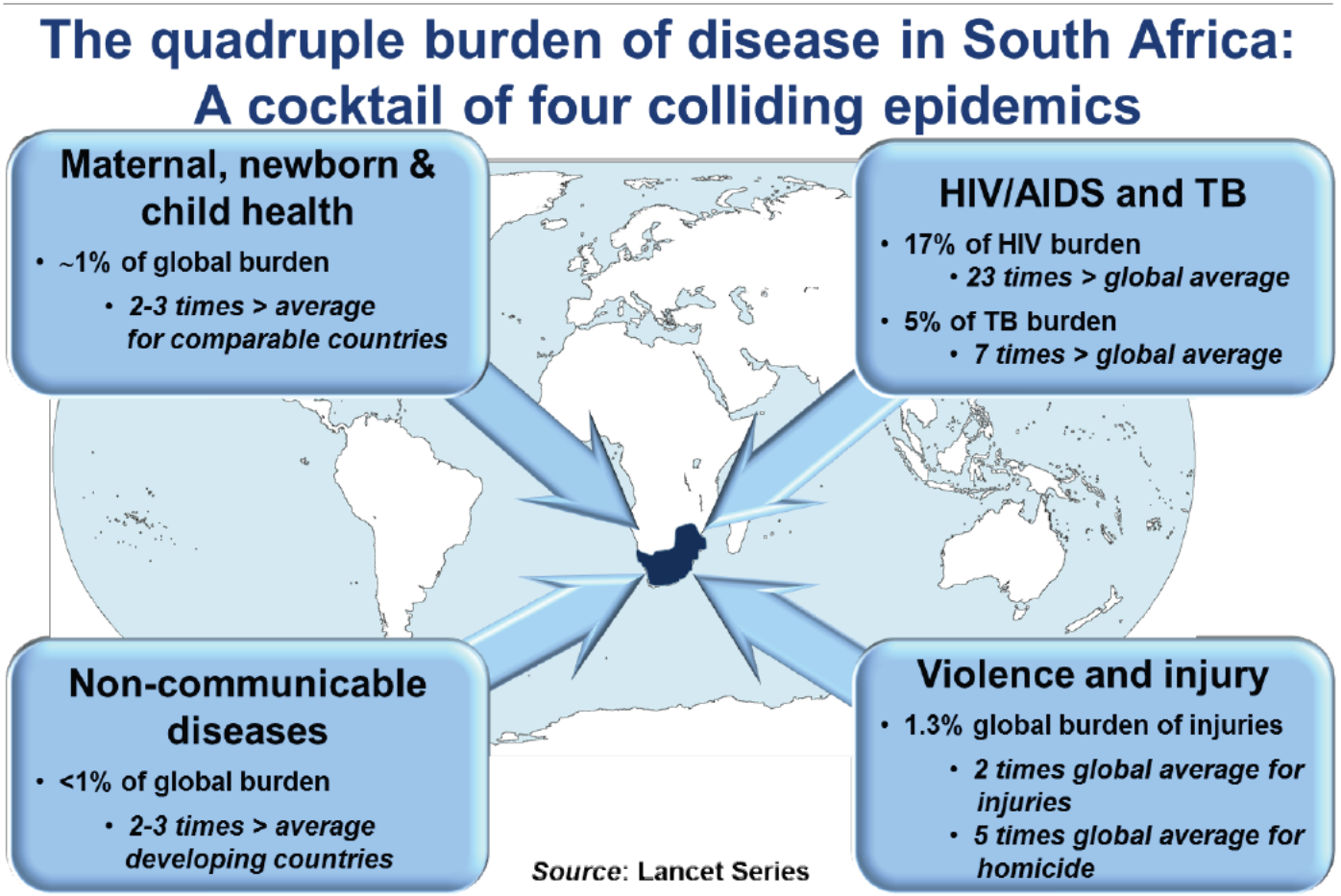
Andrew Lofts Gray[1] · Fatima Suleman[2]

Received: 9 December 2014 / Accepted: 29 June 2015

Unpacking the challenges of UHC

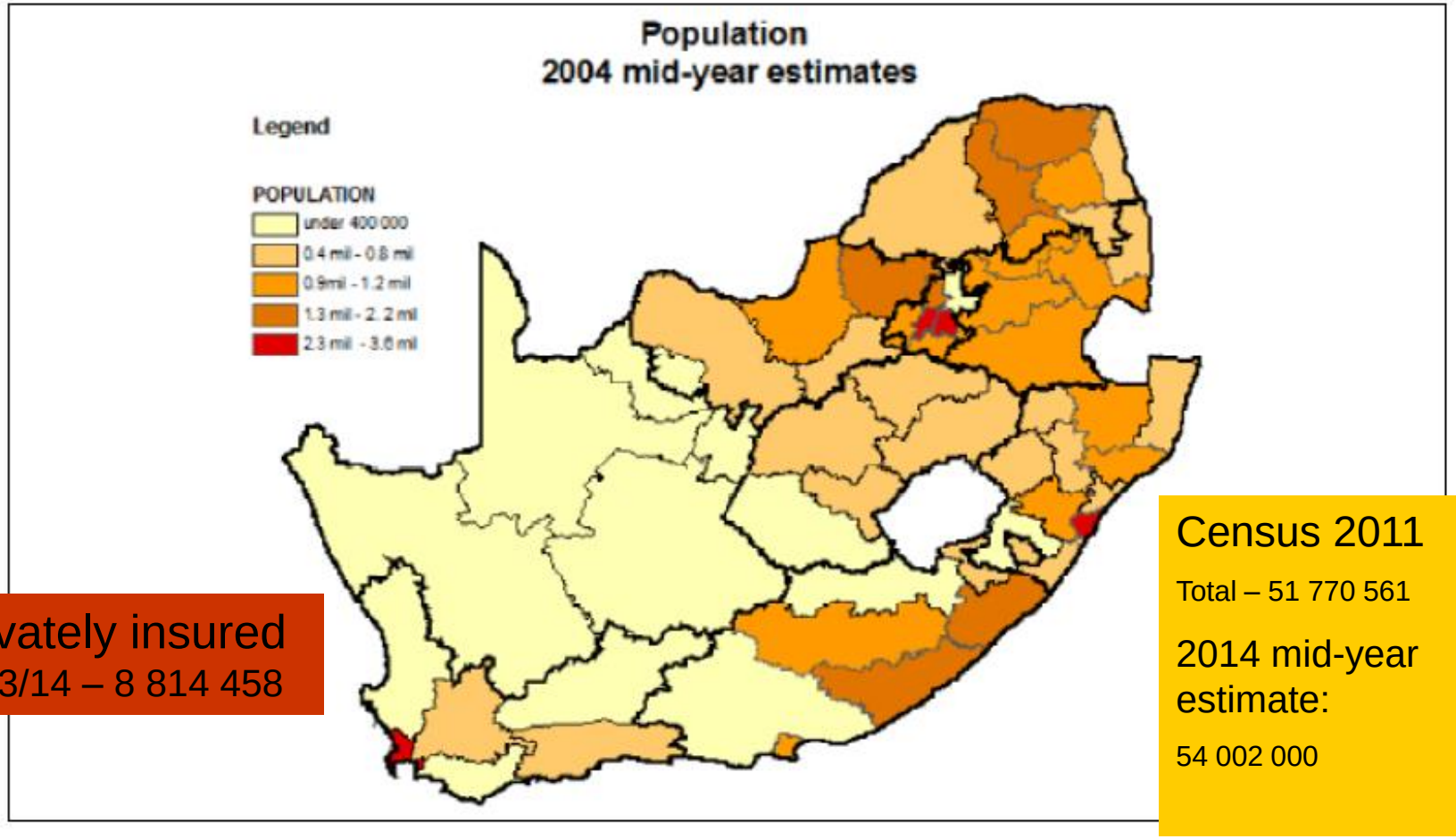
- a range of pharmaceutical pricing and reimbursement policies …
- that also stimulate necessary and appropriate innovation ...
- that ensure a responsible and stable pharmaceutical industry, in alignment with national and regional industrial policies …
- that are patient-centred and cognisant of human rights ...

South Africa – an examplar



The district system – 52 districts

Map 1: Population by Health District in South Africa



Privately insured
2013/14 – 8 814 458

Census 2011

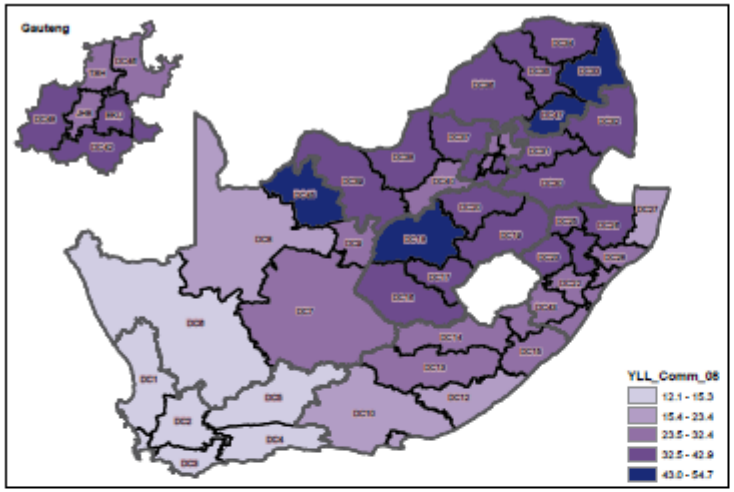
Total – 51 770 561

2014 mid-year estimate:

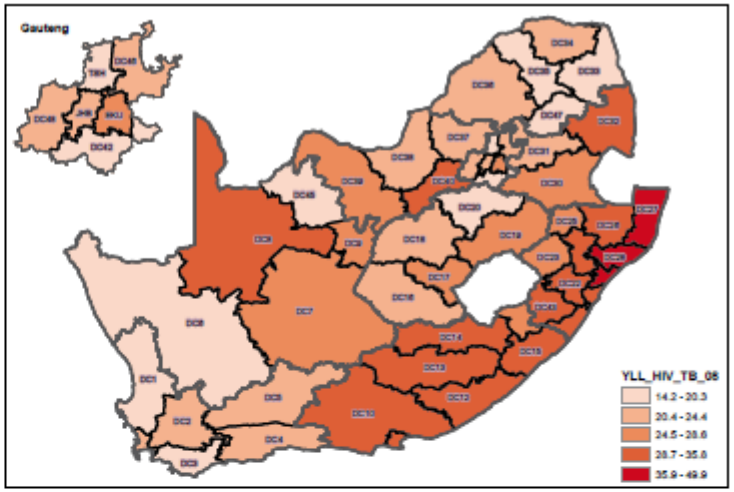
54 002 000

South Africa – unequal in every way

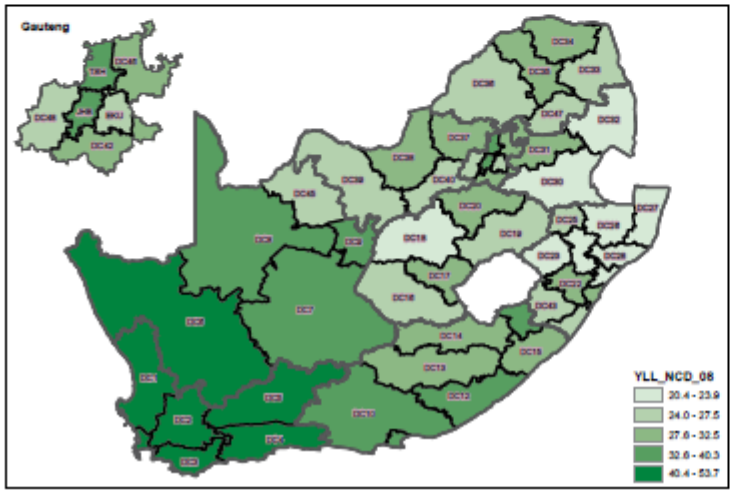
Comm/Mat/Peri/Nut



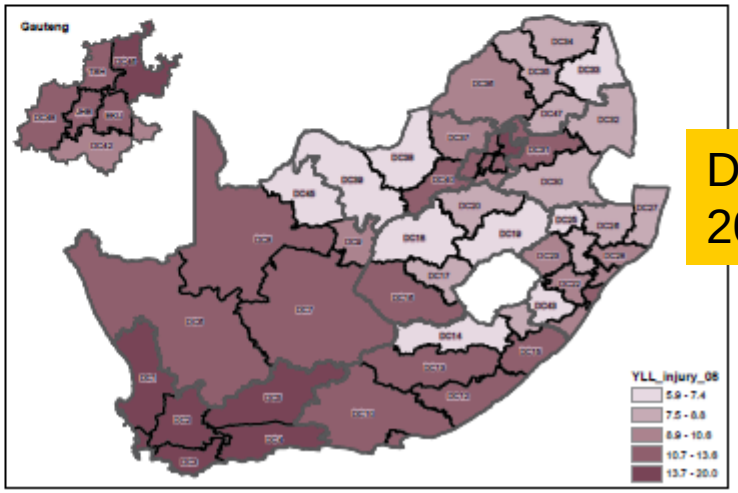
HIV and TB



Non-communicable diseases



Injuries



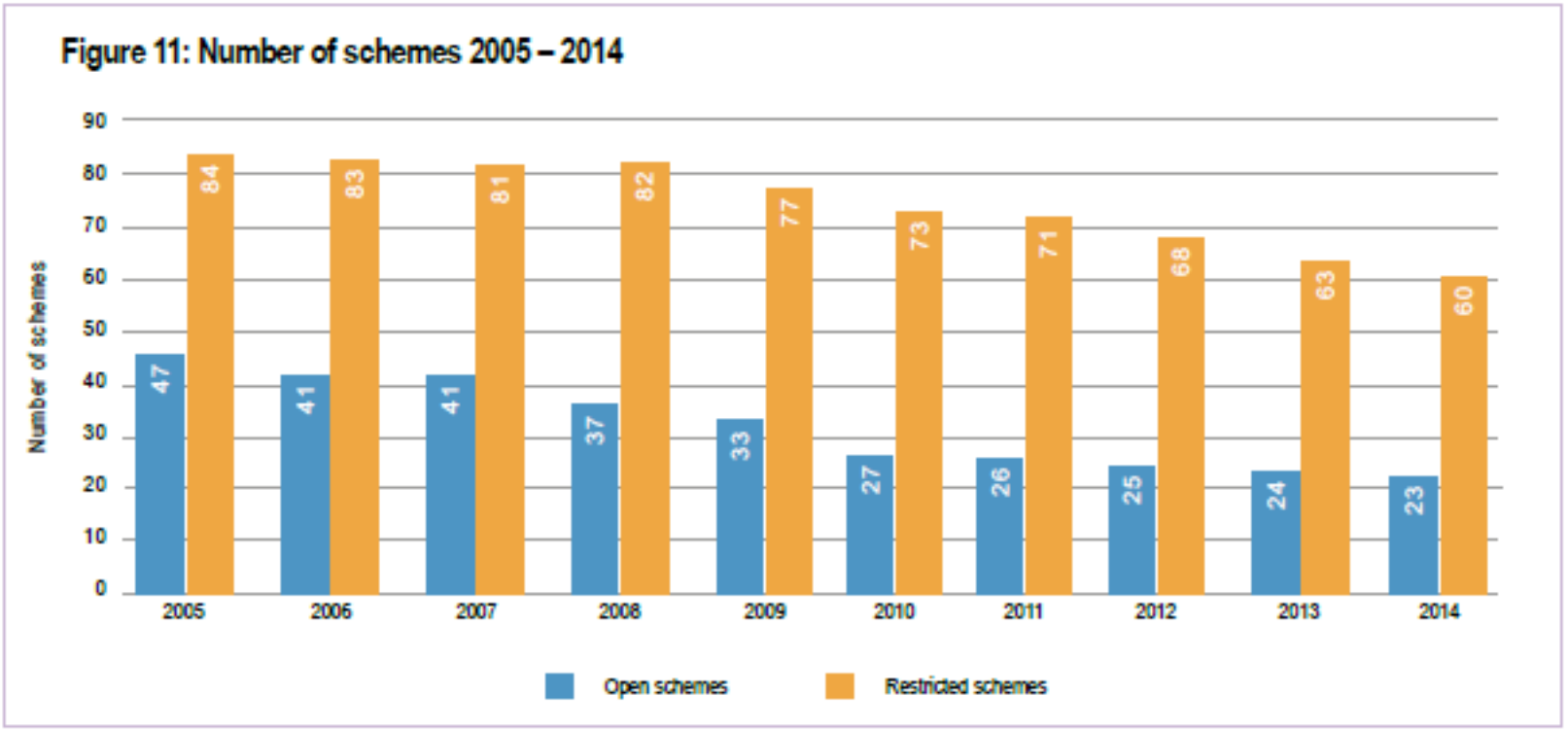
DHB 2011

XIII INTERNATIONAL AIDS CONFERENCE
DURBAN
SOUTH AFRICA

HOW AIDS CHANGED EVERYTHING

MDG 6: 15 YEARS, 15 LESSONS OF HOPE FROM THE AIDS RESPONSE

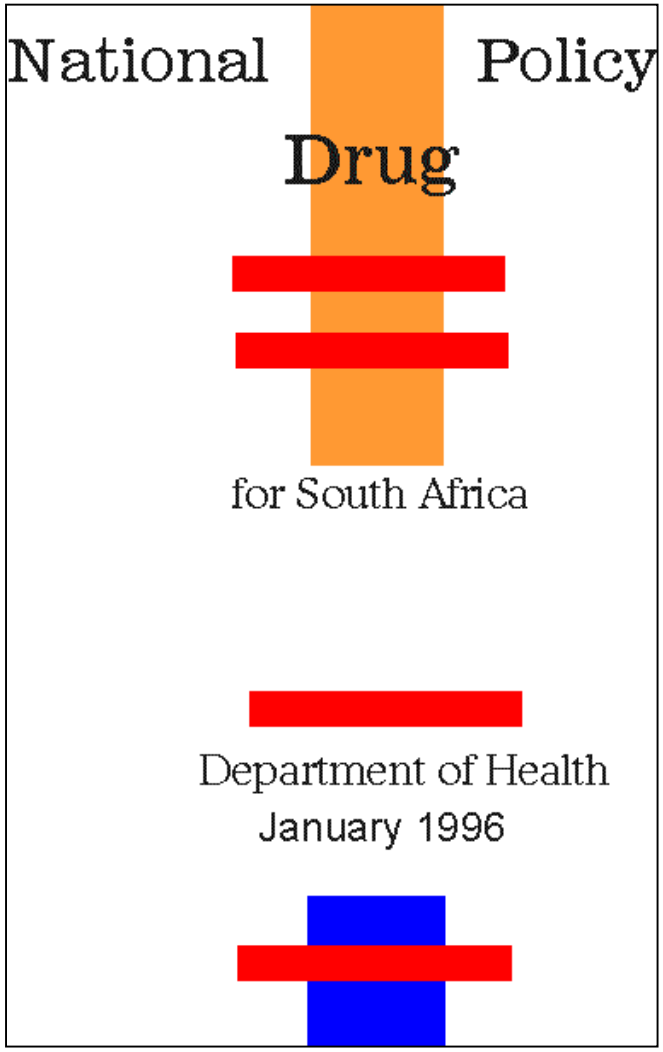
Slowly consolidating



Number of benefit options:
All schemes: 3.3 Open schemes: 6.0 Restricted schemes: 2.3

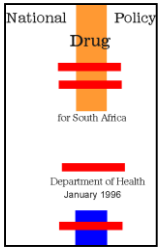
Dr Dlamini-Zuma's 7 key questions

- To develop a pricing plan for drugs (public/private)
- To develop a plan to ensure all drugs are tested and evaluated for effectiveness
- To develop an Essential Drugs List and Standard Treatment Guidelines (pub)
- To develop a generics strategy
- To prepare a plan for effective procurement and distribution
- To investigate traditional medicines
- To rationalise the structure for Pharmaceutical Services

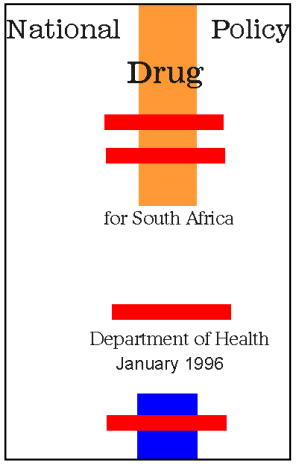


The National Drug Policy 1996

- **Health objectives**
  - To ensure the availability, accessibility of essential drugs to all
  - To ensure the safety, quality and efficacy of all drugs
  - To ensure good dispensing and prescribing
  - To promote rational use by all
  - To promote the concept of individual responsibility



NDP (2)



- **Economic objectives**
  - To lower costs in both sectors
  - To promote cost effective and rational use
  - To ensure complementary partnerships between government bodies and private providers in the pharmaceutical sector
  - To optimise the use of scarce resources through international co-operation

NDP (3)

- **National development objectives**
  - To improve skills of pharmaceutical personnel
  - To re-orient medical, paramedical and pharmaceutical education
  - To support the development of local industry
  - To build capacity in rational drug use, pharmacoeconomics and other aspects

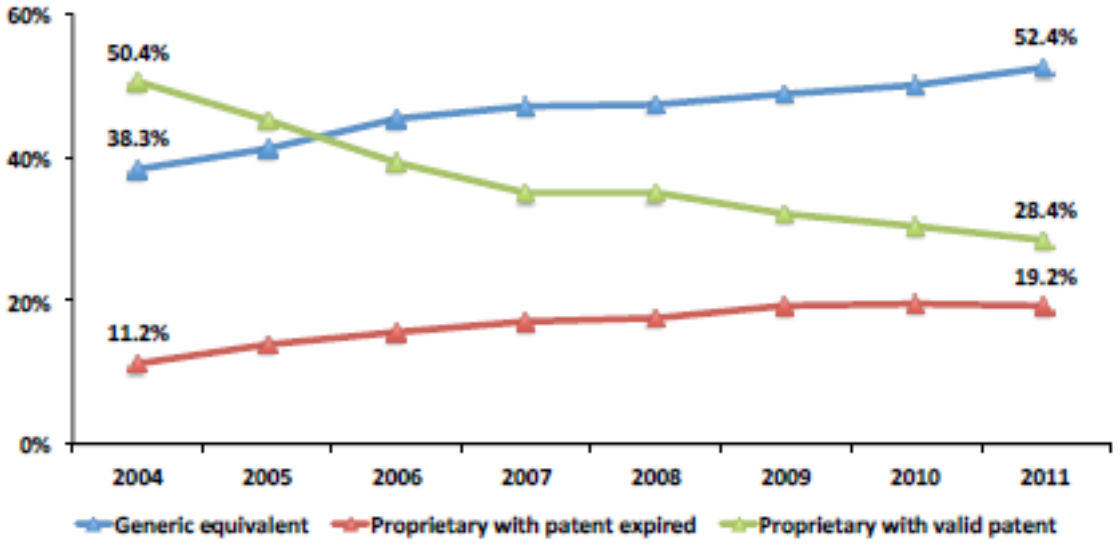
An immediate challenge

- 1997 – passage of the Medicines and Related Substances Control Amendment Act
- 1998 – interdicted by a court action (Pharmaceutical Manufacturers' Association and Others vs. President of the Republic of South Africa and Others. Case no. 4183/98, High Court of South Africa (Transvaal Provincial Division))
- 2001 – case withdrawn by the applicants
- 2003 – promulgation of the Amendment Act (after a 2002 addition)

Elements of SA pricing intervention

- Mandatory offer of generic substitution, with some safeguards
  - Mainly affecting the private sector

Figure 2: Prescriptions reimbursed by Mediscor



Source: Mediscor 2012 (21)

SA pricing interventions

- A non-discriminatory single exit price, with a ban on volume discounts (and samples) (only in the private sector), maximum annual increases, maximum dispensing fees

Table 3. Medicine expenditure in the private-sector medical scheme (insured) environment

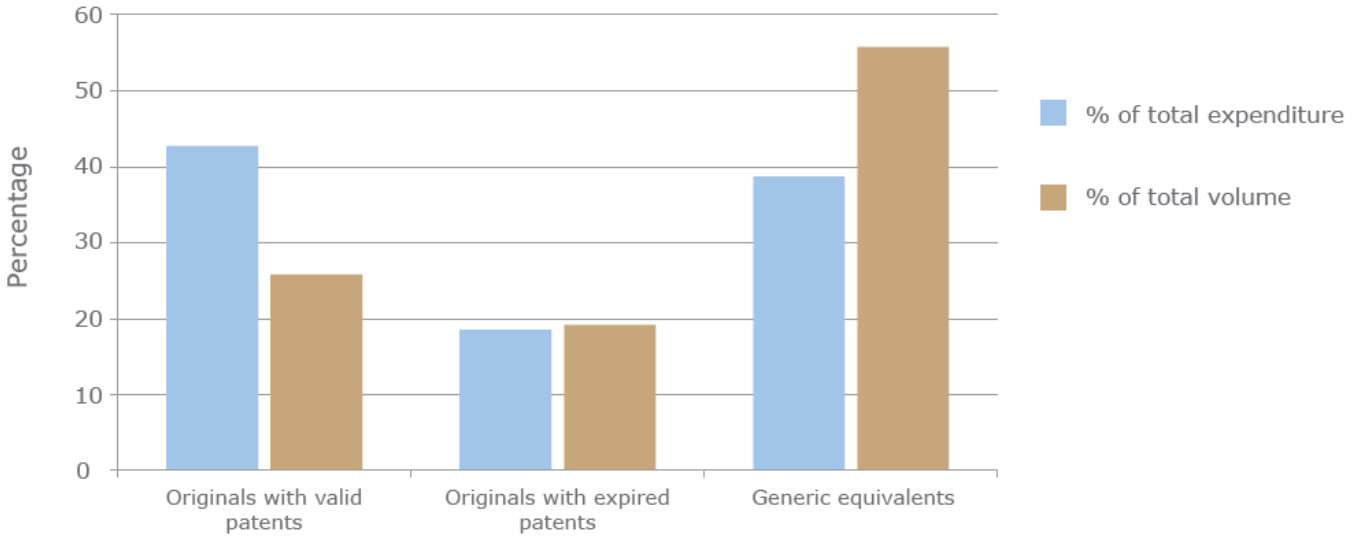
Year	% Expenditure on medicines	Medicine expenditure per beneficiary (annual) in South African Rand (unadjusted for inflation)	Annual maximum single exit price adjustments (%)*
2002	23.5	1206.39	–
2003	22.3	1241.93	–
2004	19.2	1156.79	–
2005	15.7	1053.31	–
2006	16.9	1220.65	–
2007	16.7	1257.01	5.2
2008	17.3	1422.25	6.5
2009	17.4	648.38	13.2
2010	17.0	1683.56	7.4
2011	16.3	1782.70	0
2012	15.8	1877.99	2.14
2013	16.0	2050.98	5.8

Source: Council for Medical Schemes Annual Reports 2002–2013.

Note: *The single exit price mechanism was announced in 2004 but was implemented only in 2006 and therefore adjustments came into effect as from 2007. Mandatory offer of generic substitution was implemented from 2003.

Dearth of data….but some hints

Figure 7 Expenditure and volume distribution by product type: 2014



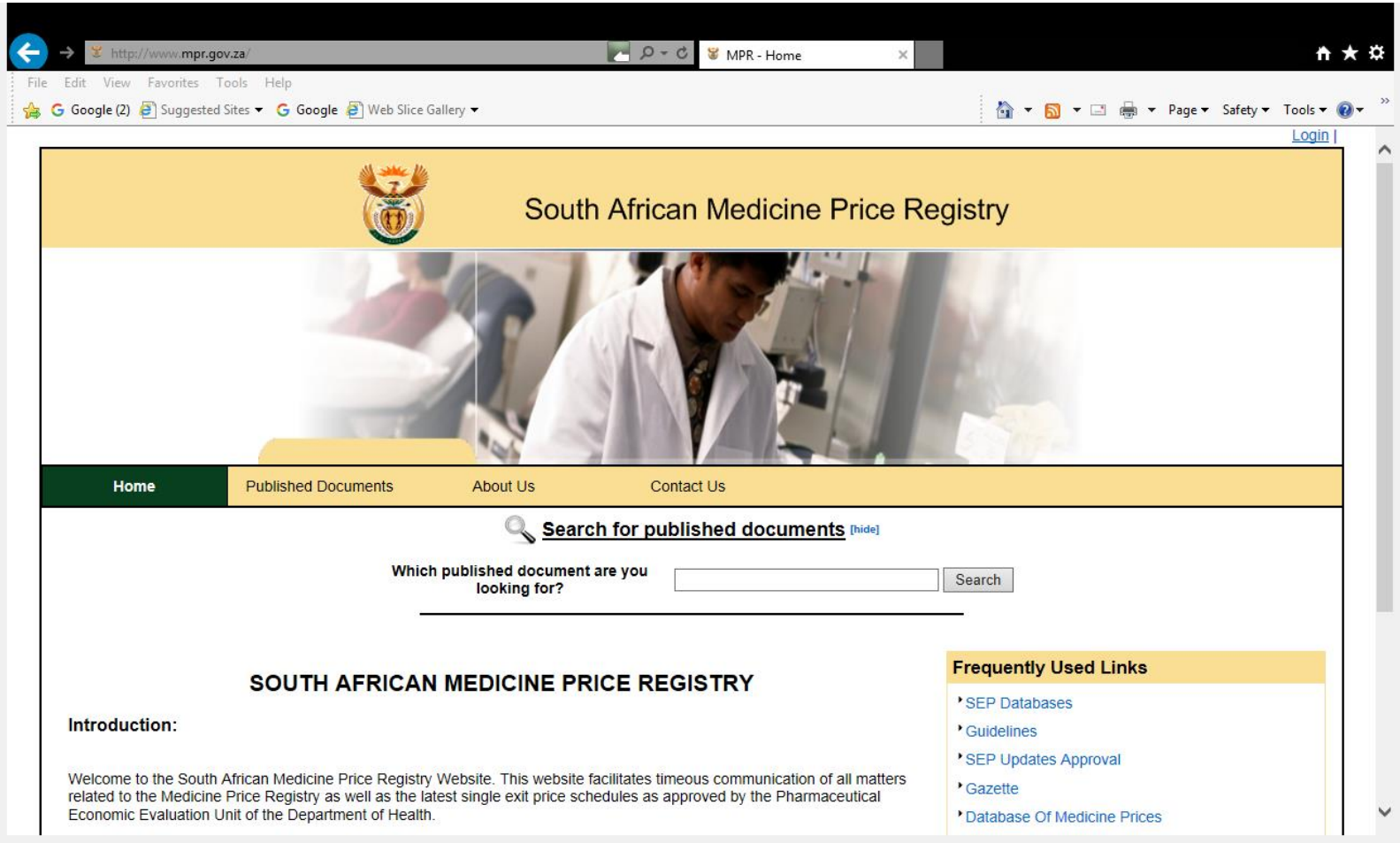
Patients and funders are increasingly being burdened by the rising costs associated with the use of speciality medicines, typically the high-cost biological medicines used to treat complex medical conditions. This phenomenon has been noted by many role players in the healthcare industry, both locally and internationally.

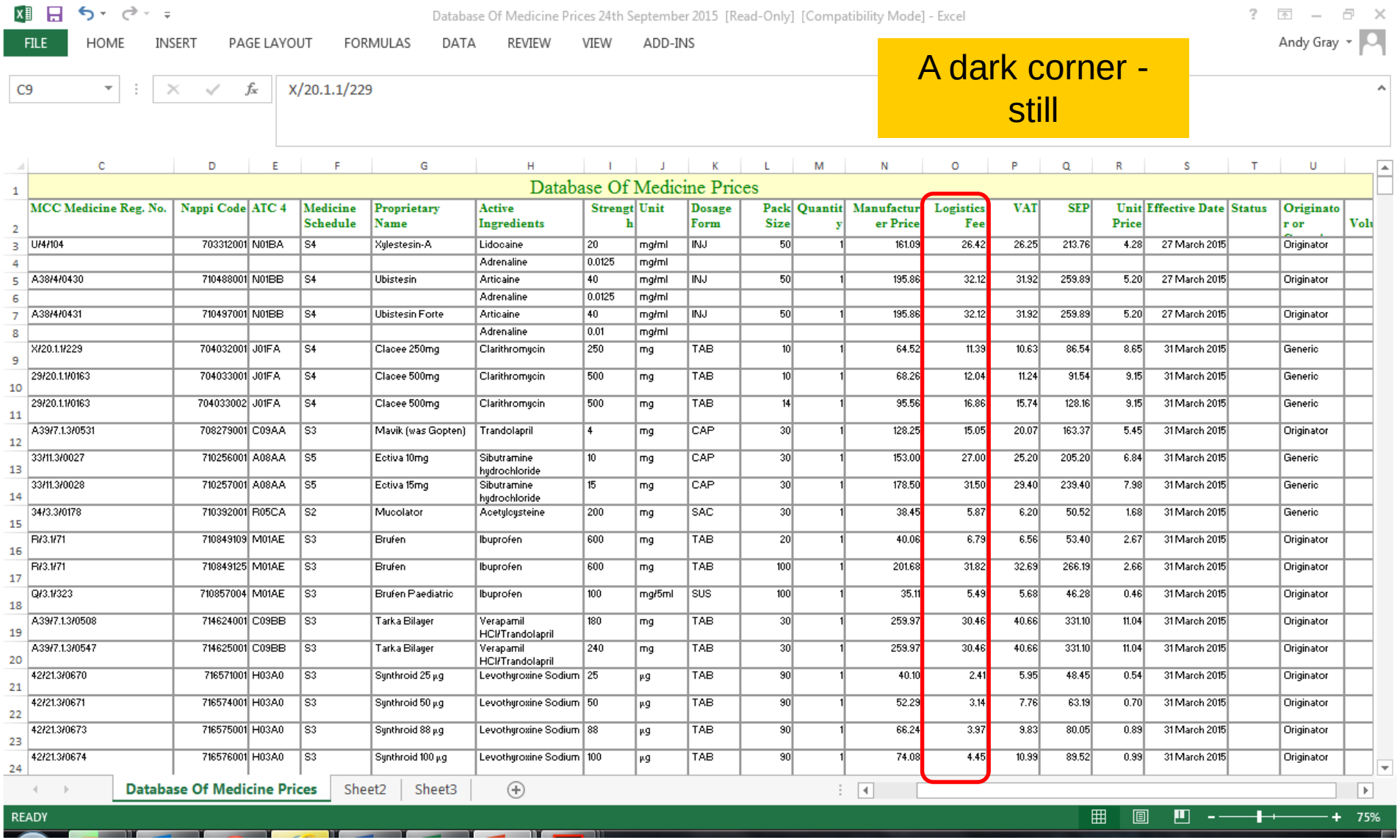
Medicines
Review 2014

w.mediscor.net

mediscor pbm
Pharmaceutical Benefit Management

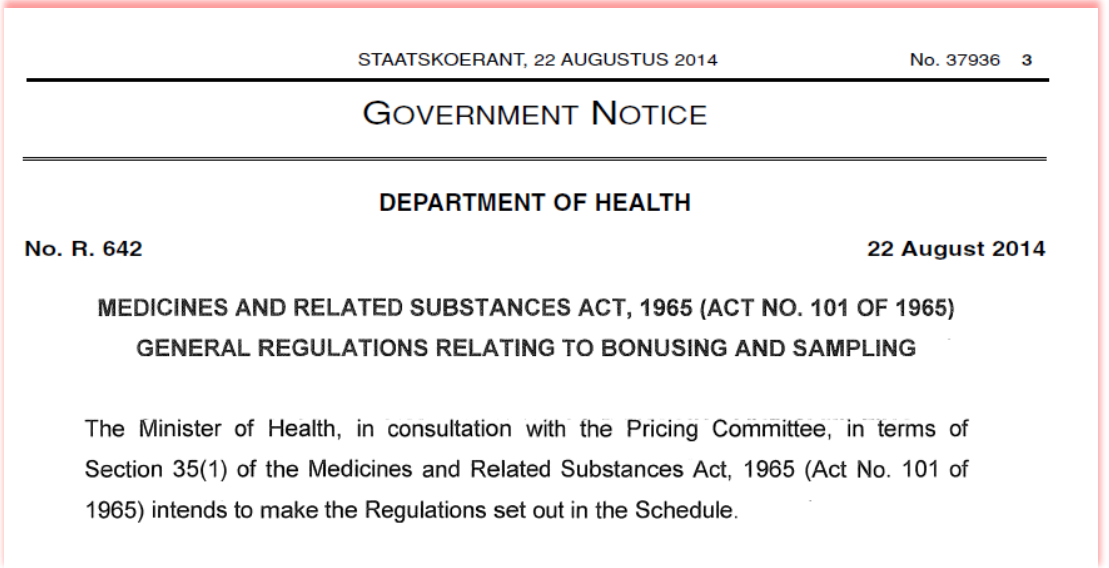
Transparency – a key goal




Database Of Medicine Prices 24th September 2015 [Read-Only] [Compatibility Mode] - Excel
FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW ADD-INS
Andy Gray
C9
X/20.1.1/229
A dark corner - still
Database Of Medicine Prices
MCC Medicine Reg. No. | Nappi Code | ATC 4 | Medicine Schedule | Proprietary Name | Active Ingredients | Strength | Unit | Dosage Form | Pack Size | Quantity | Manufacturer Price | Logistics Fee | VAT | SEP | Unit Price | Effective Date | Status | Originator
X/20.1.1/229 | 704032001 | J01FA | S4 | Clacee 250mg | Clarithromycin | 250 | mg | TAB | 10 | 1 | 64.52 | 11.39 | 10.63 | 86.54 | 8.65 | 31 March 2015 | Generic
29/20.1.1/0163 | 704033001 | J01FA | S4 | Clacee 500mg | Clarithromycin | 500 | mg | TAB | 10 | 1 | 68.26 | 12.04 | 11.24 | 91.54 | 9.15 | 31 March 2015 | Generic
29/20.1.1/0163 | 704033002 | J01FA | S4 | Clacee 500mg | Clarithromycin | 500 | mg | TAB | 14 | 1 | 95.56 | 16.86 | 15.74 | 128.16 | 9.15 | 31 March 2015 | Generic
A39/7.1.3/0531 | 708279001 | C09AA | S3 | Mavik (was Gopten) | Trandolapril | 4 | mg | CAP | 30 | 1 | 128.25 | 15.05 | 20.07 | 163.37 | 5.45 | 31 March 2015 | Originator
33/11.3/0027 | 710256001 | A08AA | S5 | Ectiva 10mg | Sibutramine hydrochloride | 10 | mg | CAP | 30 | 1 | 153.00 | 27.00 | 25.20 | 205.20 | 6.84 | 31 March 2015 | Generic
33/11.3/0028 | 710257001 | A08AA | S5 | Ectiva 15mg | Sibutramine hydrochloride | 15 | mg | CAP | 30 | 1 | 178.50 | 31.50 | 29.40 | 239.40 | 7.98 | 31 March 2015 | Generic
34/3.3/0178 | 710392001 | R05CA | S2 | Mucolator | Acetylcysteine | 200 | mg | SAC | 30 | 1 | 38.45 | 5.87 | 6.20 | 50.52 | 1.68 | 31 March 2015 | Generic
R/3.1/71 | 710849109 | M01AE | S3 | Brufen | Ibuprofen | 600 | mg | TAB | 20 | 1 | 40.06 | 6.79 | 6.56 | 53.40 | 2.67 | 31 March 2015 | Originator
R/3.1/71 | 710849125 | M01AE | S3 | Brufen | Ibuprofen | 600 | mg | TAB | 100 | 1 | 201.68 | 31.82 | 32.69 | 266.19 | 2.66 | 31 March 2015 | Originator
Q/3.1/323 | 710857004 | M01AE | S3 | Brufen Paediatric | Ibuprofen | 100 | mg/5ml | SUS | 100 | 1 | 35.11 | 5.49 | 5.68 | 46.28 | 0.46 | 31 March 2015 | Originator
A39/7.1.3/0508 | 714624001 | C09BB | S3 | Tarka Bilayer | Verapamil HCl/Trandolapril | 180 | mg | TAB | 30 | 1 | 259.97 | 30.46 | 40.66 | 331.10 | 11.04 | 31 March 2015 | Originator
A39/7.1.3/0547 | 714625001 | C09BB | S3 | Tarka Bilayer | Verapamil HCl/Trandolapril | 240 | mg | TAB | 30 | 1 | 259.97 | 30.46 | 40.66 | 331.10 | 11.04 | 31 March 2015 | Originator
42/21.3/0670 | 716571001 | H03A0 | S3 | Synthroid 25 µg | Levothyroxine Sodium | 25 | µg | TAB | 90 | 1 | 40.10 | 2.41 | 5.95 | 48.45 | 0.54 | 31 March 2015 | Originator
42/21.3/0671 | 716574001 | H03A0 | S3 | Synthroid 50 µg | Levothyroxine Sodium | 50 | µg | TAB | 90 | 1 | 52.29 | 3.14 | 7.76 | 63.19 | 0.70 | 31 March 2015 | Originator
42/21.3/0673 | 716575001 | H03A0 | S3 | Synthroid 88 µg | Levothyroxine Sodium | 88 | µg | TAB | 90 | 1 | 66.24 | 3.97 | 9.83 | 80.05 | 0.89 | 31 March 2015 | Originator
42/21.3/0674 | 716576001 | H03A0 | S3 | Synthroid 100 µg | Levothyroxine Sodium | 100 | µg | TAB | 90 | 1 | 74.08 | 4.45 | 10.99 | 89.52 | 0.99 | 31 March 2015 | Originator
Database Of Medicine Prices
Sheet2
Sheet3
READY
75%

For every action, a reaction …

- Potential incentive schemes to reward larger buyers
  - Data fees; co-marketing fees; off-invoice bonusing



STAATSKOERANT, 22 AUGUSTUS 2014 No. 37936 3

GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

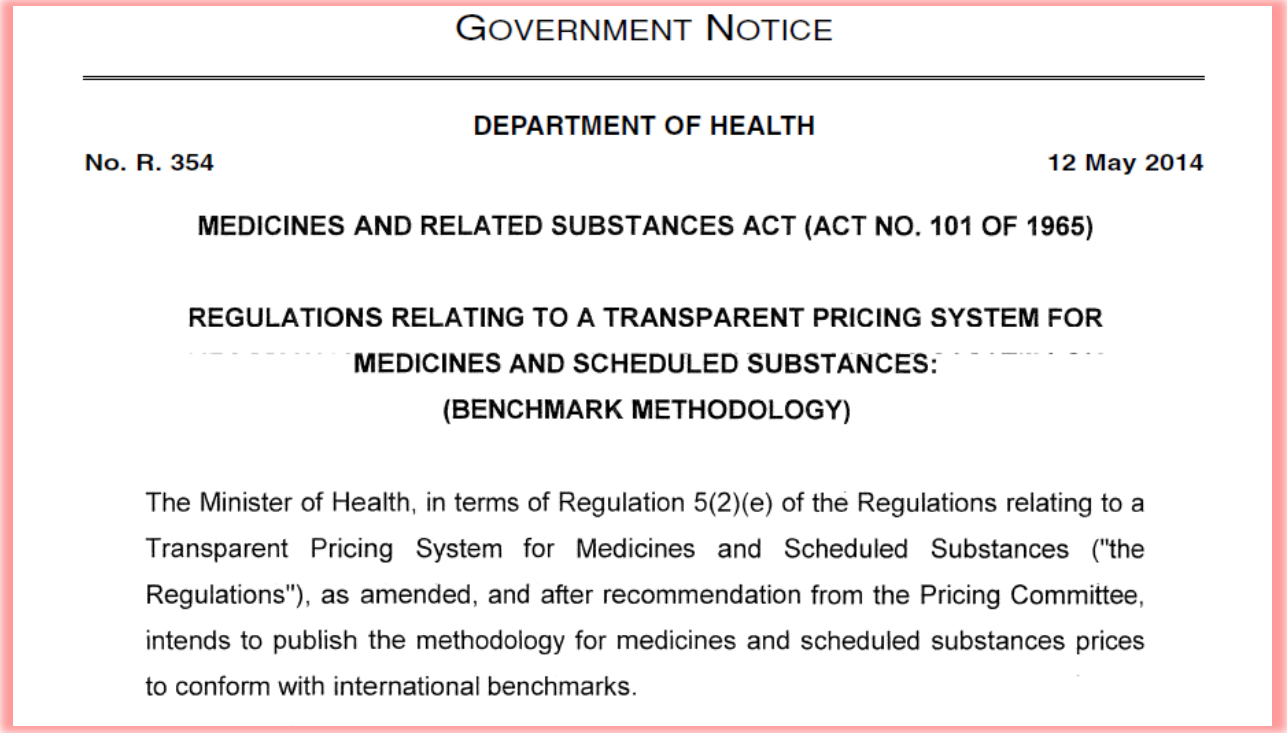
No. R. 642 **22 August 2014**

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)
GENERAL REGULATIONS RELATING TO BONUSING AND SAMPLING

The Minister of Health, in consultation with the Pricing Committee, in terms of Section 35(1) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) intends to make the Regulations set out in the Schedule.

International benchmarking

- Australia, New Zealand, Canada, Spain
- Two-phase introduction proposed



GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 354 12 May 2014

MEDICINES AND RELATED SUBSTANCES ACT (ACT NO. 101 OF 1965)

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: (BENCHMARK METHODOLOGY)

The Minister of Health, in terms of Regulation 5(2)(e) of the Regulations relating to a Transparent Pricing System for Medicines and Scheduled Substances ("the Regulations"), as amended, and after recommendation from the Pricing Committee, intends to publish the methodology for medicines and scheduled substances prices to conform with international benchmarks.

Pharmacoeconomic submissions

- Guidelines for such submissions published in 2013
- Submission remains voluntary
- Consequences of the analysis by the Department of Health are somewhat unclear

NHI Green Paper published for comment in August 2011

White Paper (the final version) expected "imminently"

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

EMBARGOED UNTIL 5h00 FRIDAY 12 AUGUST

NATIONAL HEALTH INSURANCE
IN SOUTH AFRICA

POLICY PAPER

GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. 657 **12 August 2011**

NATIONAL HEALTH ACT, 2003

POLICY ON NATIONAL HEALTH INSURANCE

The Minister of Health intends, in terms of section 85 of the Constitution of the Republic of South Africa, 1996 (Act No.108 of 1996) and section 3 of the National Health Act, 2003, (Act No. 61 of 2003) after consultation with the National Health Council, to determine the policy in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed policy to the Director-General: Health, Private Bag X828, Pretoria, 0001, within a period of two months from the date of publication of this notice.

A long gestation

- Commission on Old Age Pension and National Insurance (1928)
- Committee of Enquiry into National Health Insurance (1935)
- National Health Service Commission (1942 – 1944) - **Gluckman**
- Health Care Finance Committee (1994)
- Committee of Inquiry on National Health Insurance (1995) - **Broomberg-Shisana**
- The Social Health Insurance Working Group (1997)
- Committee of Inquiry into a Comprehensive Social Security for South Africa (2002) - **Taylor**
  - Ministerial Task Team on Social Health Insurance (2002)
- Polokwane Resolution 53 (2007)
- Advisory Committee on National Health Insurance (2009)
- And …. 14 years to go, from …..when?

So what has to change?

- Public sector
  - Based on centralised tender system, a standard EML (usually 1 product per class; often 1 supplier)
  - No purchaser-provider split
  - Almost no user fees
  - No other pricing policies

- Private sector
  - Some pricing policies in place (generics)
  - Disparate (and at times illogical or even perverse) reimbursement lists
  - Some internal reference pricing
  - Many issues pending

Other elements to consider

- Significant manufacturing capacity
- A commitment to build the local industry, including active pharmaceutical ingredient (API) production; vaccine capacity
- A slow process to reform intellectual property policies (SA already TRIPS+)

Some observations on the future

#1: we're all in this together

"Trastuzumab price would need to decrease between 69.6 percent to 94.9 percent to became CE in LA."

International Journal of Technology Assessment in Health Care, 31:1/2 (2015), 2–11.

doi:10.1017/S0266462315000914

Assessments

IMPLICATIONS OF GLOBAL PRICING POLICIES ON ACCESS TO INNOVATIVE DRUGS: THE CASE OF TRASTUZUMAB IN SEVEN LATIN AMERICAN COUNTRIES

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Some observations on the future

#2: expanding the process of health technology assessment to low- and middle-income countries?

- greater transparency
- data sharing
- publication of models that can be repopulated with locally-determined cost data
- application of this suite of methods to the selection and appropriate pricing of the bulk of reimbursed medicines, as well as to new and expensive medicines

Some observations on the future

#3: greater emphasis on the means to ensure responsible use of medicines

The responsible use of medicines means:

- *That a medicine is only used when necessary and that the choice of medicine is appropriate based on what is proven by scientific and/or clinical evidence to be most effective and least likely to cause harm. This choice also considers patient preferences and makes the best use of limited healthcare resources.*
- *There is timely access to and the availability of quality medicine that is properly administered and monitored for effectiveness and safety.*
- *A multidisciplinary collaborative approach is used that includes patients and those in addition to health professionals assisting in their care.*

Some observations on the future

#4: more attention to systems which allow for a reliable estimate of the value of medicines under typical use

BUT, performance-based pricing must not provide a fig-leaf behind which unacceptable launch prices can be hidden

Some observations on the future

#5: reimbursement policies and processes will also need to measured against their effects on responsible use, and adjusted where their effects are shown to be perverse and not in the interests of patients

#6: consideration will need to be paid to the effect of pricing and reimbursement policies on necessary and appropriate innovation

Finally ….

- Standing still is not an option, and complacency is entirely unwarranted