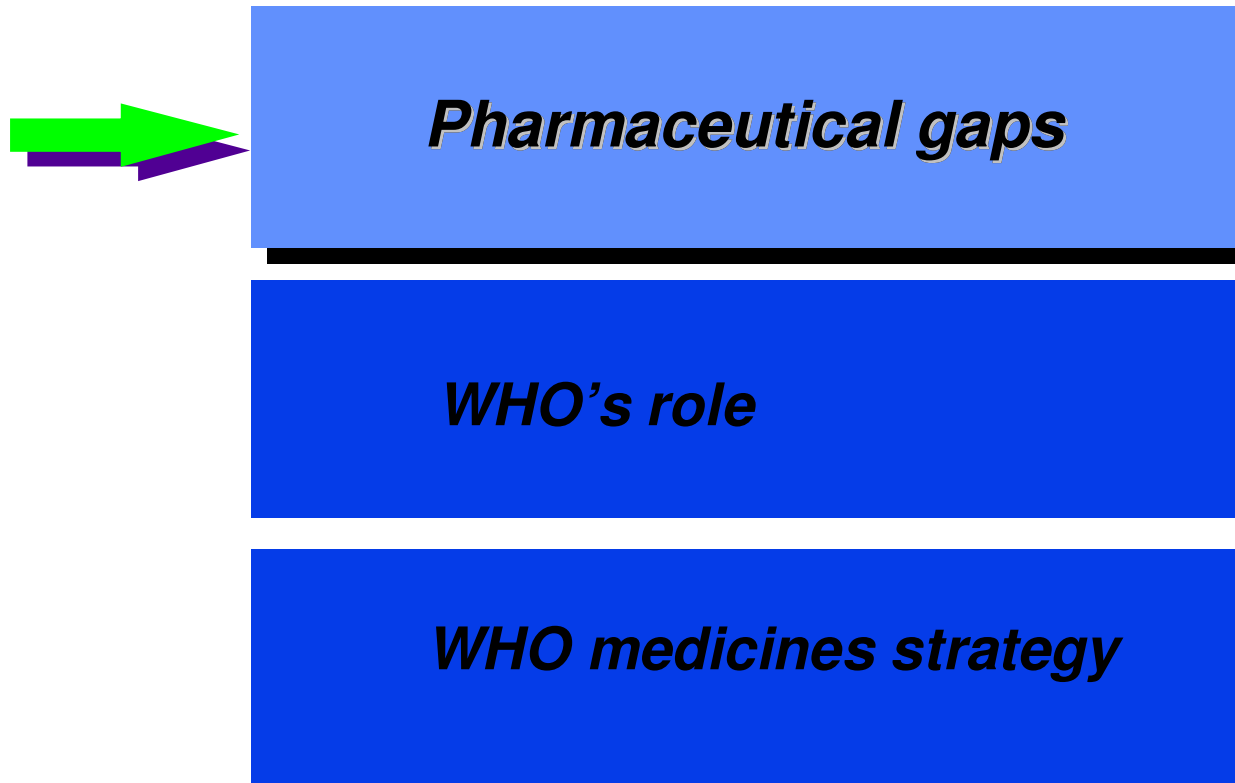

Importance of Generic Drugs to the Global Healthcare

EGA Annual Meeting
5-6 October, 2000
Kraków

Lembit Rägo, MD, PhD, Coordinator
Quality Assurance and Safety: Medicines (QSM)
Essential Drugs and Medicines Policy (EDM)
Health Technology and Pharmaceuticals (HTP) Cluster
World Health Organization
E-mail: ragol@who.ch



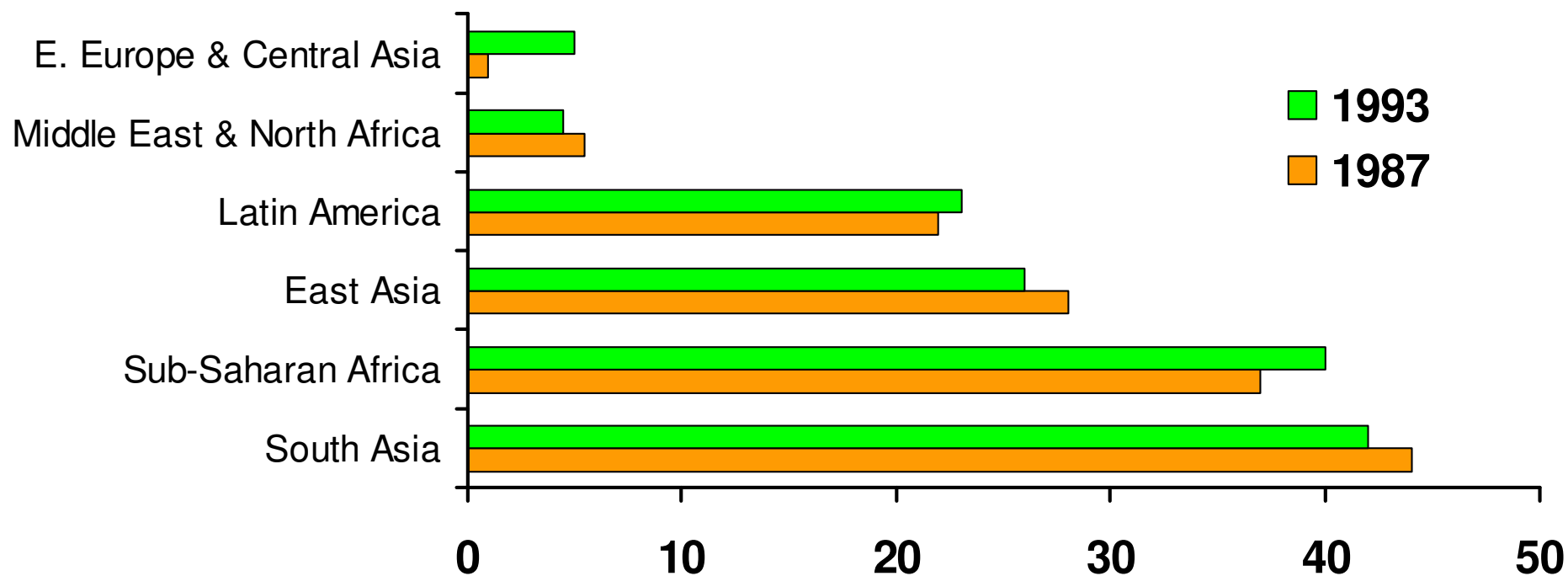
Bridging the Pharmaceutical gaps World Wide: WHO's Role



Pharmaceutical gaps

Economic gap - percent of population below the poverty line has changed little in 2 decades

Percentage of population below poverty line (US \$1 per day)

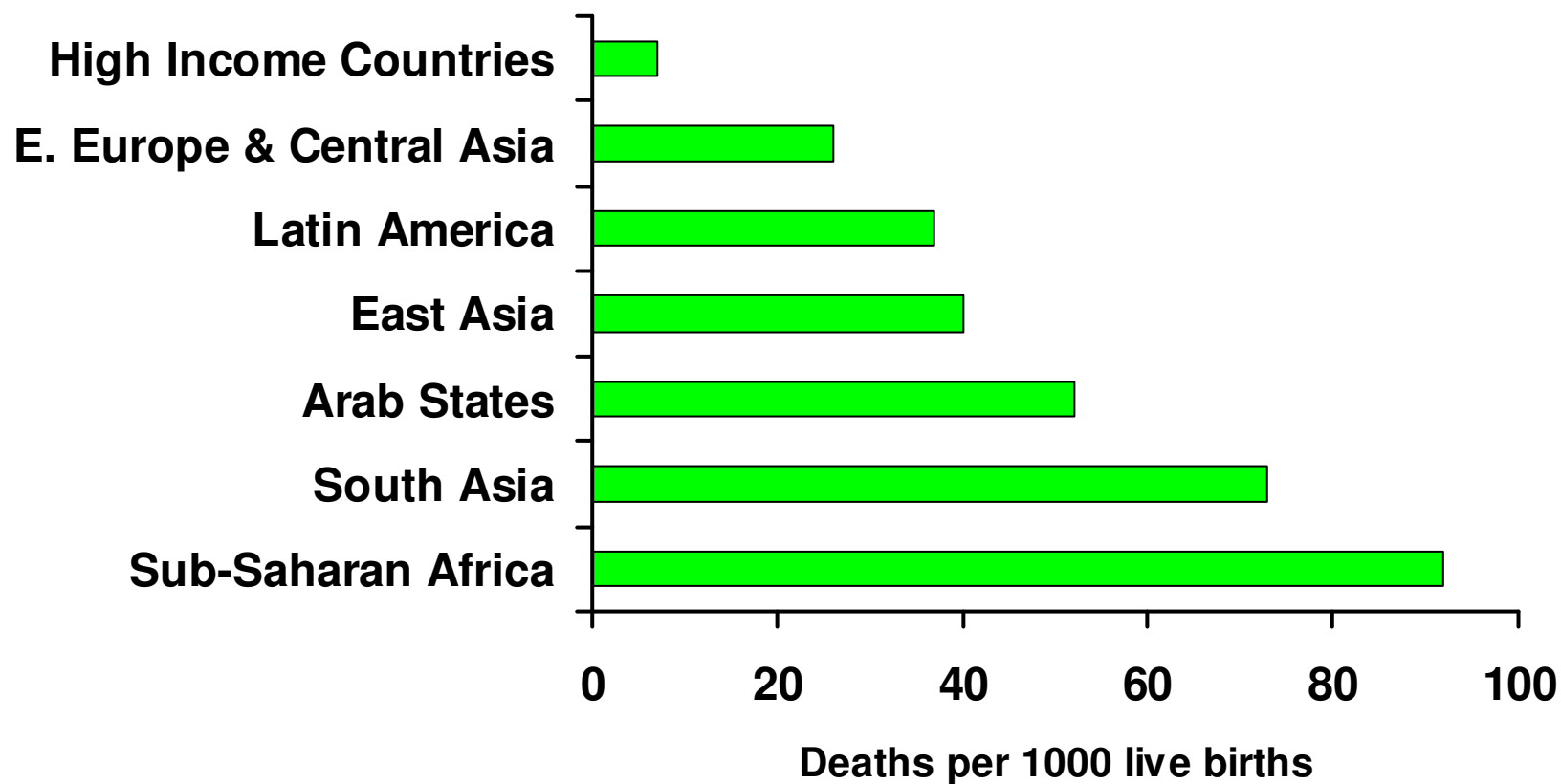


WHO - EDM



Pharmaceutical gaps

Health Status Gap - infant mortality still varies 10-fold among regions of the world

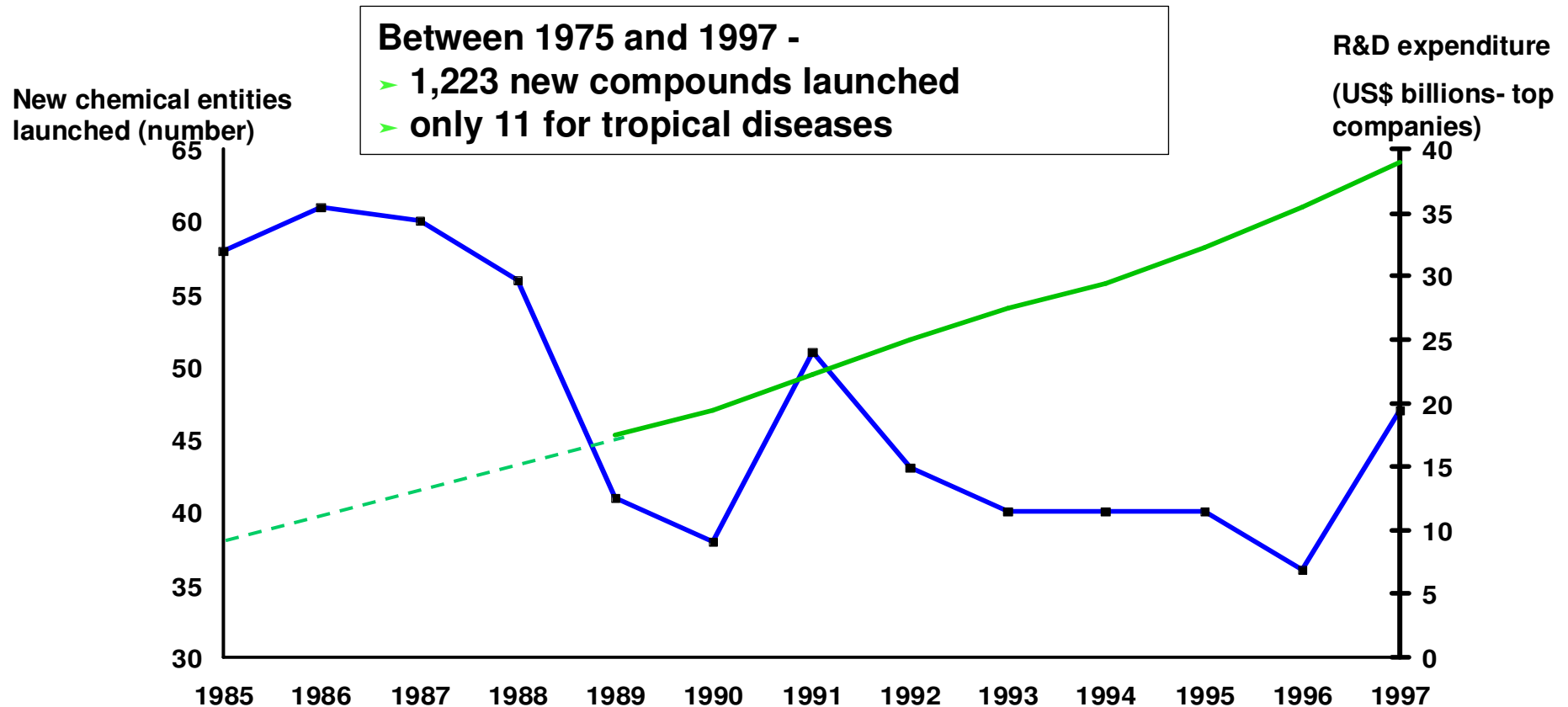


WHO - EDM



Pharmaceutical gaps

R&D Gap - expenditures grow, new drugs are launched, but few for tropical diseases



Sources: D. Gannaway and Price WaterhouseCoopers (1999) R&D, NCE data; P. Trouiller et al (1999) tropical research data

WHO - EDM



Pharmaceutical gaps

Therapeutic gap - growing resistance is affecting prevalent infectious diseases

■ Malaria

- chloroquine resistance in 81/92 countries

■ Tuberculosis

- 2 - 40 % primary multi drug resistance

■ Gonorrhoea

- 5 - 98 % penicillin resistance in *N. gonorrhoeae*

■ ARI and bacterial meningitis

- 12 - 55 % penicillin resistance in *S. pneumoniae*

■ Diarrhoea: shigellosis

- 10-90+ % amp, 5-95% TMP/SMZ resistance



Pharmaceutical gaps

Health literacy gap - basic information is lacking in many countries, while information expands in others

■ Among high income countries -

- 300+ million world-wide internet users by 2000
- 2/3 of users search for health information
- 43% of 700,000 US doctors or their staff browse the Web
- 67% of doctor's patients have Internet information

■ Among low and middle income countries -

- available information often under-utilized
- 1/2 of drugs with sufficient information for safe, effective use
- only 1/4 of drug packets in Asia contain inserts
- 45% of adult women are illiterate - over 90% in some countries

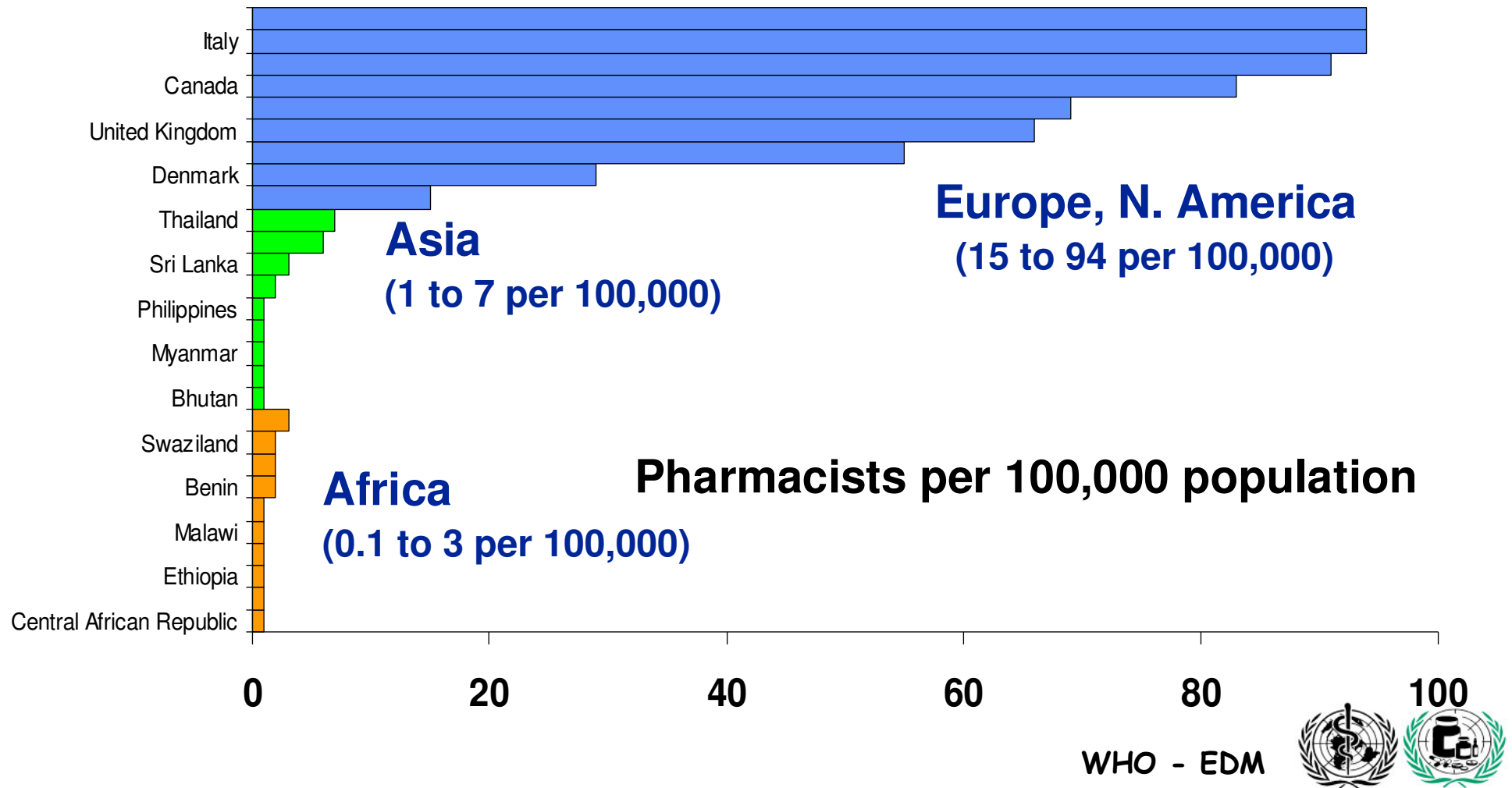
Source: D. Gannaway (1999), World Development Report (1997), WHO/DAP (1998), WHO/EDM (1999)

WHO - EDM



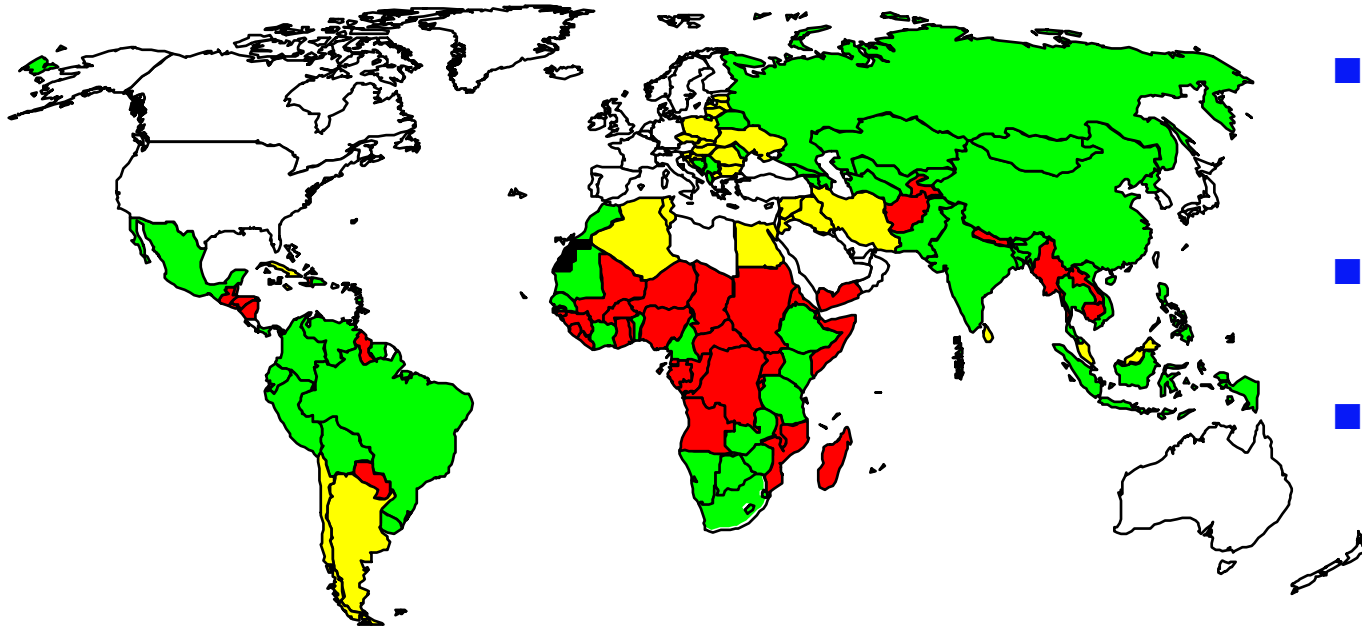
Pharmaceutical gaps

Pharmacy service gap - nearly a 100-fold variation in pharmacists per 100,000 population



Pharmaceutical gaps

Access gap - financing, delivery and other constraints still limit access to essential drugs



- >1/3 of world's population lacks regular access
- 320 million in Africa have <50%
- Problem worsens with economic pressures

Percentage of populations and number of countries with regular access to essential drugs:

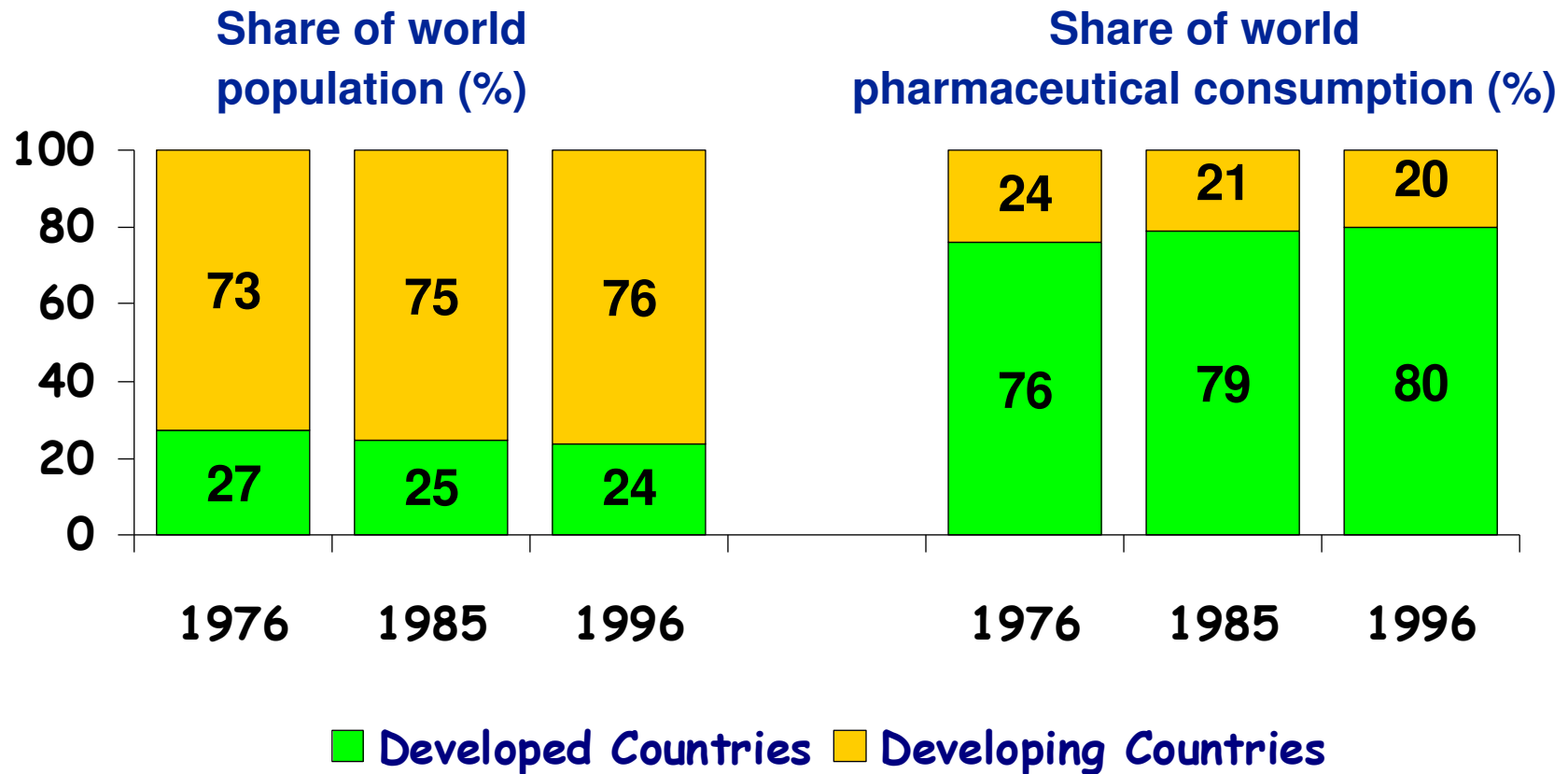
■ 1 = <50%	(43)
■ 2 = 50-80%	(64)
■ 3 = 80-95%	(30)
■ 4 = >95%	(41)
■ 5 = No data available	(1)

WHO - EDM



Pharmaceutical gaps

Population-consumption gap - Developing countries are 76% of world population, only 20% of consumption



Pharmaceutical gaps

Equity gap - differences in pharmacy care, drug costs, safety nets create a cumulative burden

■ In developed countries

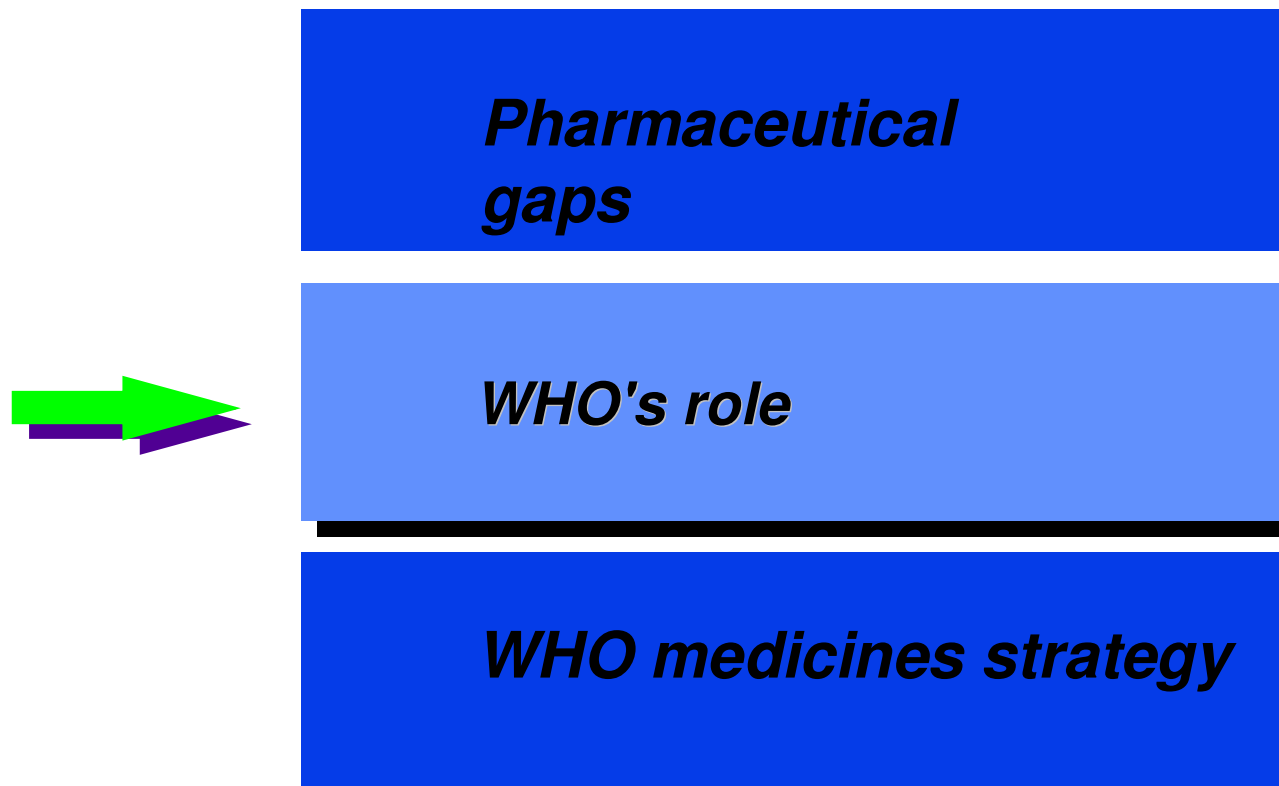
- 1 pharmacist for every 2000 to 3000 people
- antibiotics for simple pneumonia cost 2-3 hours' wages
- one-year's treatment for HIV infection equals 4-6 months' salary
- the majority of drug costs are reimbursed

■ In developing countries

- sometimes only 1 pharmacist per 1 million people
- antibiotics for simple pneumonia may cost 1 month's wages
- one year's HIV treatment would consume 20 years' income
- most households buy medicines out-of-pocket



Bridging the Pharmaceutical gaps World Wide



WHO's role

Reaching out and tackling public health priorities

■ Reaching out to -

- 191 Member State governments
- G-8 - International Monetary Fund - World Bank
- UNICEF - UNAIDS - other UN agencies
- Pharmaceutical and other private companies
- Nongovernmental organizations

■ Tackling public health priorities -

- Massive effort - malaria, HIV-AIDS, tuberculosis
- Tobacco free initiative
- Polio eradication



WHO - EDM



WHO's role

Four strategic directions for attacking public health priorities

- 1. Reducing excess mortality and disability**
 - especially among poor and for priority health problems
- 2. Reducing risk factors**
 - major environmental, economic, social risk factors
- 3. Developing health systems**
 - equity and cost-effectiveness in financing and delivery
- 4. Promoting the health dimension in development**
 - putting health in the centre of the development agenda

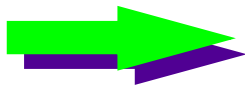


Bridging the Pharmaceutical gaps World Wide

Pharmaceutical gaps

WHO's role

WHO medicines strategy



WHO - EDM



WHO medicine strategy

What guides and anchors WHO's work in essential drugs and medicines policy?

- **Global norms, standards, guidelines, nomenclature**
 - WHO constitution
 - Expert Committees/Expert Panels
 - WHO Collaborating Centres
- **Essential drugs and national drug policies**
 - 1975 resolution introducing **essential drugs** concept
 - Revised drug strategy (1986) and subsequent resolutions
- **WHO medicines work today**
 - Governing bodies - Assembly, Exec. Board, Regional Committees
 - Cabinet
 - Meeting of Interested Parties - MIP



WHO medicine strategy

Global norms, standards, guidelines, nomenclature

■ **Global norms and standards in**

- production and inspection
- quality control, good storage practices etc.

■ **Requirements for drug registration and model legislation**

- covers all key issues of generics

■ **Guidelines**

- self-medication products
- on internet

■ **Nomenclatures, classifications**

- INNs (generic names)
- ATC classification
- Daily Defined Doses (DDDs)



PARACETAMOL (4'-hydroxyacetanilide;
 p-acetamidophenol; N-(4-hydroxyphenyl)
 acetaminophen; acetaminophen)
 アセトアミノフェン
 Acetaminophen
 N-(4-Hydroxyphenyl)acetamide
 Acetamide, N-(4-hydroxyphenyl)
 对乙酰氨基酚【典】
 Acetaminophenum



INNs

Dorcol Zolben Alvedon Mono Vips Sinpro
 Fanalgic Eu-Med P Malgis Anacin-3
 Nina Treupel mono
 Panamax Algina Neuridal Hedex Dial-a-gesc Reliv
 Tempra Ben-u-ron Nebs Dolotugin Exdol Momentum Panadol
 Gardan Animal



WHO - EDM



WHO medicine strategy

What are the priorities for WHO's medicines strategy for the next four years?

- **Access to essential drugs**
 - for priority health problems (malaria, TB, childhood, HIV/AIDS)
 - for poor and vulnerable populations
- **Quality and safety of all medicines**
 - creating and maintaining global guidelines and standards
 - supporting effective drug regulation & quality assurance
- **Rational use of medicines**
 - by health professionals
 - by households
- **National drug policies**
 - integrated in national health policies and systems
 - emphasis on implementation and monitoring



WHO medicine strategy

How does WHO work in the field of essential drugs and medicines policy?

■ Globally

- Policy directions - e.g., globalization, public-private mix
- Agency linkages - UN, bilaterals, roundtable group, other NGOs
- Guidance, norms, standards, technical tools

■ Regionally

- Biennial planning and coordination meetings for country work
- Regional networks - drug regulators, rational drug use
- Regional courses - national policy, GMP, community education

■ Nationally

- National advisors - a “new generation”
- Advice and support to national governments, professionals, NGOs
- Large-scale projects - 3 to 6 years



Conclusion

Bridging the global pharmaceutical gaps

Pharmaceutical gaps - substantial gaps and inequities in economics, health resources, access, other key areas

WHO's role - reaching out, tackling public health priorities, pursuing 4 strategic directions

WHO medicines strategy - access, quality & safety, rationale use, policy - global, regional, country action

