Generic Medicine in South Africa –

Past, Present and Future

15th Annual IGPA Conference 2012
Kyoto - Japan

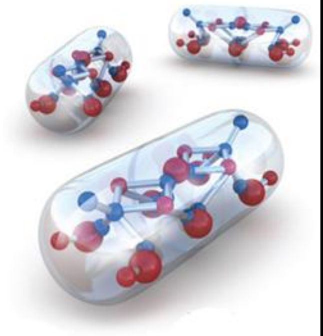
Dr. Fathima Docrat
Chief Executive Officer

The **National Association of Pharmaceutical Manufacturers** (NAPM), is a voluntary, nonprofit organization consisting of South African, generics-based pharmaceutical manufacturers and distributors

Established in 1977, its primary objective remains the championing of affordable healthcare by **promoting the use of generic medicines**

NAPM
National Association of Pharmaceutical Manufacturers

NAPM Fact File



Founded in 1977

One of the oldest pharmaceutical association in South Africa

Established relationships with stakeholders in SA's healthcare landscape

Represents SA internationally as a member of IGPA
A founding member of the Southern African Generics Medicines Association (SAGMA)

Through our efforts we aim to increase the generic market share by value in South Africa to 45% by 2015

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NAPM's Vision & Mission

Our Vision

To ensure the provision of access to **affordable, safe, quality medicines** for all South Africans.

The NAPM's goal is to ensure a local vibrant pharmaceutical industry that is benchmarked against developed countries.

Our Mission

To ensure that the healthcare sector plays a constructive role in our country's economic growth, through development and transformation, thereby creating an environment can thrive, expand, and be competitive, with the ultimate aim to enhance access of medicines to all of our country's citizens.

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The NAPM' Role

The NAPM is championing affordable healthcare by promoting quality generic medicines for all South Africans

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NAPM Structure

NAPM Head Office

The office is supported by an EXCO and various sub-committees

- Intellectual Property Sub-Committee
- National Health Insurance Sub-Committee
- Scientific Sub-Committee
- Marketing Sub-Committee
- Trade & Industry Sub-Committee
- Marketing Code Sub-Committee
- Pricing Sub-Committee

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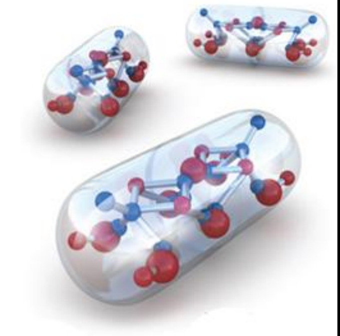

Members

Abex Pharmaceuticals
Activa Health
Akacia Healthcare
Aurobindo Pharma
Austell Laboratories
Afrika Biopharma
Cipla Medpro
Di Medicine Registration Consultants
Dr Reddy's Laboratories
Ferring SA
Litha Healthcare Group Limited
Mc Pharma
Medreich SA
Mylan
Pharma Dynamics
Pharmachem
Primapharma
Ranbaxy
Sandoz SA
Sekpharma
Teva Pharmaceuticals
Watson Pharma
Zydus Pharmaceuticals

Representing almost 90% of generic companies in South Africa, and representing a generics market share of approximately 45%.

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South Africa : Demographics

Population: 51.8 million

Population: half under 39 years

Life expectancy at 52 years

GDP per capita: $11,100 (2011)

GDP real growth rate: 3.1% (2011 est.)
2.9% (2010 est.)

Unemployment: 25.3%

Inflation rate 6 % ave. 2012

Key fact: over 85% of the SA population is still uninsured

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Sources: Statistics South Africa - Census 2012; IMF; SA DoH; World Bank, KPMG; SA Revenue Service, SA Pharmacy Council

South Africa : Healthcare Landscape

Healthcare expenditure of GDP at 8.1 % (13.8 bUSD)

Private coverage of 7.5m people public coverage of 51.8 m

4.1 % of GDP spent on private health = 16.2 % of population

4.2 % of GDP spent on the public health sector = 84 % of population

Private sector spending @ R11 150 pp vs Public sector spending @ R2 766 pp

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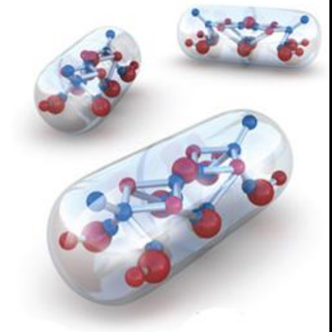
Sources: Statistics South Africa - Census 2012; IMF; SA DoH; World Bank, KPMG; SA Revenue Service, SA Pharmacy Council

South Africa: Healthcare Landscape



HIV/Aids: New patients on ARV's increased by almost 50% to 617 147 in 2011 – increasing life expectancy

Quadruple disease burden (HIV/TB, maternal and child mortality, non-communicable diseases, injuries)

NHI to cost approx. R10.4 billion per year, above current spend

NHI to cost R145 billion over next 14 years

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Sources: Statistics South Africa - Census 2012; IMF; SA DoH; World Bank, KPMG; SA Revenue Service, SA Pharmacy Council

The Development & Impact of Generic Medicine Usage in South Africa

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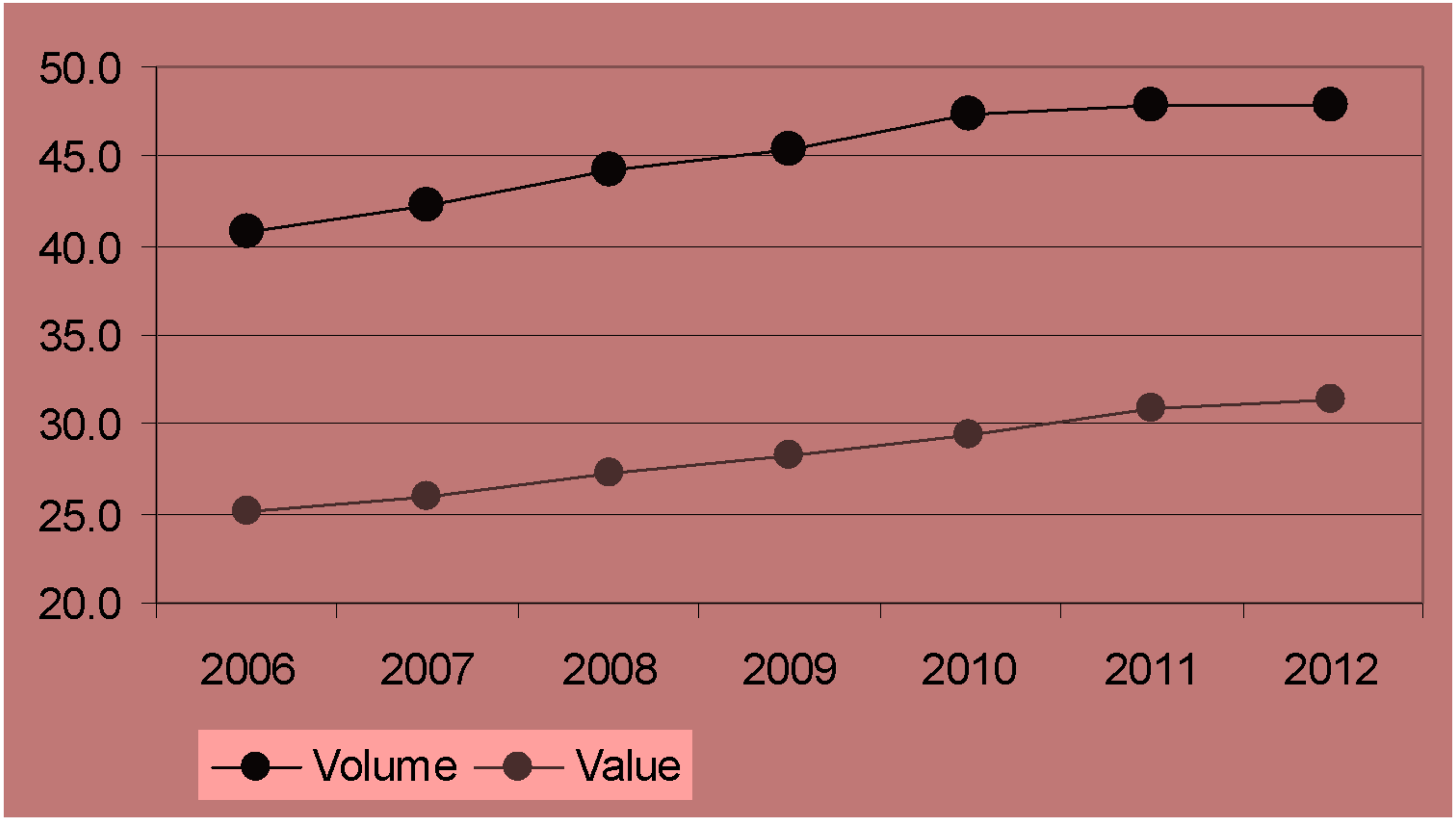
Generic share of Drug Market – 7 Year Trend in South Africa



IMS:TPM:Sep 2012

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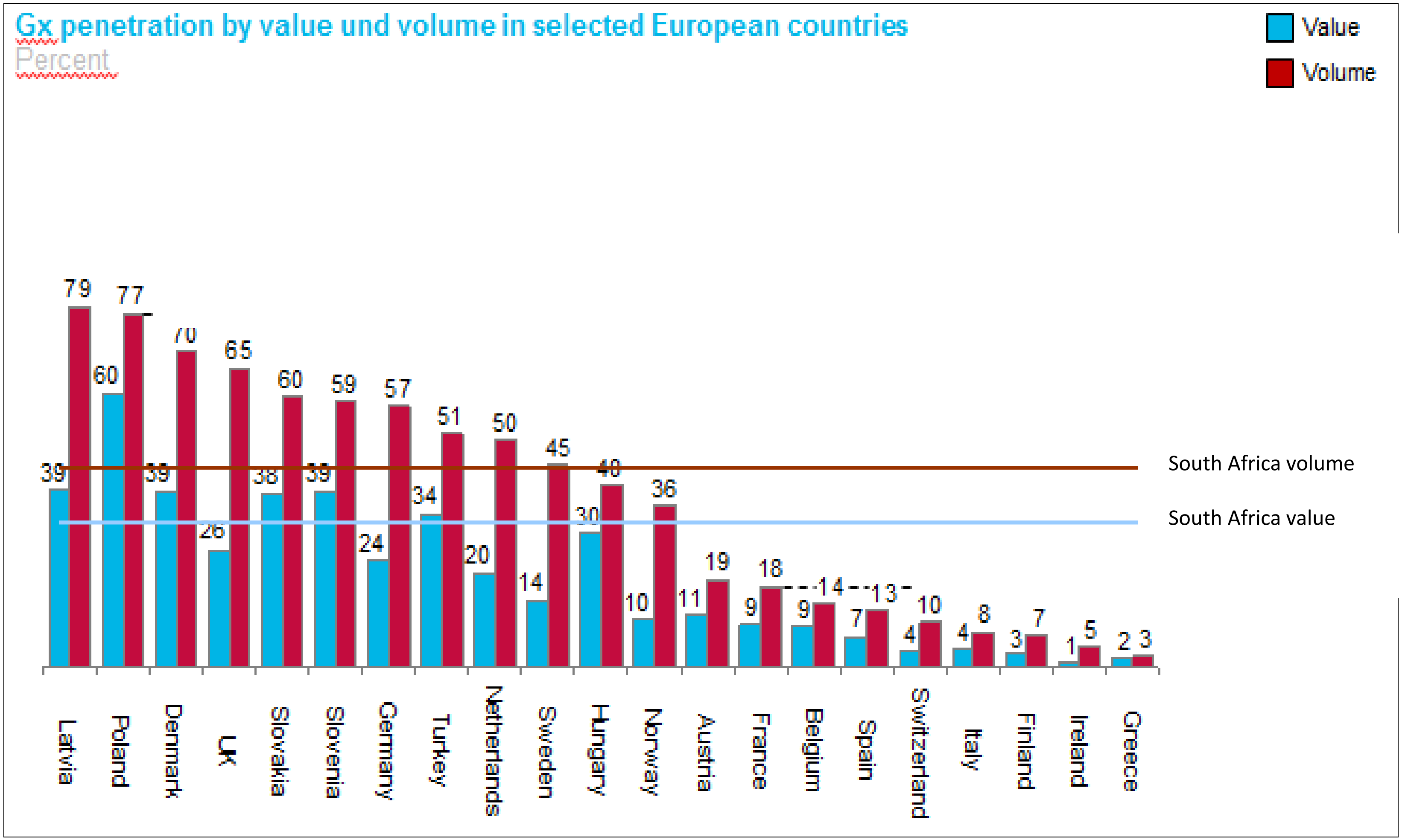
Comparing SA to mature markets in Europe, suggest there is room for further Gx growth



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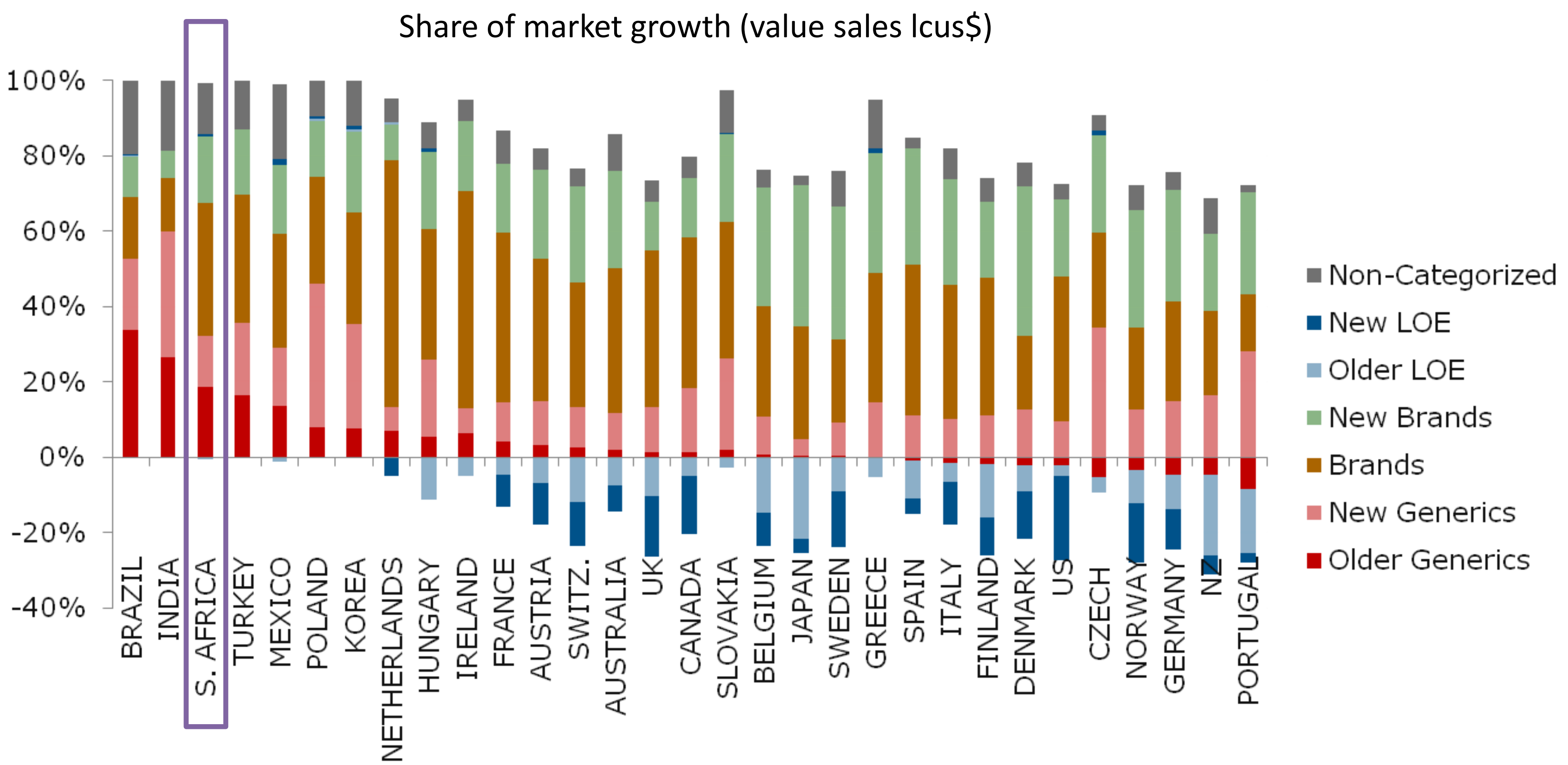
However, old Gx contribute more to the Gx market in South Africa as the introduction of new generics is slow!



Source: IMS Health MIDAS Sales Data. MAT DEC 2010. Note new products includes those launched in the previous two years.
Note countries ordered by the contribution of older generics to total market growth

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Registration time survey

	Survey 1 2005/6	Survey 2 2006/7	Survey 3 2007/8	Survey 4 2008-11
Number of members participating	9	6	13	8
Total number of products reg'd	402	83	103	132
Number of products registered via fast-track procedure	86	8	31	19
Number of products registered via "routine" procedure	316	75	72	113

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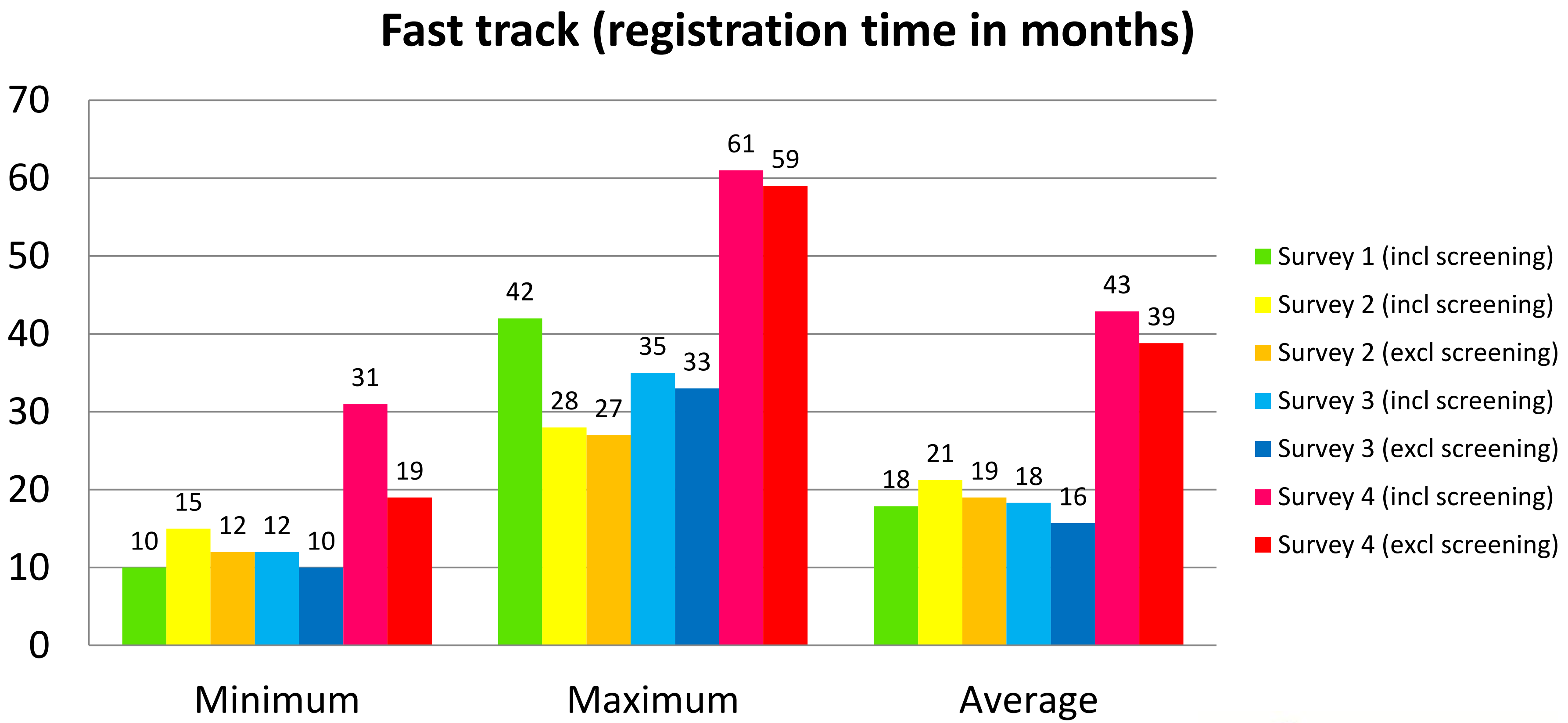
Average, Minimum and Maximum Registration times – Fast track



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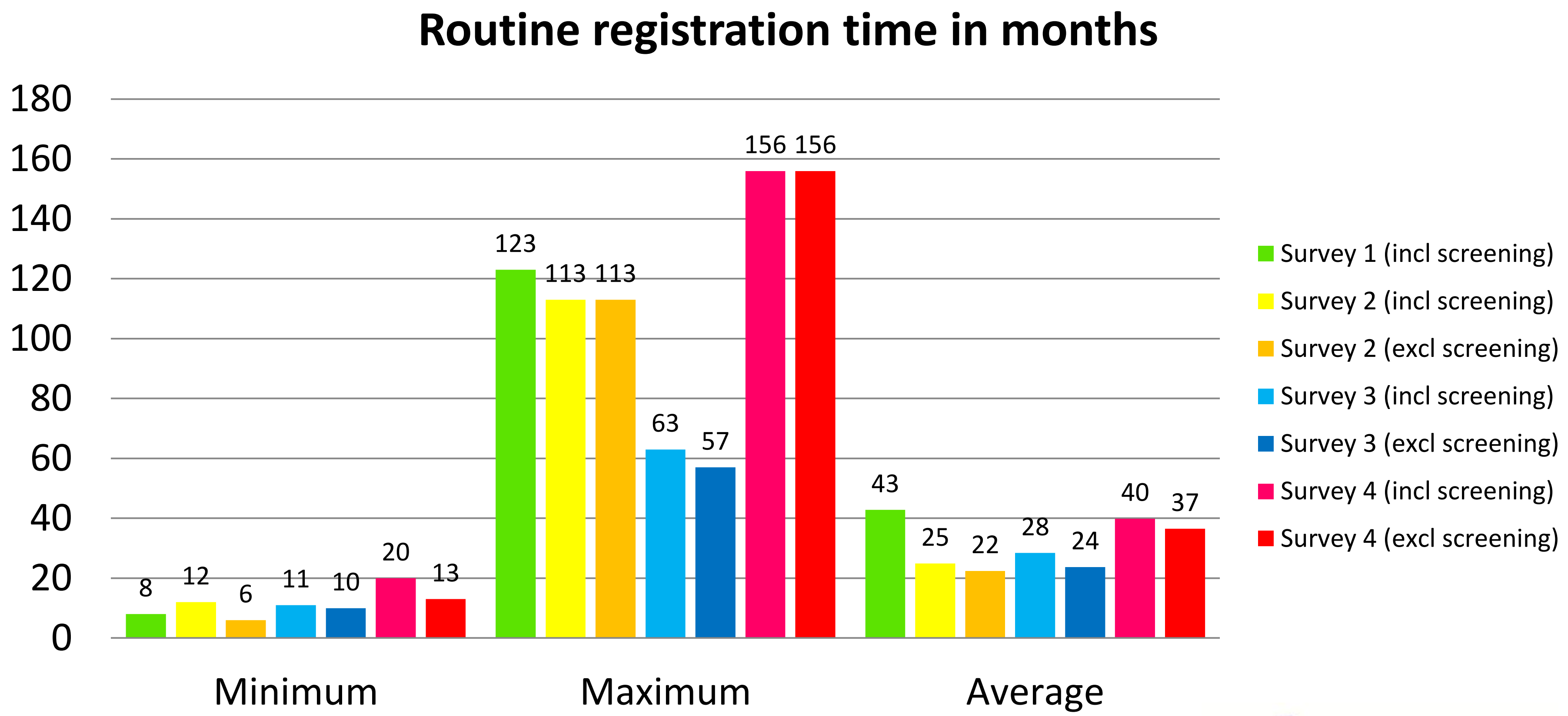
Average, Minimum and Maximum Registration times – “Routine”



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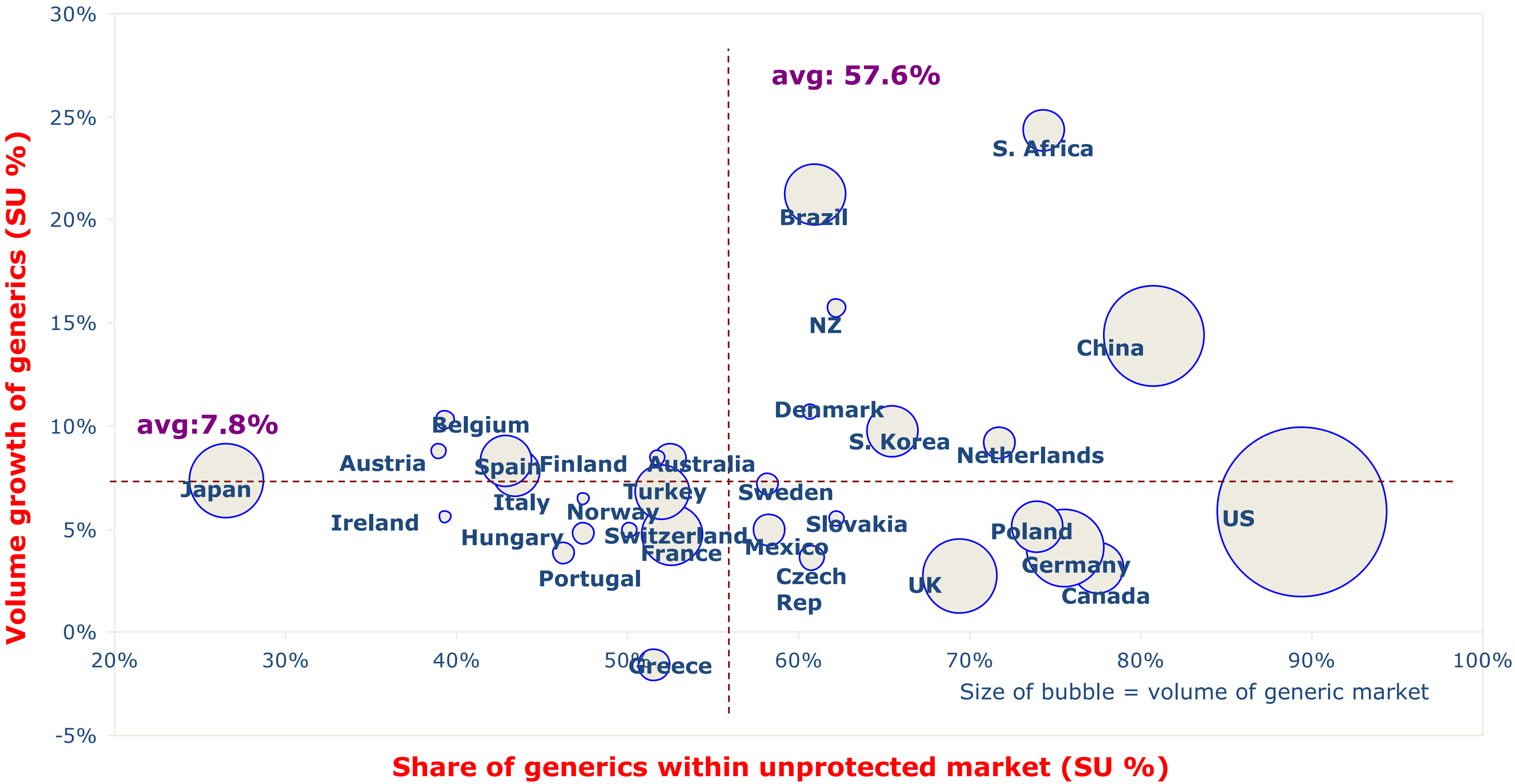
When Generics are introduced they achieve high penetration relatively quickly



*Source: IMS Health, MIDAS, Market Segmentation, MAT September 2010, Rx only. *Market Segmentation countries Except for China – data for MAT May 2010. Unprotected market = Never protected + no longer protected.*

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Drivers for increased Generic Utilisation

Macro Issues

Manufacture Capacity

Rational & Assurance for generics

Vertical Integration (API)

Quality of MCC submissions

Patent protection

Fast track approvals

Perverse Incentives

Pseudogenerics

Marketing Code

Generics Industry

Drivers for increased Generic Utilisation

- **Generic vs Originator**
  Access to affordable and sustainable healthcare.
  How to achieve similar market shares as to EU & US. Enabling legislation and clear rational why generic medicines should become SA's (and indeed any emerging markets') key pharmaceutical needs source.
- **Patent Protection & Intellectual Property**
  Ever greening is anti- competitor, anti-consumer and monopoly extending as it gives limited choice while ensuring greater costs onto the consumer.
- **Pseudogenerics**
  Are they anti-competitive and do they negatively impact or unduly influence the pricing models of "true generics"? Is SEP pricing legislation fair to generic companies?
- **Vertical Integration (API)**
  Nearly 95% of Active Pharmaceutical Ingredients (API's) are imported and make up approximately 70% of the price of finished pharmaceuticals.

Drivers for increased Generic Utilisation

- **Generic Approvals**
  MCC to allow generic companies a quicker more cost effective method for submitting and gaining approvals for generic drugs
- **Perverse Incentives**
  In some European markets where only price controls have been used, generic market growth has slowed down as it does not help to increase volume and expand market access. Use of generics is the single most important driver to reducing overall cost.
  As generics are often half the price of originator medicines it results in a much lower Single Exit Price (SEP). Pharmacists in South Africa are really dis-incentivised from dispensing the cheaper equivalent medication. This does not benefit government, medical aid schemes and most importantly the South African public, who are already under pressure to manage their expenses.
- **Marketing Code of Conduct**
  The NAPM has been supportive of the marketing code developed jointly by industry players. The NAPM, however, have repeatedly called on government to legislate sanctions against offenders if self-regulation fails.

Drivers for increased Generic Utilisation

Supportive of the TAC (Treatment Action Campaign) and MSF joint efforts

www.fixthepatentlaw.org

South Africa's patent law has NO examination

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GPs and Pharmacists Urged to Get Involved in IP Debate

by WEBMASTER on NOVEMBER 5, 2012 in NEWS

Dr Fathima Docrat, NAPM's new CEO

GPs and independent pharmacists would do well to tune into the current debate over the pending changes to the intellectual property (IP) laws, because the outcomes will affect them in the long run.

That's the view of Dr Fathima Docrat, newly appointed CEO of the National Association of Pharmaceutical Manufacturers (NAPM), one of the longest-standing associations for the pharmaceutical manufacturing industry, representing the largest group of local generics manufacturers and importers.

The Department of Trade and Industry (DTI) is in the process of changing IP regulations and has called for input from civil society in order to ensure that the views of all interest groups are heard in the run up to the promulgation of new IP laws.

The main argument around the debate insofar as it affects the pharmaceutical industry revolves around changing IP laws to make production and supply of affordable generics easier. Lobbyists, such as the Treatment Action Campaign (TAC) and Medicines Sans Frontiers (MSF) are campaigning intensively for stricter control over the granting of pharmaceutical patents and for changes that will entrench IP flexibilities already allowed by the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights. If they succeed, it will result in

Latest Issue - November 2012

Latest Issue

Past Issues
- October 2012
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- July 2012
- June 2012

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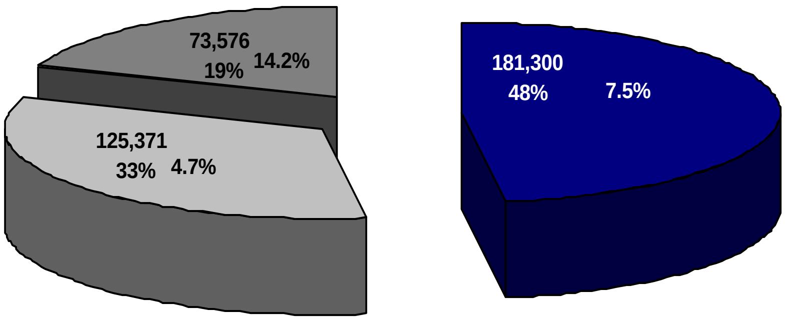
Market Growth 2012-2020

Volume – MAT June 2012

PERCENTAGE OF TOTAL NUMBER OF PRESCRIPTIONS

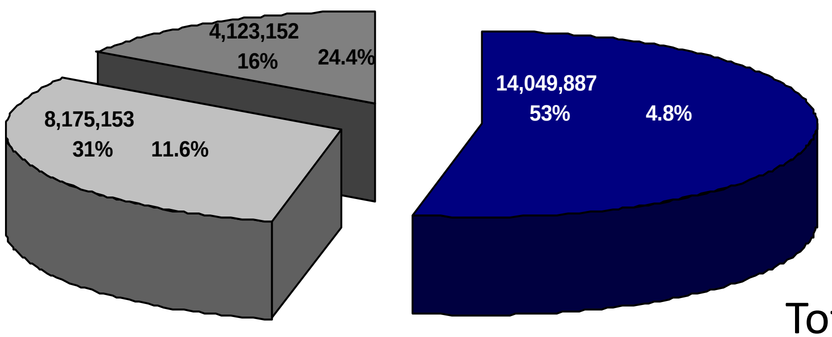


Total: 380,248m

PERCENTAGE OF TOTAL MARKET COST

- NON GENERIC PRODUCTS
- GENERIC PRODUCTS
- NON CATEGORIZED PRODUCTS

Value – MAT June 2012



Total: 26,348m

IMS:TPM:June 2012

THANK YOU

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