

# Pharmaceutical Sector Country Profiles

## WHO experience

Dr Gilles Forte

Mr Enrico Cinnella

Essential Medicines and  
Pharmaceutical Policies

WHO HQ

### WHO Medicines Strategy as part of WHO Medium-term Strategic Plan 2008-2013 :

#### Strategic Objective (SO-11) :

To ensure improved access, quality and use of medical products and technologies

#### Organization-

11.1 Formula access, technology

#### WHA-54.11/2001

*Improve indicators and tools for measuring results and impact of pharmaceutical policies; harmonize them with those of other agencies; support countries to develop national pharmaceutical profiles to be used as a official and reliable source of information on the national pharmaceutical sector;*

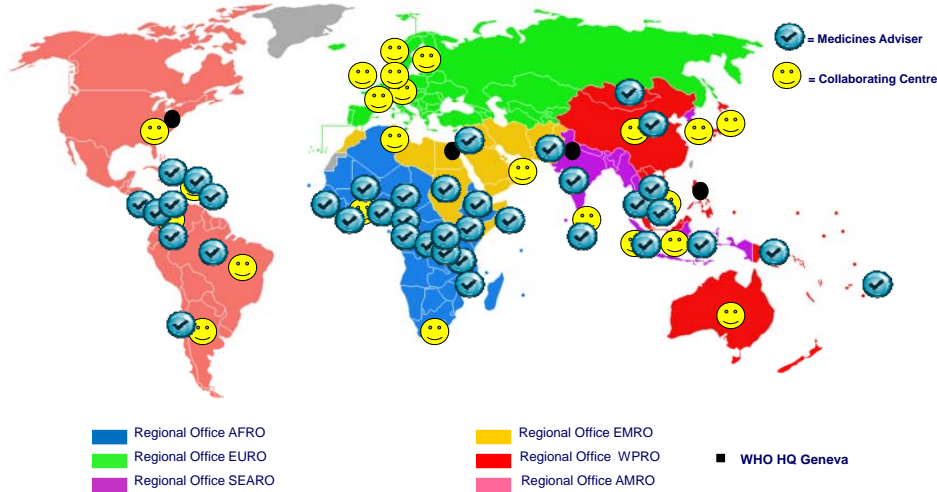
11.2 International norms, standards and guidelines for the quality, safety, efficacy and cost-effective use of medical products and technologies developed and their national and/or regional implementation advocated and supported;

11.3 Evidence-based policy guidance on promoting scientifically sound and cost-effective use of medical products and technologies by health workers and consumers developed and supported within the Secretariat and regional and national programmes.



## WHO: 193 Member States 6 Regional Offices

(Source: <http://www.who.int/about/regions/en/index.html>)



3 | WHO/GF Pharmaceutical Sector Country Profiles | September 27, 2011



## WHO Pharmaceutical Sector Monitoring Tools

### High-level policy information (Country Profiles)

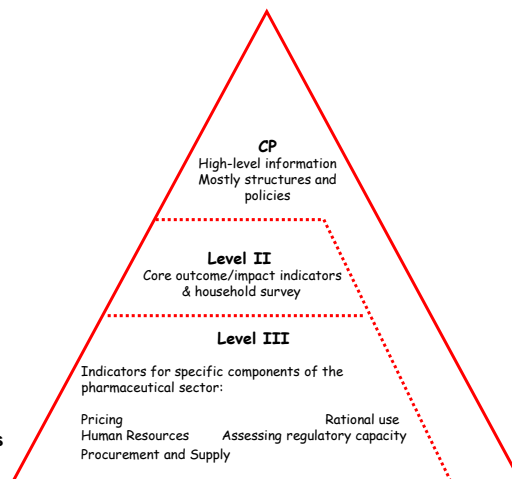
- Questionnaire to Ministry of Health
- Mostly Pharmaceutical sector indicators on structures & policies
- Data on outcomes from Level II and III.
- Regularly carried out

### Household and health facilities surveys (Level II)

- Surveys based on samples
- Monitoring of pharmaceutical policy outcome and impact.
- Upon request

### Topic-specific studies (Level III)

- More detailed indicators for monitoring and evaluating specific areas/components
- Upon request



4 | WHO/GF Pharmaceutical Sector Country Profiles | September 27, 2011



## Specific added value of Country Profiles

- Global updated information on country pharmaceutical sector to inform planning on WHO medicines goals;
- Large number of countries involved (156 in 2007);
- Systematic data collection allowing comparison across time;
- Consolidated country information made available for national planning and policy formulation;
- Information also made available for partners collaboration and support;
- Limited financial and human resources needed;
- Mostly Yes/No question;
- Allows:
  - A unique source of information on the global situation
  - Comparisons within regions and groups of countries i.e. by income levels; regional policies;
  - Comparisons over time.

## CONTENT of the QUESTIONNAIRE (1)

- The questionnaire is divided into 9 chapters:

- Health and Demography
- Health Services.
- Policy Issues.
- Medicines Trade and F
- Medicines Regulation.
- Medicines Financing.
- Pharmaceutical Procurement
- Selection and Rational
- Household data/access

5.00 Clinical trials			
Core Questions ( <a href="#">click here for help</a> )			
		Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting <a href="#">Clinical Trials</a> by the MRA	Yes <input type="checkbox"/> No <input type="checkbox"/>	
5.08.02	Legal provisions exist requiring the agreement by an <a href="#">ethics committee/institutional review board</a> of the Clinical Trials to be performed	Yes <input type="checkbox"/> No <input type="checkbox"/>	
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes <input type="checkbox"/> No <input type="checkbox"/>	
5.08.04	Comments and References		
Supplementary questions ( <a href="#">click here for help</a> )			
		Year	Source
5.08.065	Legal provisions exist for GMP compliance of investigational products	Yes <input type="checkbox"/> No <input type="checkbox"/>	
5.08.063	Legal provisions require sponsor, investigator to comply with <a href="#">Good Clinical Practices (GCP)</a>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
5.08.075	National GCP regulations are published by the Government.	Yes <input type="checkbox"/> No <input type="checkbox"/>	

**CONTEN**

- For each indicator, give a clear definition, collect data, whether through treatment...
- Data from national level,
  - Le...
  - S...
  - R...

7 | WHO/GF Pharmaceutical Sector Country Profiles | September 27, 2011

World Health Organization

## 2011 Survey: ensure quality information is collected

- A manual with instructions to fill in the questionnaire has been developed to guide data collection;
- A glossary with definitions of key items has been produced to make sure questions are interpreted consistently across countries and regions;
- Names and contacts of respondents are collected;
- Year and source of each piece of information is recorded and key documents are attached. Fields for comments are provided to allow respondents to provide more nuanced information;
- Data is endorsed by a senior Official at the Ministry of Health.
- Quality checking of information provided is conducted by WHO at HQ and Regional Offices. This is done through:
  - Checking with previous information available on the country.
  - Checking for internal consistency in the questionnaire.
  - Cross checking with other sources and profiles (for example, National Health Accounts).

8 | WHO/GF Pharmaceutical Sector Country Profiles | September 27, 2011

World Health Organization

## 2011 Survey: reduce burden of data collection

- Questionnaires have been pre-filled with information available and countries fill in gaps, thereby reducing the burden of data collection;
- The Country Profile is developed by international experts; it reduces data collection burden;
- The questionnaire has replaced the WHO/GF tool to replace the Country Profile. Currently joint efforts about 75 Countries;
- Discussions are moving forward with national agencies and WHO Technical



### Pharmaceutical Sector Country Profile Questionnaire

INSERT COUNTRY NAME

## Strengthen country health

- The survey is coordinated and involves relevant national and international partners;
- Country profiles cover all countries;
- Country profiles cover all countries;
- Country profiles cover all countries; health observatories

#### Foreword

This 2010 Pharmaceutical Country Profile for Austria has been produced by the Austrian Federal Ministry of Health with support of the World Health Organization.

This document contains information on structures, process and outcomes of the pharmaceutical sector in Austria. Some of the data comes from global sources (e.g. the World Health Statistics) or from surveys conducted in the previous years, while other pieces of information have been collected at country level in 2010. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

On behalf of the Federal Ministry of Health of Austria, I wish to express my appreciation towards Dr. Sabine Vogler from Gesundheit Österreich GmbH (GÖG) / Austrian Health Institute for her contribution to the data collection and to the development of this profile and Ms. Christine Leopold for her support in the data collection. Additional thanks are expressed to the following organizations and institutions for providing data and information: Austrian Federal Ministry of Health, Austrian Federal Ministry of Finance, Austrian Medicines Agency (AGES), Main Association of Austrian Social Security Institutions, Austrian Chamber of Pharmacists, Austrian Association of Pharmaceutical Manufacturers.

It is my hope that partners, researchers and all those that are interested in the pharmaceutical sector of Austria will find this profile a useful tool in their activities.



Name: Dr. Clemens Martin AUER  
 Function in the Ministry of Health: Director General  
 Date: 23. September 2010

Signature:

## Promote dissemination and visibility of information collected

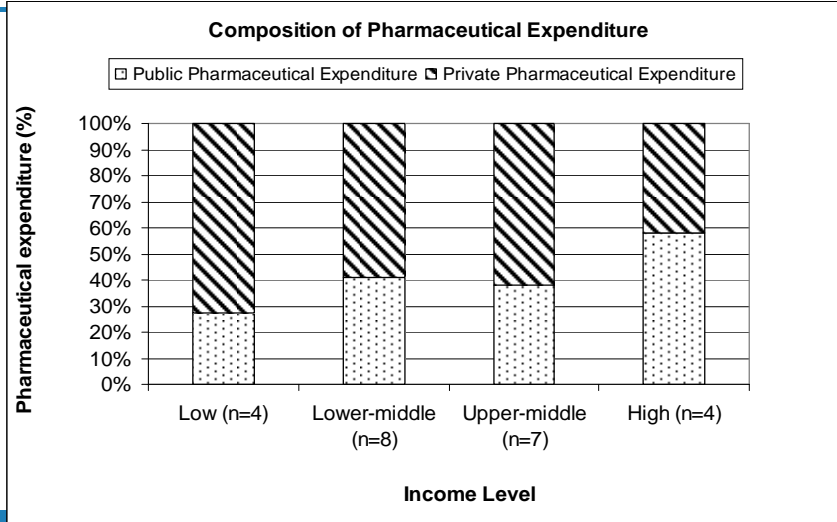
PH  
SI  
CA

Fat  
Mo

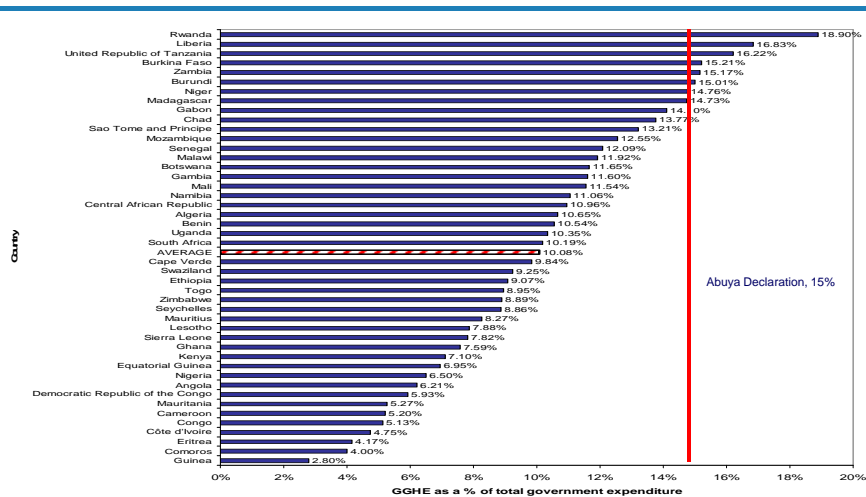
ation

## RESULTS

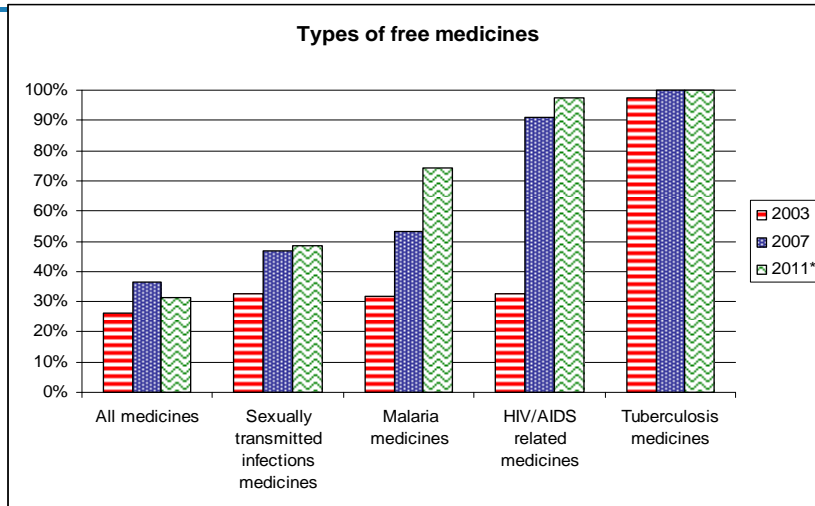
# Public and private expenditure on Medicines



# Health exp as % of govt budget in Africa



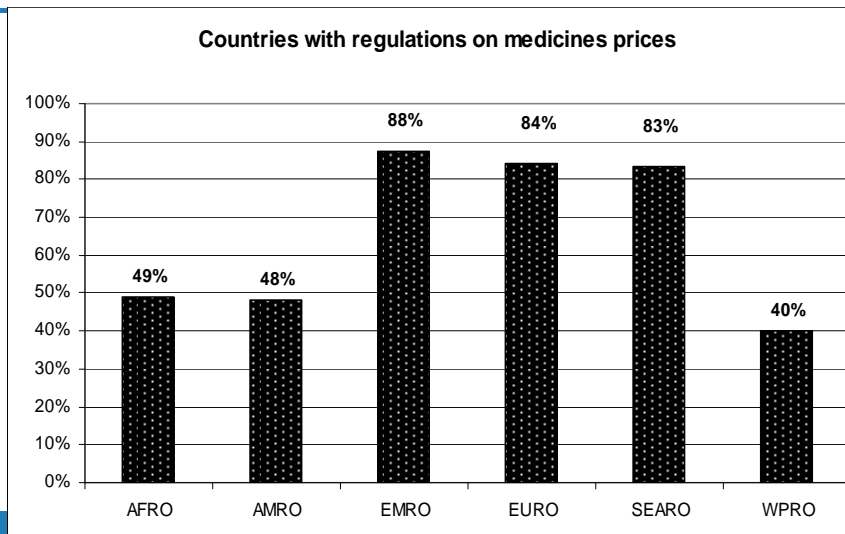
## Free medicines in Africa, 2003-2011



15 | WHO/GF Pharmaceutical Sector Country Profiles | September 27, 2011



## Pricing Policies, Global view

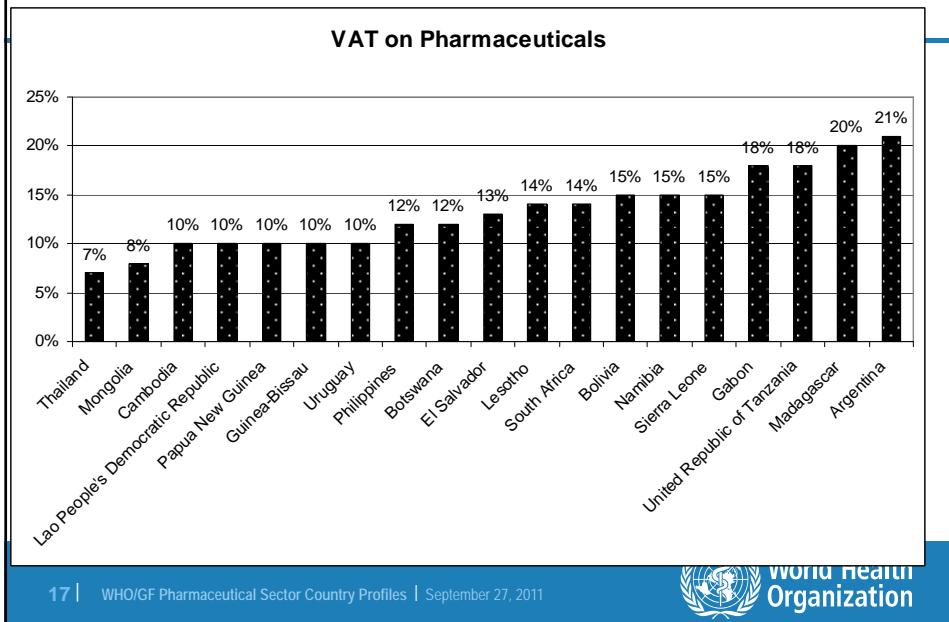


16 | WHO/GF Pharmaceutical Sector Country Profiles | September 27, 2011

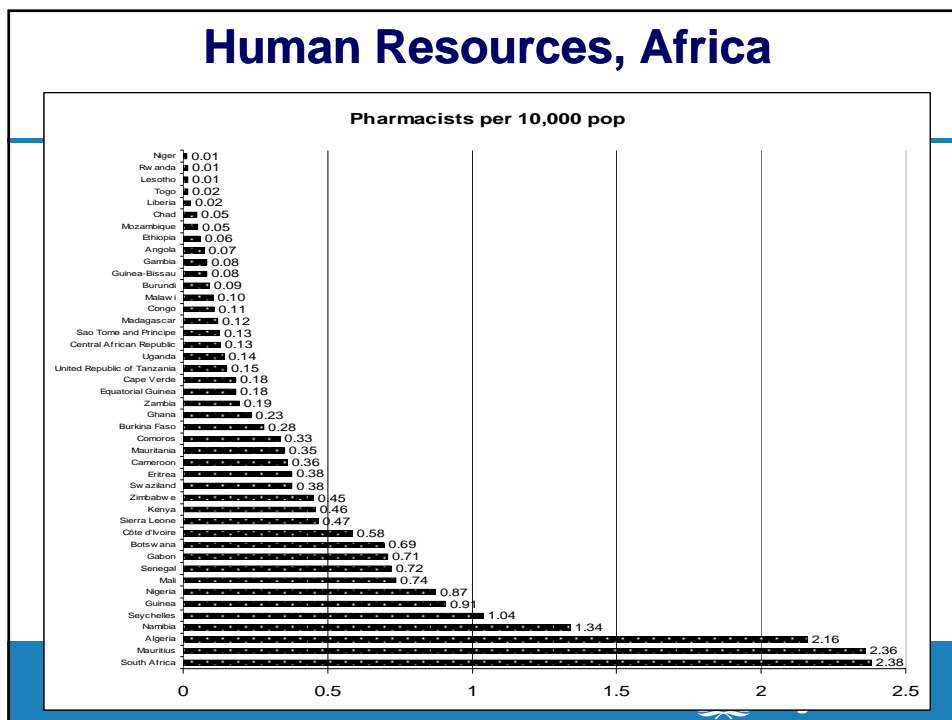




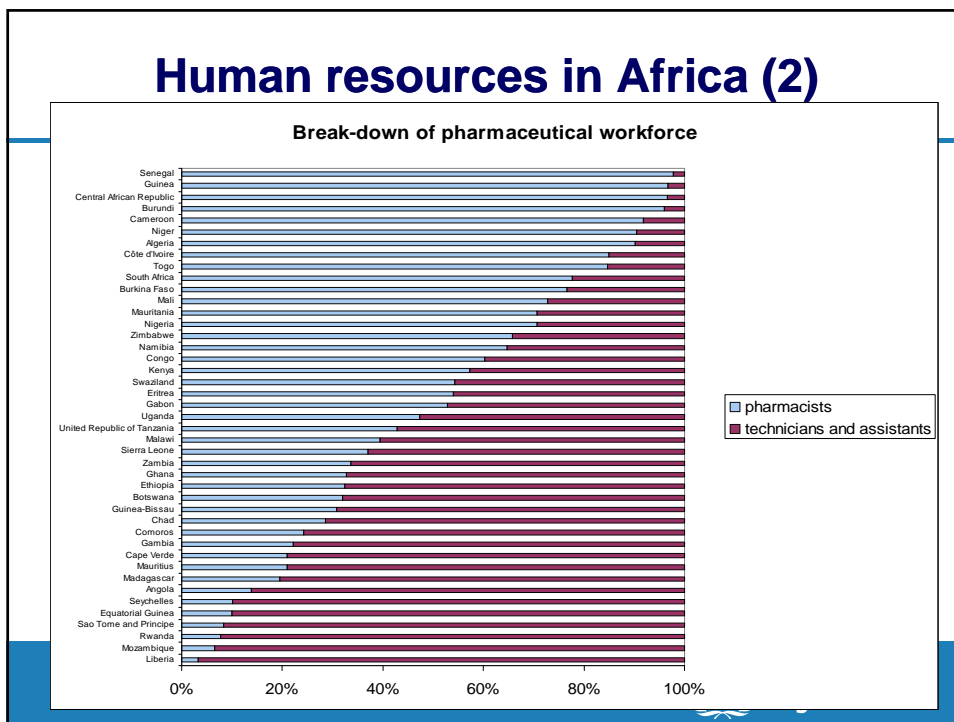
## Taxes on medicines



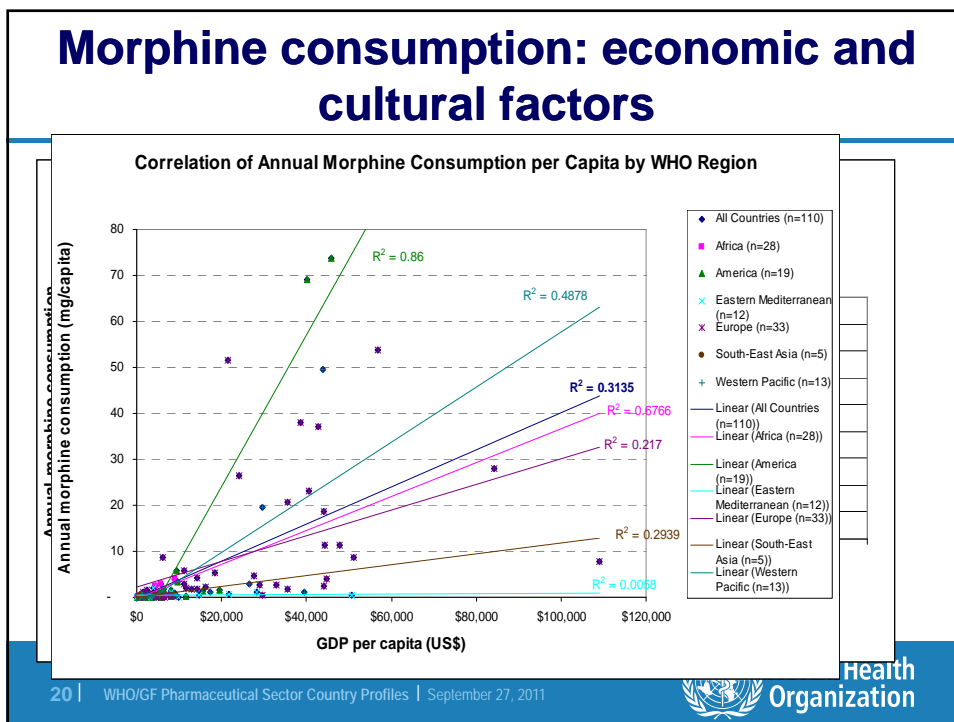
## Human Resources, Africa



## Human resources in Africa (2)



## Morphine consumption: economic and cultural factors



## WAY FORWARD

- Between 2010 and 2011, WHO and GF have rolled out the project to the 193 WHO member states.
- As at today, 84 questionnaires have been returned and 16 profiles are available on the web.
- The information collected so far shows who low- and middle-income countries have less capacity for regulating and monitoring prices of medicines.
- Need to collect more information on systems and practices in extra-european countries and to share successful experiences.