# Are we there yet? Destination SAHPRA


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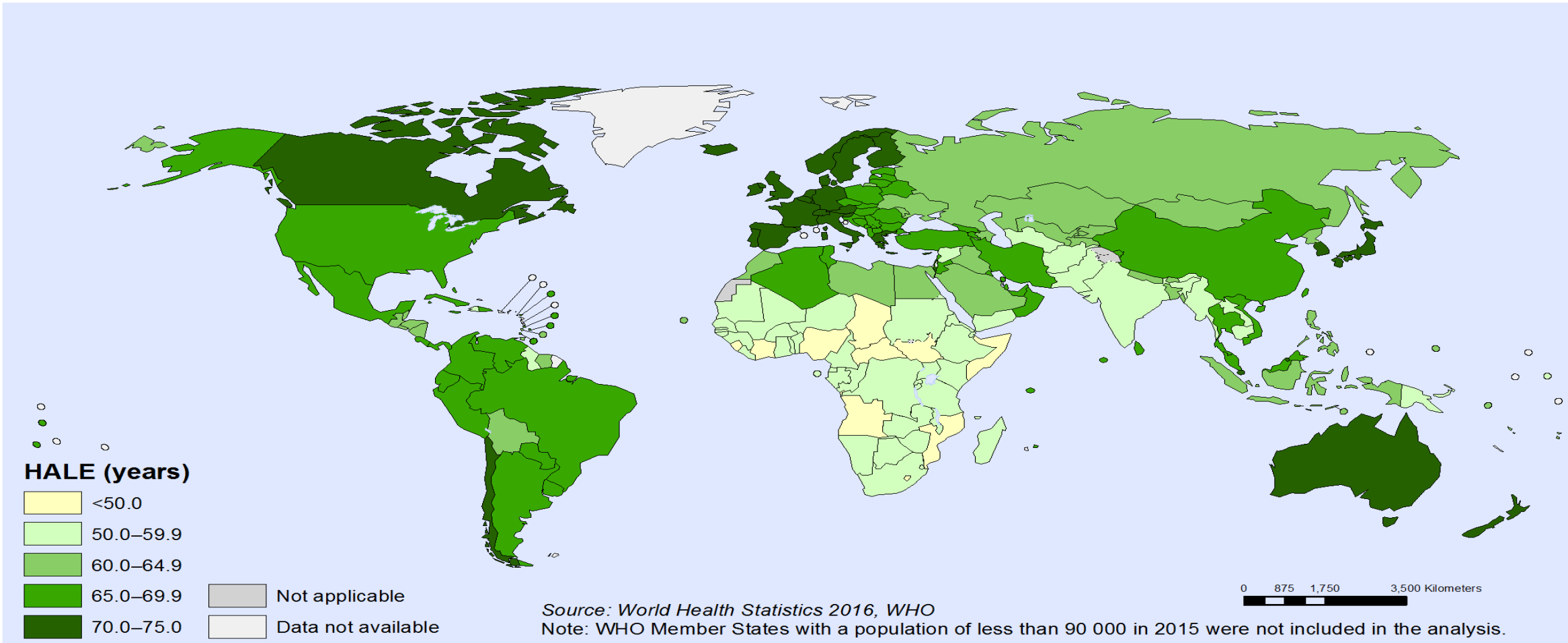
Chairperson, South African Medicines Control Council

# SAAPI 2017 Conference

INDUSTRY IN TRANSITION, 5- 6 OCTOBER , BYTES CONFERENCE CENTRE, MIDRAND

- The context
- SAHPRA

# Healthy life expectancy (HALE) at birth, both sexes, 2015



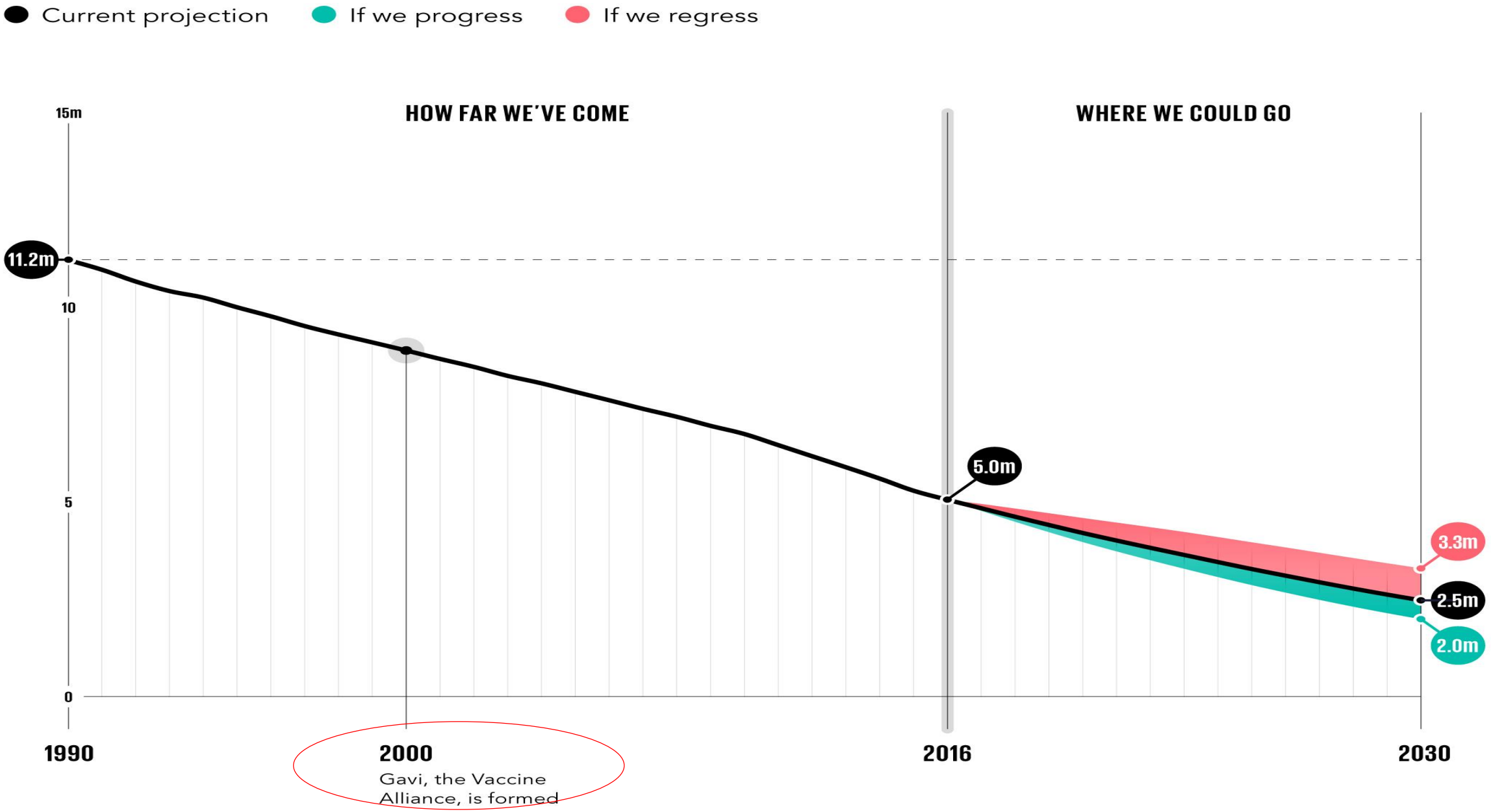

*Source: World Health Statistics 2016, WHO*
Note: WHO Member States with a population of less than 90 000 in 2015 were not included in the analysis.



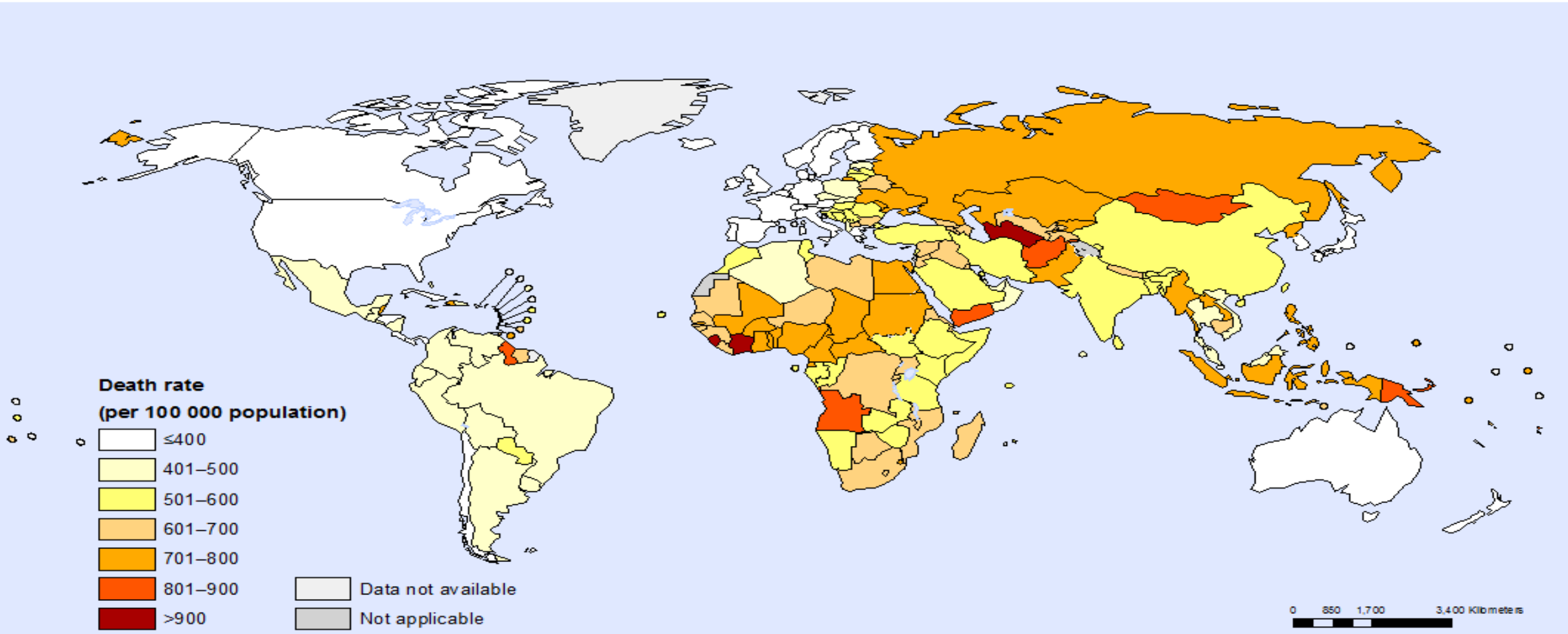
Data Source: World Health Organization
Map Production: Information Evidence and Research (IER)
World Health Organization

World Health Organization

# Global number of deaths of children under age 5 (in millions)



# Deaths due to noncommunicable diseases: age-standardized death rate (per 100 000 population) Both sexes, 2015




The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: Information Evidence and Research (IER)
World Health Organization

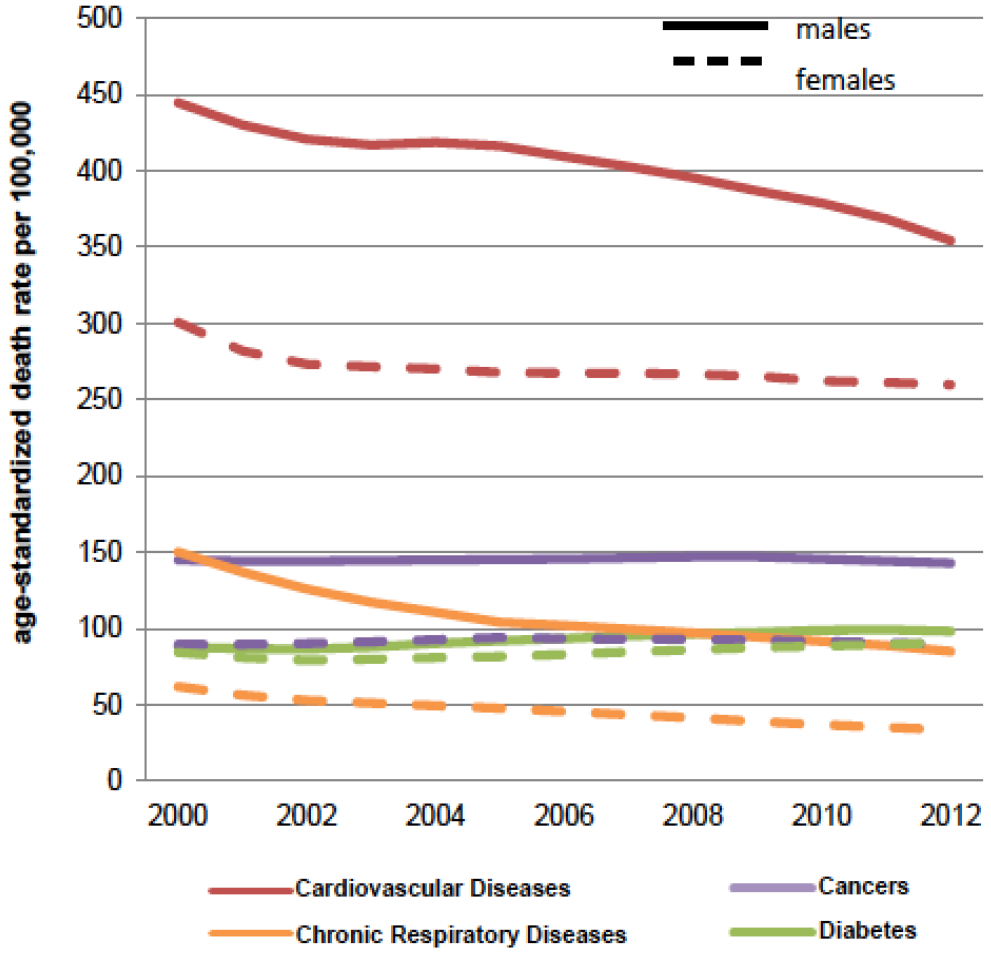
World Health Organization

# South Africa

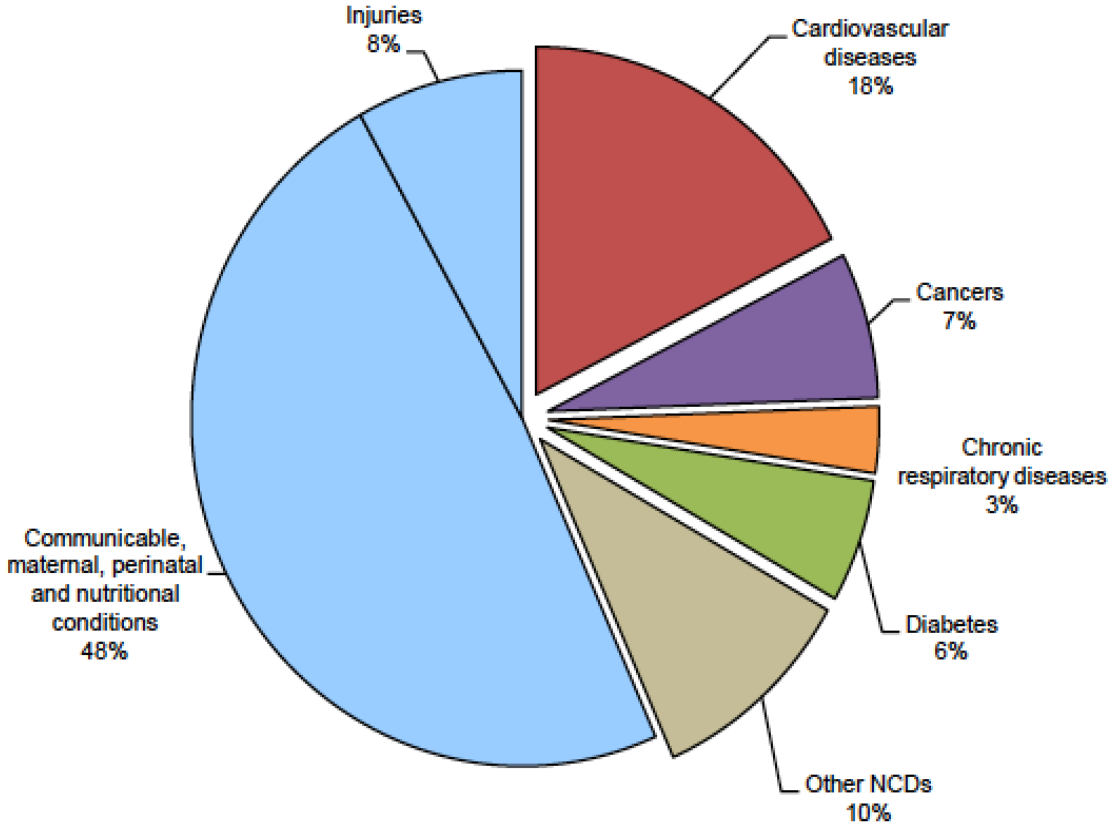
**Total population: 52 386 000**
**Income Group: Upper middle**

**Percentage of population living in urban areas: 62.0%**
**Population proportion between ages 30 and 70 years: 38.3%**

## Age-standardized death rates*

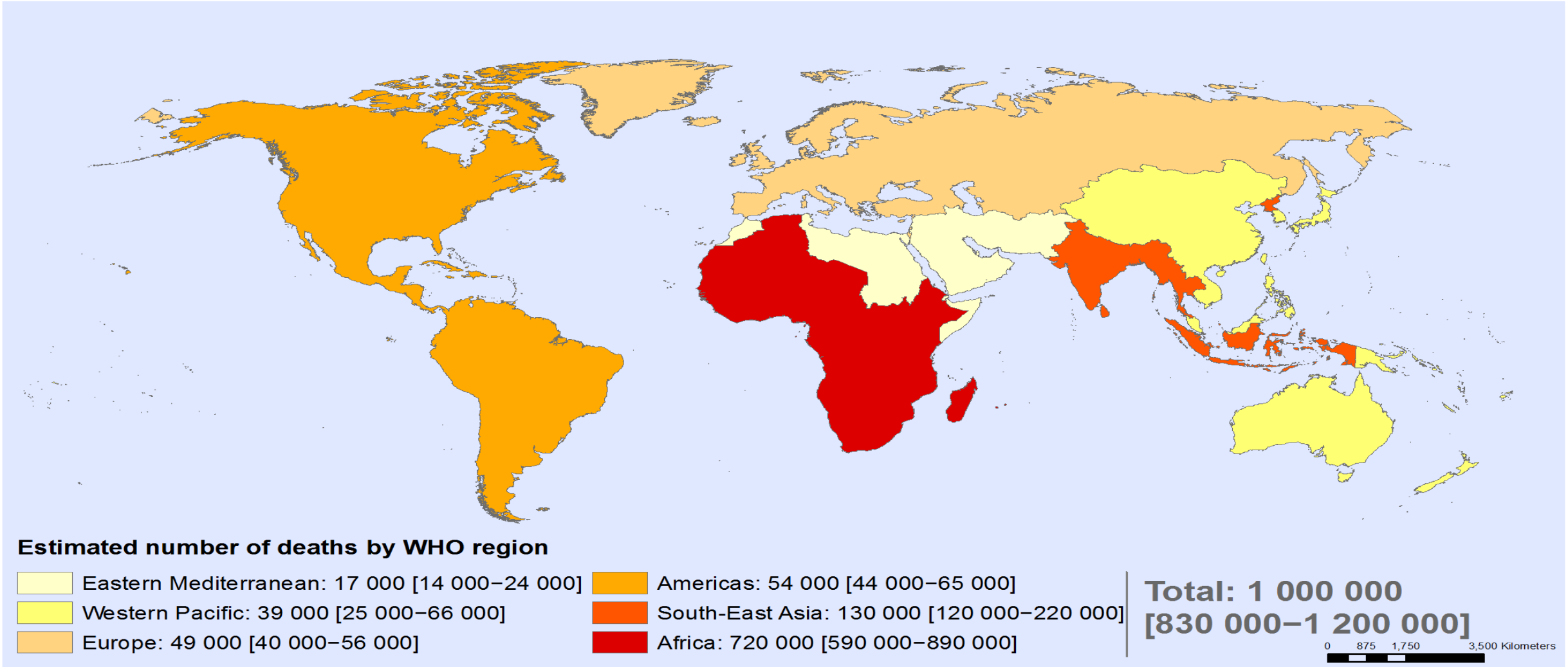



## Proportional mortality (% of total deaths, all ages, both sexes)*




**Total deaths: 608,000**
**NCDs are estimated to account for 43% of total deaths.**

# Estimated number of people dying from HIV-related causes, 2016
# By WHO region



## Estimated number of deaths by WHO region

- Eastern Mediterranean: 17 000 [14 000–24 000]
- Western Pacific: 39 000 [25 000–66 000]
- Europe: 49 000 [40 000–56 000]
- Americas: 54 000 [44 000–65 000]
- South-East Asia: 130 000 [120 000–220 000]
- Africa: 720 000 [590 000–890 000]

**Total: 1 000 000 [830 000–1 200 000]**

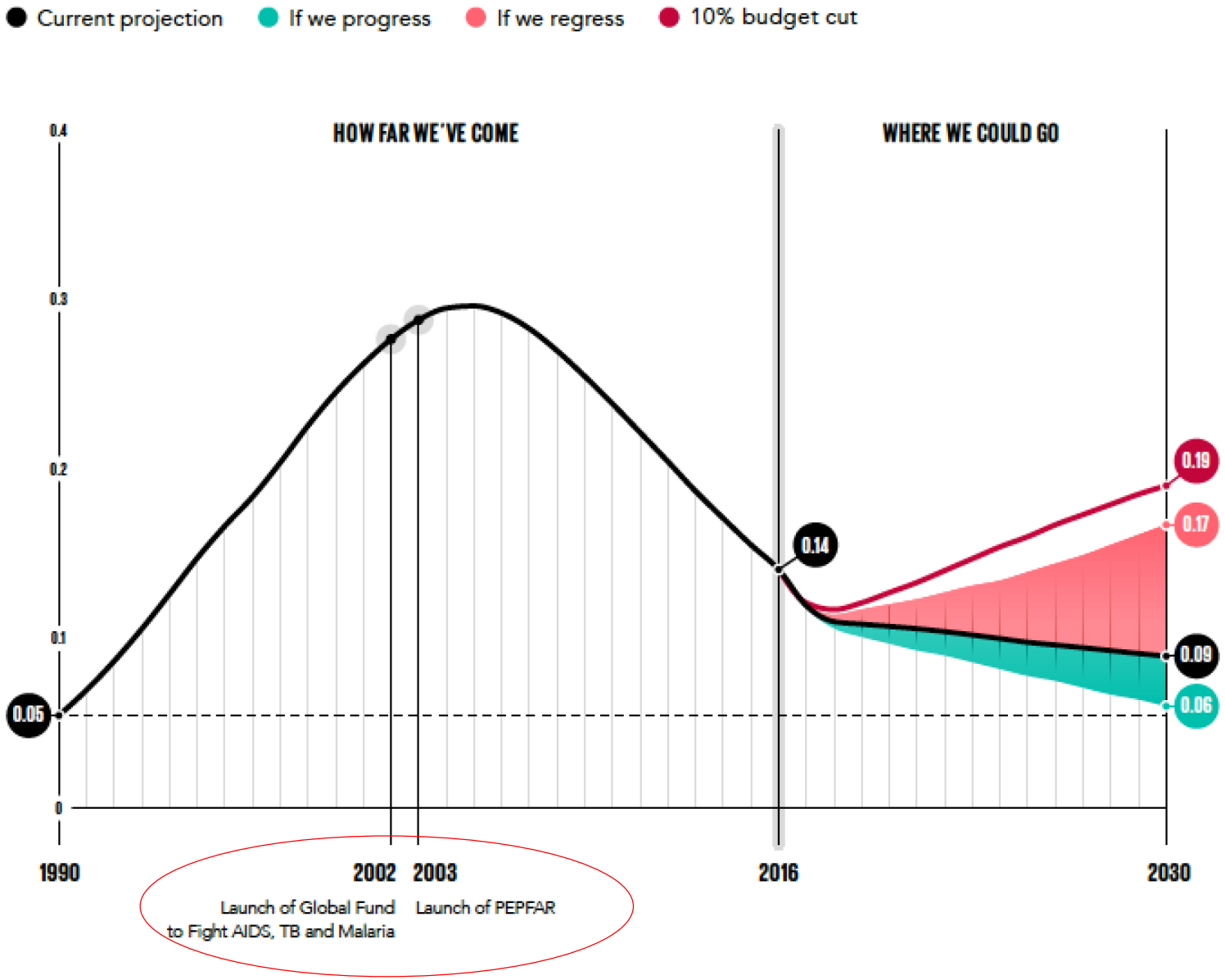
0 875 1,750 3,500 Kilometers



Data Source: World Health Organization
Map Production: Information Evidence and Research (IER)
World Health Organization

World Health Organization

# Global HIV deaths per 1,000 people




This model reflects the impact of a cut in donor funding to HIV treatment, just one aspect of global HIV programs, which also include diagnosis and prevention.

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

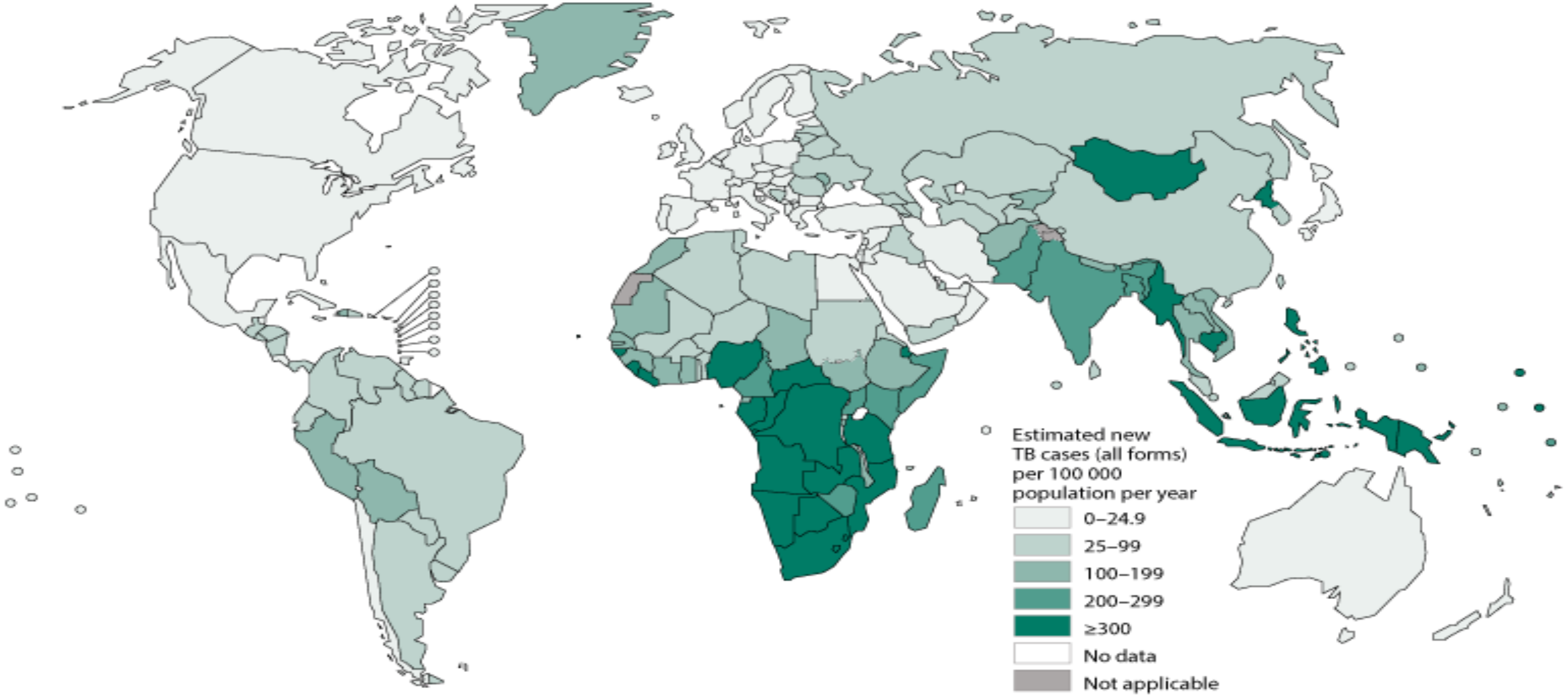
TECHNICAL BRIEF

# PREVENTING HIV DURING PREGNANCY AND BREASTFEEDING IN THE CONTEXT OF PREP

JULY 2017

World Health Organization

# Estimated TB incidence rates, 2015

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Data Source: *Global Tuberculosis Report 2016*. WHO, 2016.

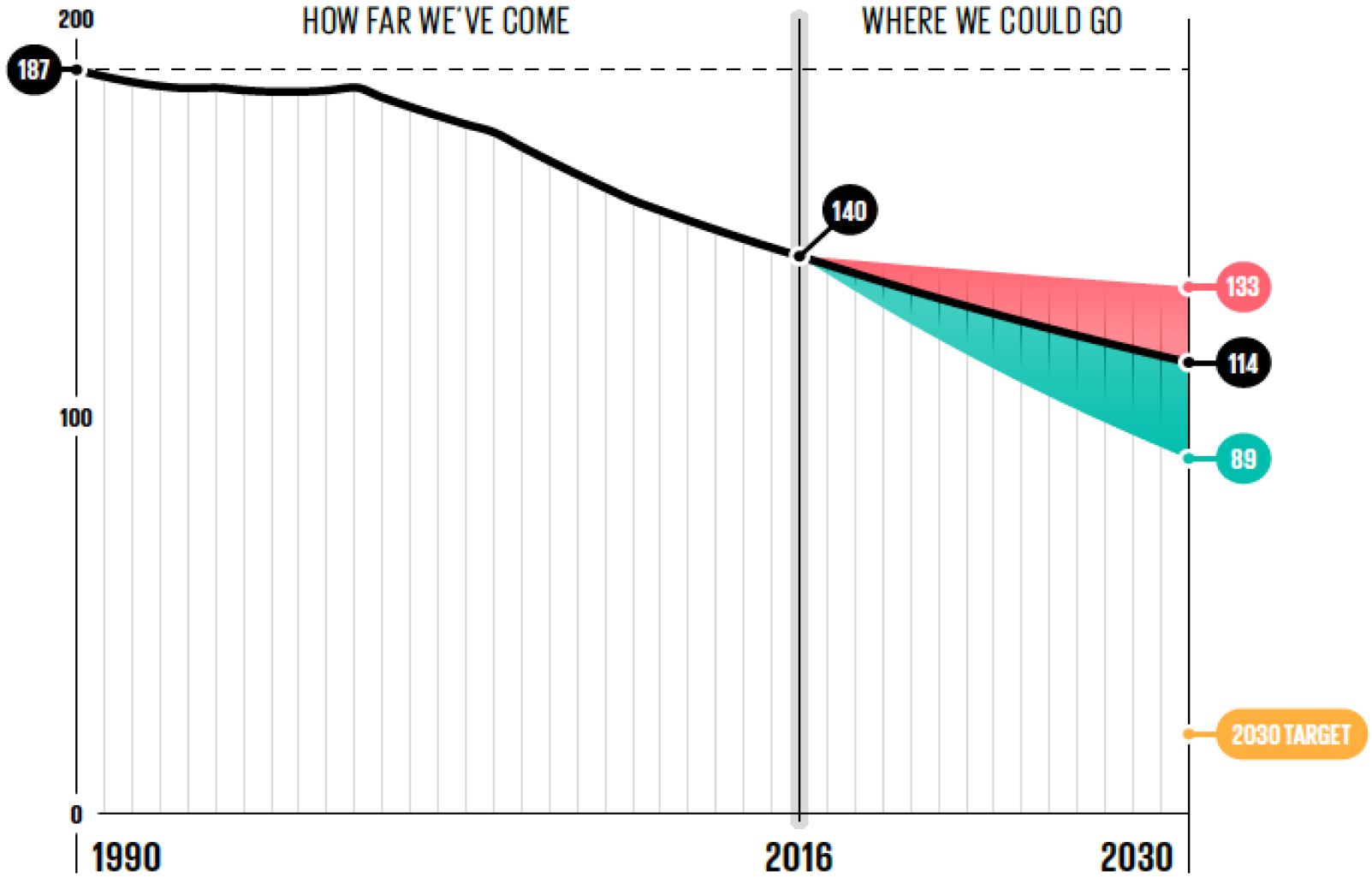


World Health Organization

# TUBERCULOSIS

## New cases of tuberculosis per 100,000 people

Since the early 2000s, a big investment in the fight against TB, especially through the Global Fund, has led to significant improvements in treatment. But the annual rate of reduction is still not enough to hit our target. We are optimistic that new tools, including a vaccine, will be available in the next decade.




Target: End the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases. Target shown on chart has been extrapolated from Stop TB Partnership target of <20 cases per 100,000 in 2030.


feature

'Bewitched' HIV/AIDS activist who rose from the dead



Women used as Aids guinea pigs

'Study to prevent Aids left me infected'

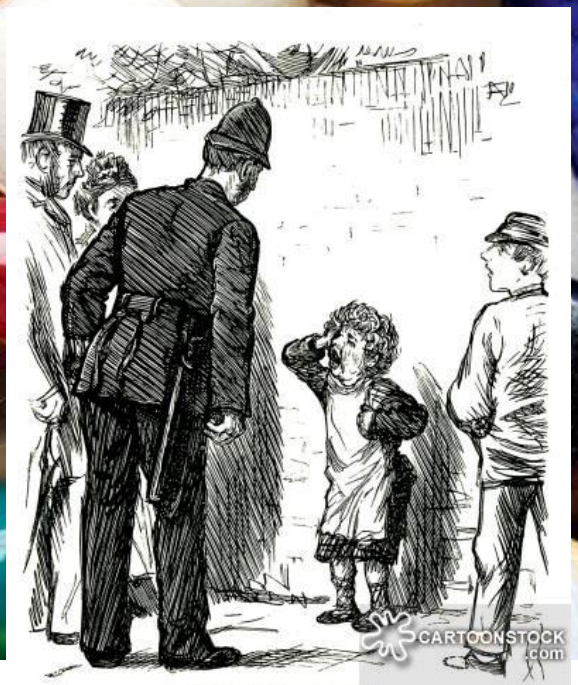



Smallpox vaccine 'triggered Aids virus'


fake.
Coartem 20/120
NOVARTIS
Genuine
Coartem 20/120
NOVARTIS

DEPARTMENT OF HEALTH
Republic of South Africa

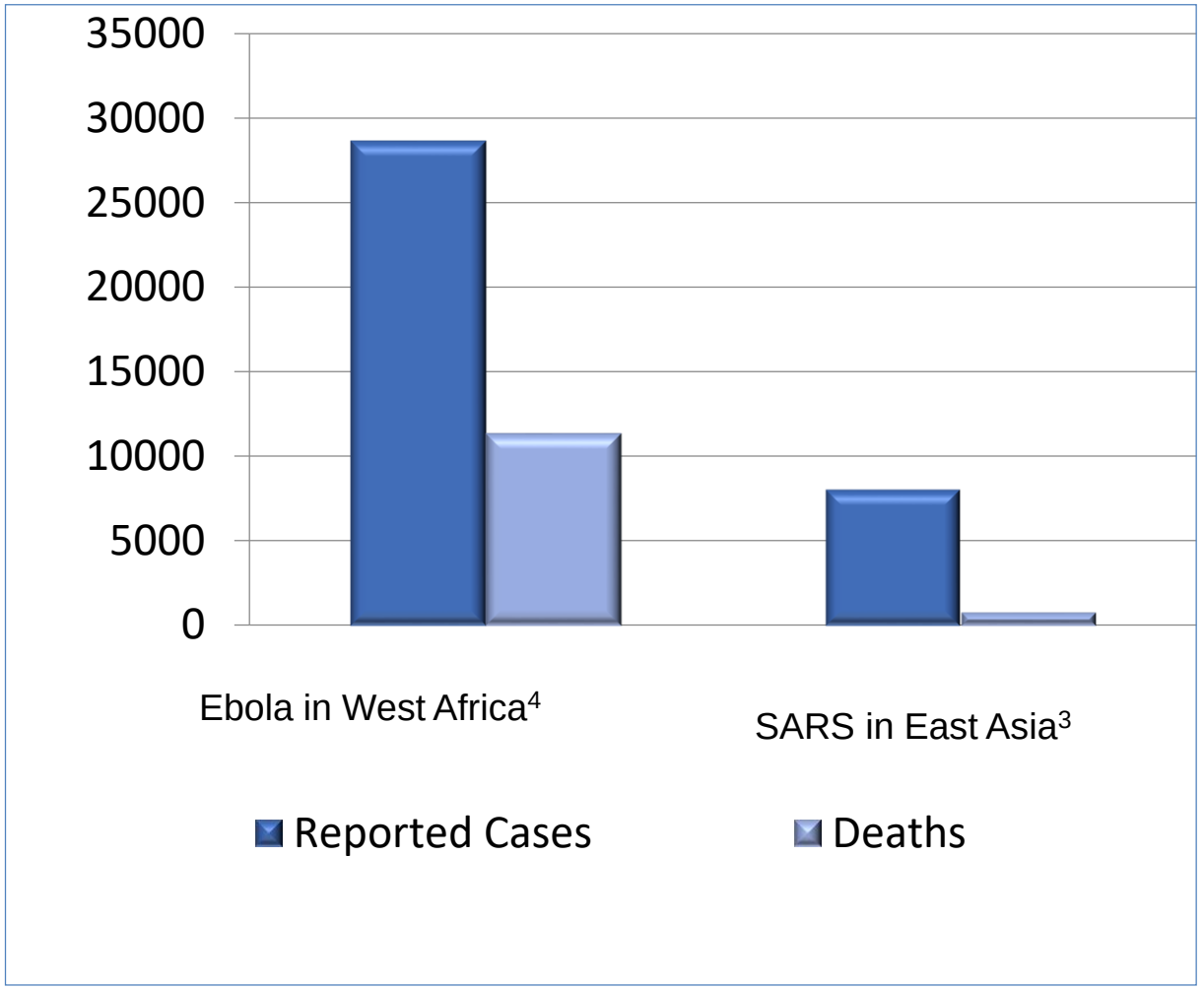
MEDICINES CONTROL COUNCIL



UNENCUMBERED.

*Policeman.* "WHERE D'YER LIVE?" *Lost Child.* "DON'T KNOW."
*Policeman.* "WHO'S YER FATHER AND MOTHER?"
*Lost Child.* "AIN'T GOT NONE."
*Policeman (perplexed).* "ARE YER MARRIED?" *Lost Child.* "NO."
*Policeman (relieved).* "AH, SHURE, THIN YE'RE ALL RIGHT! AWAY YOU GO!"
[*Crowd disperses.*

# Human Impact of Global Outbreaks




# Economic Impact of Global Outbreaks

$2.2 B

Ebola in West Africa[1]

$54 B

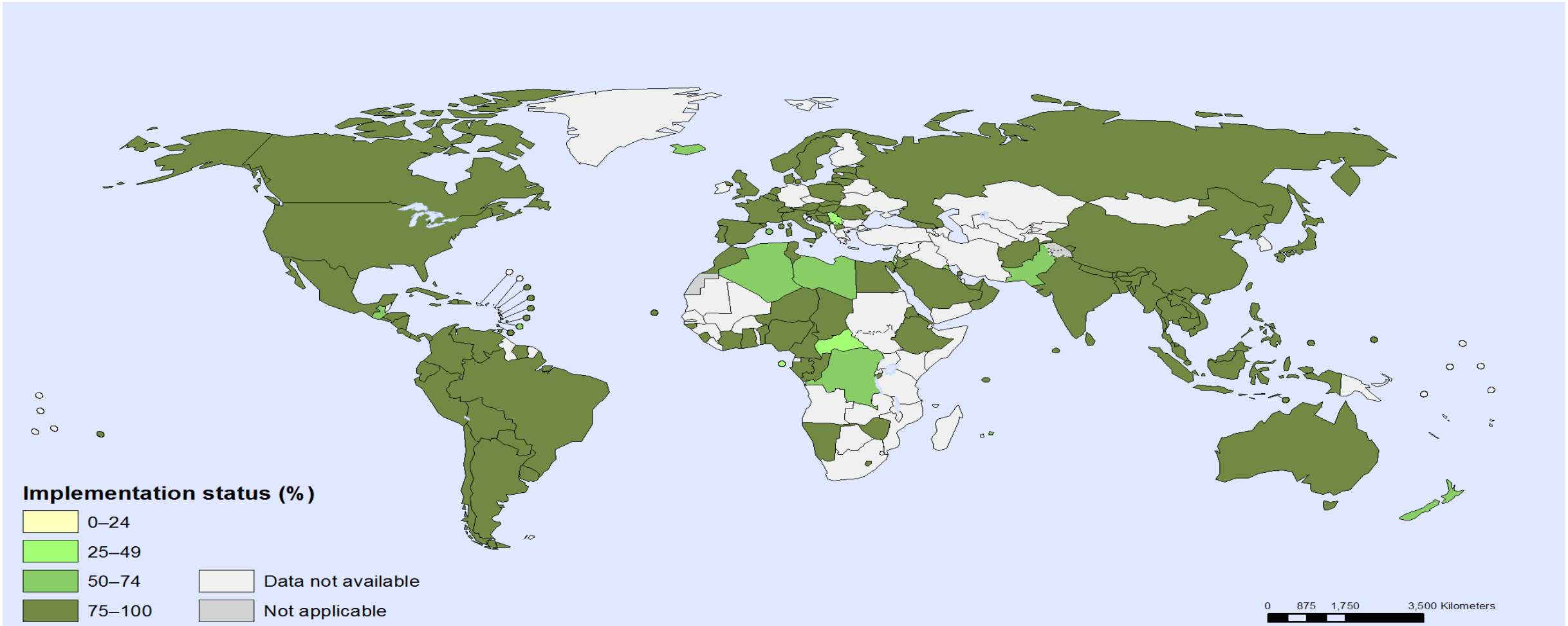
SARS in East Asia[2]

$30 B

Expected Annual Losses from the Global Economy[2]

World Bank, 2016

# International Health Regulations (IHR) monitoring framework
# Implementation status – IHR surveillance core capacity, 2016

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World Health Organization

World Health Organization

# Some of the Gaps in regulatory preparedness:

- **Lack of coordinated emergency regulatory processes**
  - Link regulatory processes with overall national preparedness planning for public health emergencies
- **Weakness of drug regulatory systems and lack of capacity**
  - Strengthen regulatory collaboration and capacity
- **Limited capacity and experience in stakeholder communication**
  - Need for guidance in communicating with the media and public
- **Poor engagement of product developers with affected regulators**
- **Weakness in regulation of supply chains**
  - Need to minimize entry of substandard and falsified products in supply chains


HOME
ABOUT THE MCC
PUBLICATIONS
NEWS & EVENTS
CONTACT THE MCC
Quality Management Systems
The MCC operates through external experts who are members of Council Committee structures

# Drug regulation ensures that

- Medicines are of the required quality, safety and efficacy before and after registration ( pharmacovigilance)
- R&D is of high quality and designed to accelerate new drug development,  improved formulations or regimens
- Patients and communities have the necessary information for rational use of medicines
- Medicines are appropriately manufactured, stored, distributed, dispensed
- Illegal manufacturing and trade are detected and adequately sanctioned
- Promotion and advertising is fair, balanced, aimed at rational drug use
- Access to medicines not hindered  by unjustified regulatory work

WHO 2017

# The role of the regulator in medicine access

- Adequate R&D
- Diagnosis
- Reliable information
- Quality of product
- Availability
- Affordability
- Accessibility
- Pharmacovigilance

# Medicines Control Council (MCC)

The Medicines and Related Substances Act, 1965

- Enacted 1965
- Provides for certain powers:
  - Minister of Health
  - Director General: Health
  - Medicines Control Council (MCC)
- MCC mandate:
  - Registration of medicines : Safety, quality and efficacy
  - Licensing of Manufacturers, Wholesalers, Importers
  - Authorization conduct of clinical trials

# History of MCC

## Historical

- 1998: Review of medicine regulatory system – Prof Graham Dukes
- 1998: Operational and Financial review - KPMG
- 1998:Transitional Task Team – Prof Helen Rees
- 1999: SAMDRA Act and its repeal
- 2002: Medical Technical Task Team – Ms Precious Matsoso (WHO)
- 2006: Parliament directed review – Prof Green-Thomson
- 2008: Act 72 of 2008
- 2012: Business case: Nicholas Crisp
- 2014: Transitional Task Team – Prof Helen Rees
- 2015: Act 14 of 2015

**Reviews support the transition to a new business model to allow for:**

- **Service delivery**
- **Communication**
- **Operational processes**

# South African Health Products Regulatory Authority

The Medicines and Related Substances Act, 1965 Amended

- Act 72 of 2008: **Establish SAHPRA**
  - 3 A Public Entity
  - Extended the mandate to include Medical Devices
- Act 14 of 2015: Transitional arrangements : MCC to SAHPRA
  - Appointment of a Governance Board
  - Expand oversight of Medical Devices to include IVD's
  - Address transitional arrangements from MCC to SAHPRA
    - Work of the MCC
    - Staff
    - Assets and contracts

# SAHPRA

SAHPRA is proposed to:

- have **full-time in-house capacity** to support product review & approval and oversee all regulatory functions
- establish **cooperation and information** sharing with other NRAs to support implementation of best practices and timely approval of products

SAHPRA will be responsible for:

- monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in the public interest.

# SAHPRA

- Act 72/2008 enacted: 1 June 2017
  - This enacted also Act 14 of 2015
- General Regulations prepared on SAHPRA Act
  - Regulations for publication: 11 August 2017
- Minister: calls for nominations for the Board to be appointed
  - Advertisement for Board members – deadline 30 June 2017
  - Board consists of 10-15 members
  - Skills of the Board identified in the Act
    - One person each: Law, governance, finance, HR, IT
    - 10 members: medicine, medical devices & IVDs, vigilance, GMP, clinical trials, public health or epidemiology
  - Nominations received: under consideration

# Status of SAHPRA

- Minister: calls for 1st meeting of the Board
  - Orientation of the Board
  - MCC will cease to exist with 1st Board meeting
  - Board appoint CEO
  - Board appointment committees to assist with work of the Board
  - CEO appoint committees to assist with work of Authority
  - Authority works through the Board
- DOH staff to transfer to SAHPRA
  - Section 197 transfer
  - Staff component: 207

# Status of SAHPRA

Business case developed for SAHPRA by Project Team

- Statutory and Legal
- Media
- Human Resources – Organisational Development
- Human Resources – Policies
- Job descriptions
- CEO performance agreement
- Finance
- Information Technology
- Implementation plan

# SAHPRA Business model

Requirements:

- effective, efficient and transparent systems of financial and risk management and internal control
- a system of internal audit under the control and direction of an audit committee complying with and operating in accordance with regulations and instructions prescribed in the PFMA
- an appropriate procurement and provisioning system which is fair, equitable, transparent, competitive and cost-effective

# SAHPRA

*S2(1) The South African Health Products Regulatory Authority is hereby established as an organ of state within the public administration but outside the public service.*

## BOARD

***S2(5) The Authority acts through its Board***
*(as it pertains to business and not execution of responsibilities of authority)*

S2C – Composition, S2D, E, F – Appointment, Chair, Disqualification

S2G – Meetings of the Board
*(1) The **meetings of the Board and the conduct of business at meetings** must be determined **by the rules of the Board.***

## COMMITTEES (OF BOARD)

S2H – Committees of Board
*The Board may appoint one or more committees from among its members to **assist** it with **the performance of its functions.***

**STATUS REPORTED**

## REGISTRATION OF MEDICINES AND MEDICAL DEVICES

***S15(3), (4), (5)***

## CEO

S3(1) Appointed by the Board (after consultation with Minister)

*S3(4) (e) is responsible for the **general administration** of the Authority and for the **carrying out of any functions assigned to the Authority** by this Act and the Minister;*

## STAFF

*S3(5) The Chief Executive Officer shall appoint suitably qualified staff and may contract other suitably qualified persons to assist the Authority in carrying out its functions.*

*S34A(3) The Chief Executive Officer may, in writing, authorise any staff member of the Authority to exercise or perform in general or in a particular case or in cases of a particular nature, **any power, duty or function conferred or imposed on the Chief Executive Officer in terms of this Act.***

## COMMITTEES (OF CEO)

*(9) The Chief Executive Officer shall, in consultation with the Board, appoint committees, as he or she may deem necessary, to investigate and report to the Authority **on any matter within its purview in terms of this Act**.*

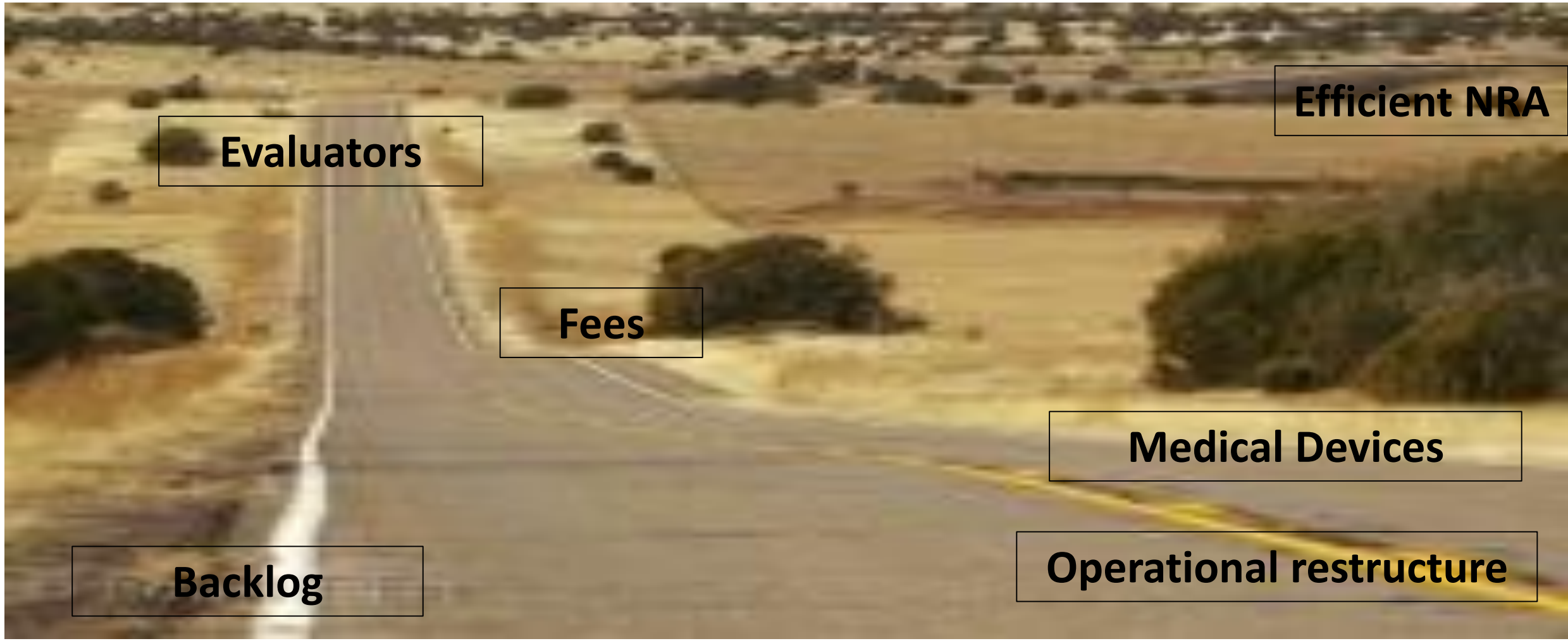
# SAHPRA versus MCC

- Business model based on business principles
- Staff employment: reporting lines – SAHPRA
- Performance driven (In-house and External staff)
- Registration and Authorizations issued by Authority
- Transparency
- Retain revenue
- MoU with other Regulators
  - Allow for acceptance of international evaluation reports

# SAHPRA vs. Existing Model
# The fundamental differences

| SAHPRA | Existing Model |
|---|---|
| Medicines, Devices (incl. IVD's and Radiation Control), CAMS | Medicines, (Radiation Control part of NDOH) |
| System driven | Paper driven |
| Service delivery with defined timelines | Service delivery with backlogs |
| Fully resourced | Under resourced |
| Increased employed and contracted evaluators (80/20) | Limited employed evaluators (20/80) |
| Public entity – Fully accountable | Part of the Department of Health |
| Transparent industry relations | Stretched industry relations |
| Increased and retained fee income | No fee retention |
| Agency format | Traditional government format |
| Proactive performance measurement (managed service levels) | Reactive |
| Accrual based accounting | Cash based accounting |

# Closure


Evaluators
Efficient NRA
Fees
Medical Devices
Backlog
Operational restructure


Thank you !
And thanks to Joey Gouws
www.mccza.com

# Assessment pathways for medicines, vaccines & diagnostics

**Full/Traditional approval**

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES

FDA U.S. FOOD & DRUG ADMINISTRATION

swissmedic
Schweizerisches Heilmittelinstitut

Health Canada

pmda

**"Accelerated" approval**

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA U.S. FOOD & DRUG ADMINISTRATION

Other SRAs

**Prequalification**

World Health Organization

**Article 58 Scientific Opinion**

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

**Conditional Marketing Approval**

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

**"Animal Rule" Approval**

FDA U.S. FOOD & DRUG ADMINISTRATION

**Approval under Exceptional Circumstances**

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

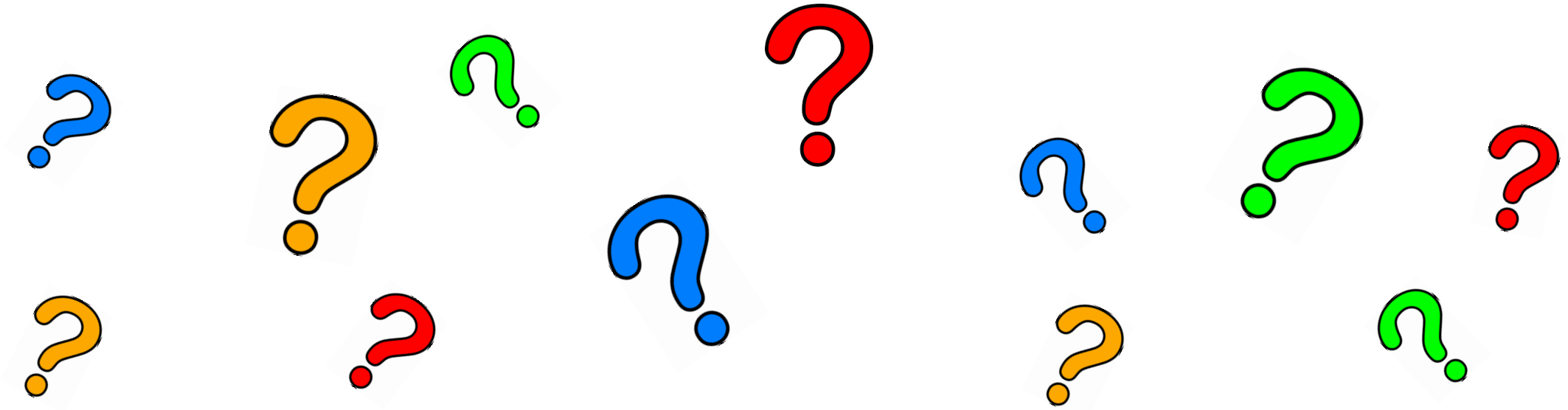
**Emergency Use and Assessment Listing (EUAL)**

World Health Organization

# Pathways in LMICs (likely to be first hit by epidemic)?

**Most authorities have “full” or “abbreviated” (based on reliance),**

**but not conditional, emergency, exceptional use, compassionate use options..**



# What do we understand by regulatory tools and pathways?

- **Regulatory tools** are policies, plans, projects or programs "in pursuit of specific societal outcomes that are not achievable through normal market-based or incentive mechanisms".
  - Definition from: neat.ecosystemsknowledge.net/regulatory-tools.html
  - **e.g. Guidelines, Reference Standards, Policies, Procedures….**
- **Regulatory pathways** are options to facilitate the submission and assessment of regulatory information
- Identification of tools and pathways aims to decrease and manage uncertainties
-

# Tools for regulatory preparedness

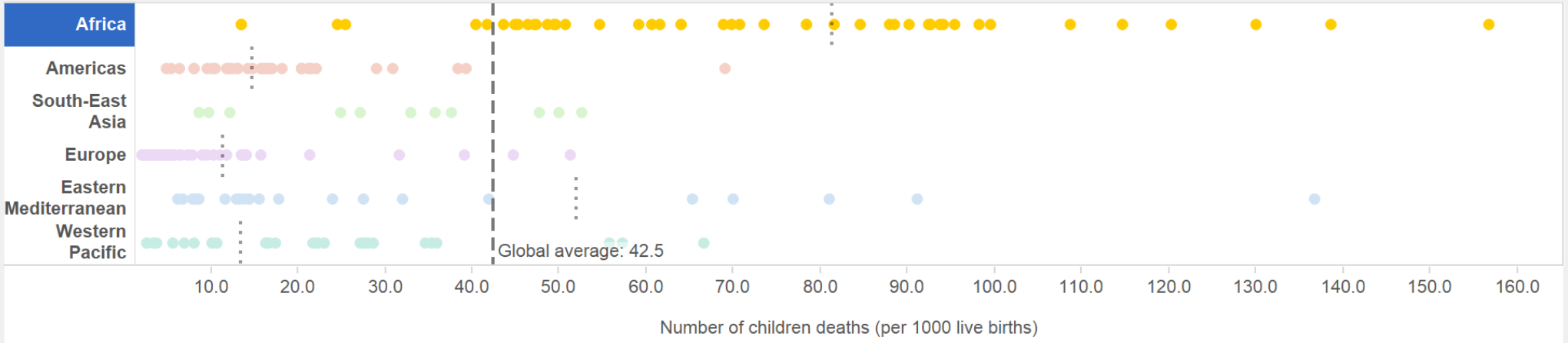
- **Regulatory tools in emergency preparedness should help to:**
  - ✓ Provide “increased capacity to recognize the promise in treatments that might otherwise be discarded”;
  - ✓ Detect “unsafe or ineffective therapies more quickly”; and
  - ✓ Generate “studies that will inform a wide range of innovation, not just individual products”.

# Under-five mortality rate (per 1000 live births), 2015

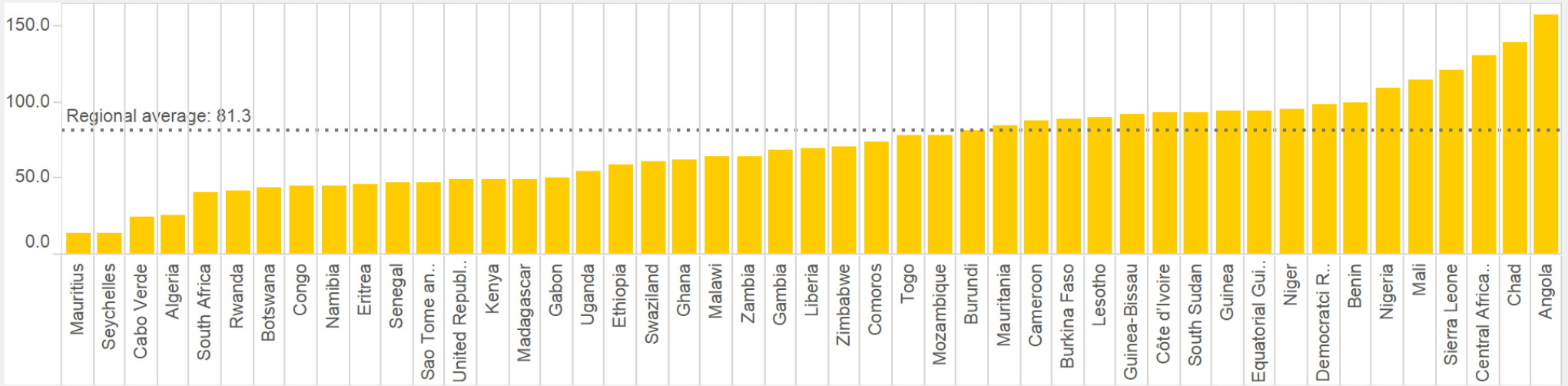
## In Sub-Saharan Africa, 1 child in 12 dies before his or her fifth birthday

Each circle/bar represents a country. The dotted grey line indicates the regional average, and the dashed grey line indicates the global average.
Click on a region name to display the distribution by country (within that region) as a bar graph.

### Under-five mortality rate (per 1000 live births) by WHO region, 2015

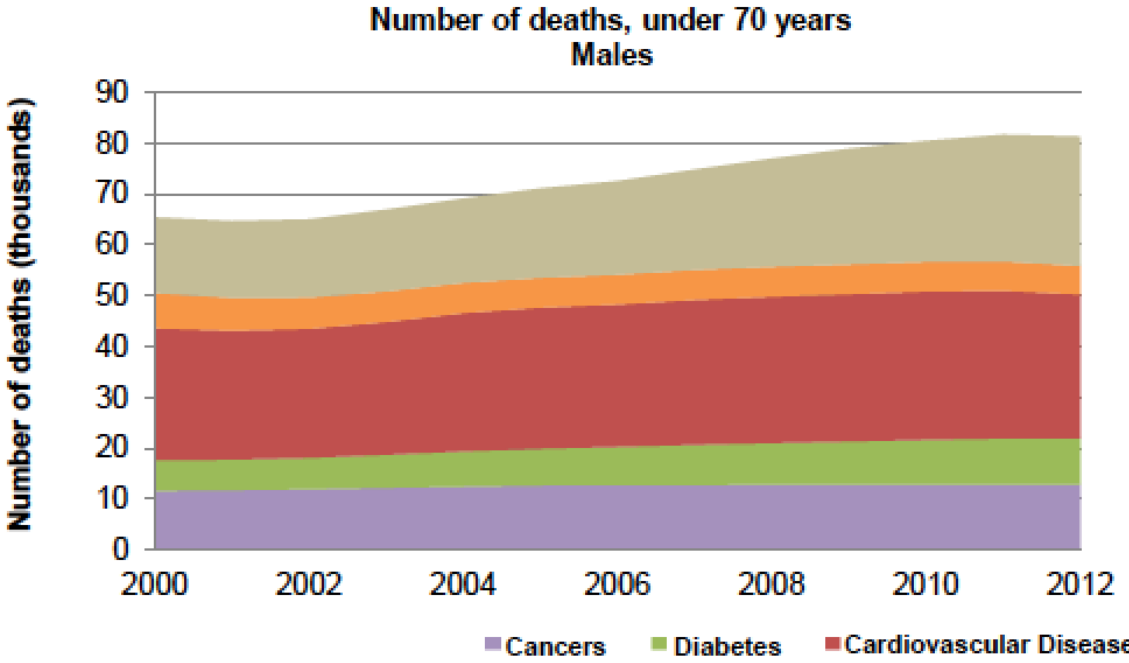


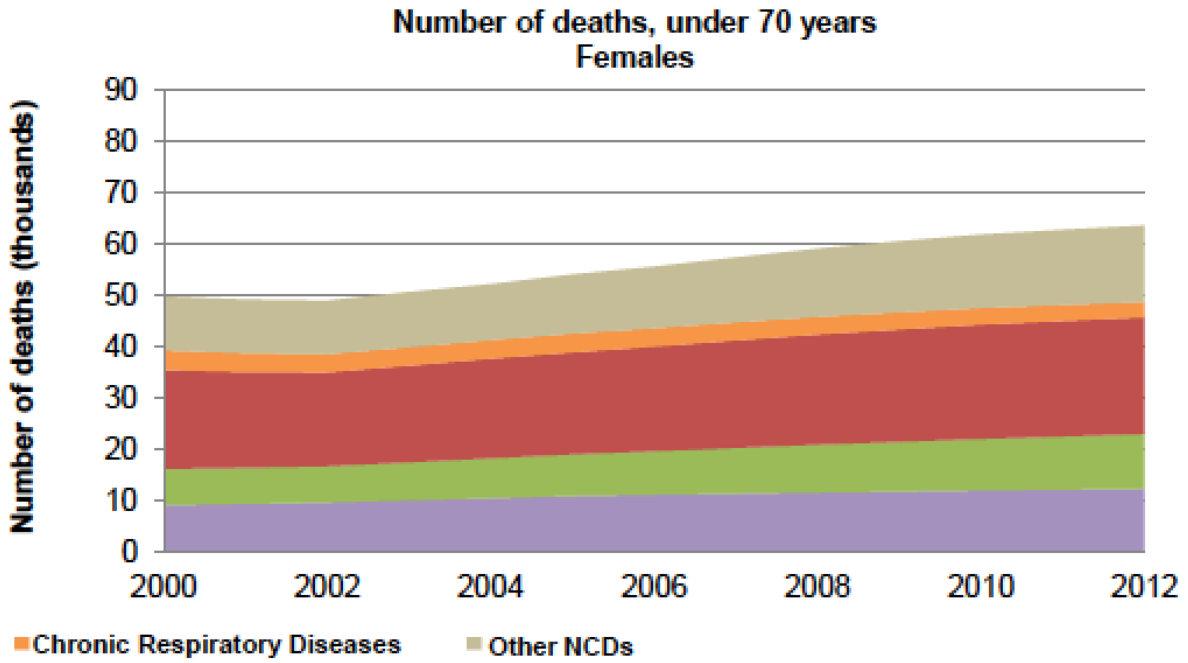

### Distribution by country (in selected WHO region) mouse-over the y-axis to sort



## Premature mortality due to NCDs*

**The probability of dying between ages 30 and 70 years from the 4 main NCDs is 27% .**



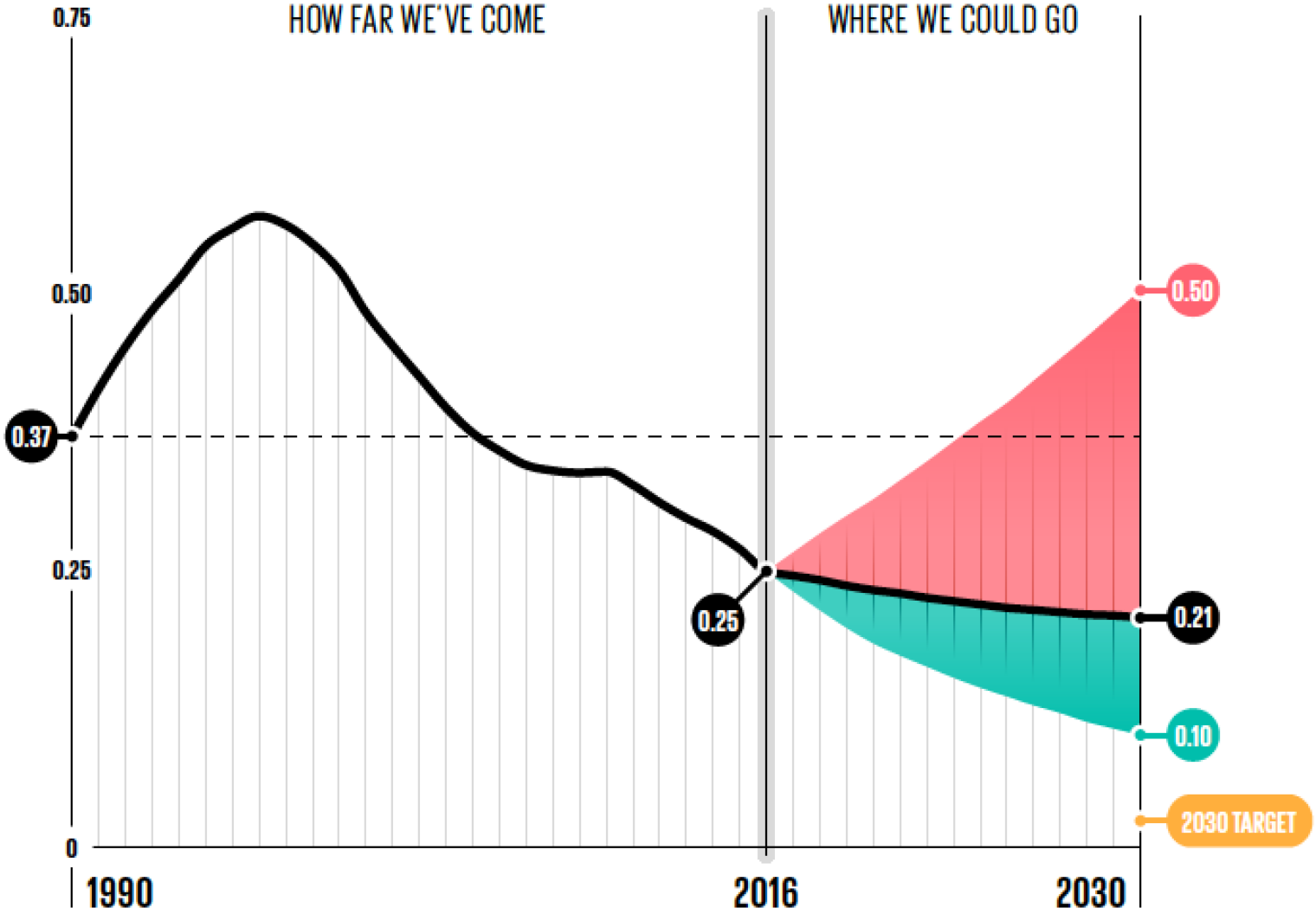

## Adult risk factors

| | males | females | total |
|---|---|---|---|
| Current tobacco smoking (2011) | 28% | 8% | 18% |
| Total alcohol per capita consumption, in litres of pure alcohol (2010) | 18.4 | 4.2 | 11.0 |
| Raised blood pressure (2008) | 35.2% | 32.4% | 33.7% |
| Obesity (2008) | 21.0% | 41.0% | 31.3% |

# HIV

## New cases of HIV per 1,000 people

In the early 2000s, the Global Fund, PEPFAR, and domestic spending in endemic countries helped bring new HIV infections way down. As the sense of crisis dissipated, however, the rate of decline slowed. Eventually, new prevention methods will help speed up the decline, but for now, we have to bend this curve using currently available methods. That means continuously searching for new ways to deliver solutions and sharing best practices widely.




Target: End the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases. Target shown on chart has been extrapolated from UNAIDS target of 200,000 new infections among adults in 2030.