



# Medicines and Biologicals

## In the Americas:

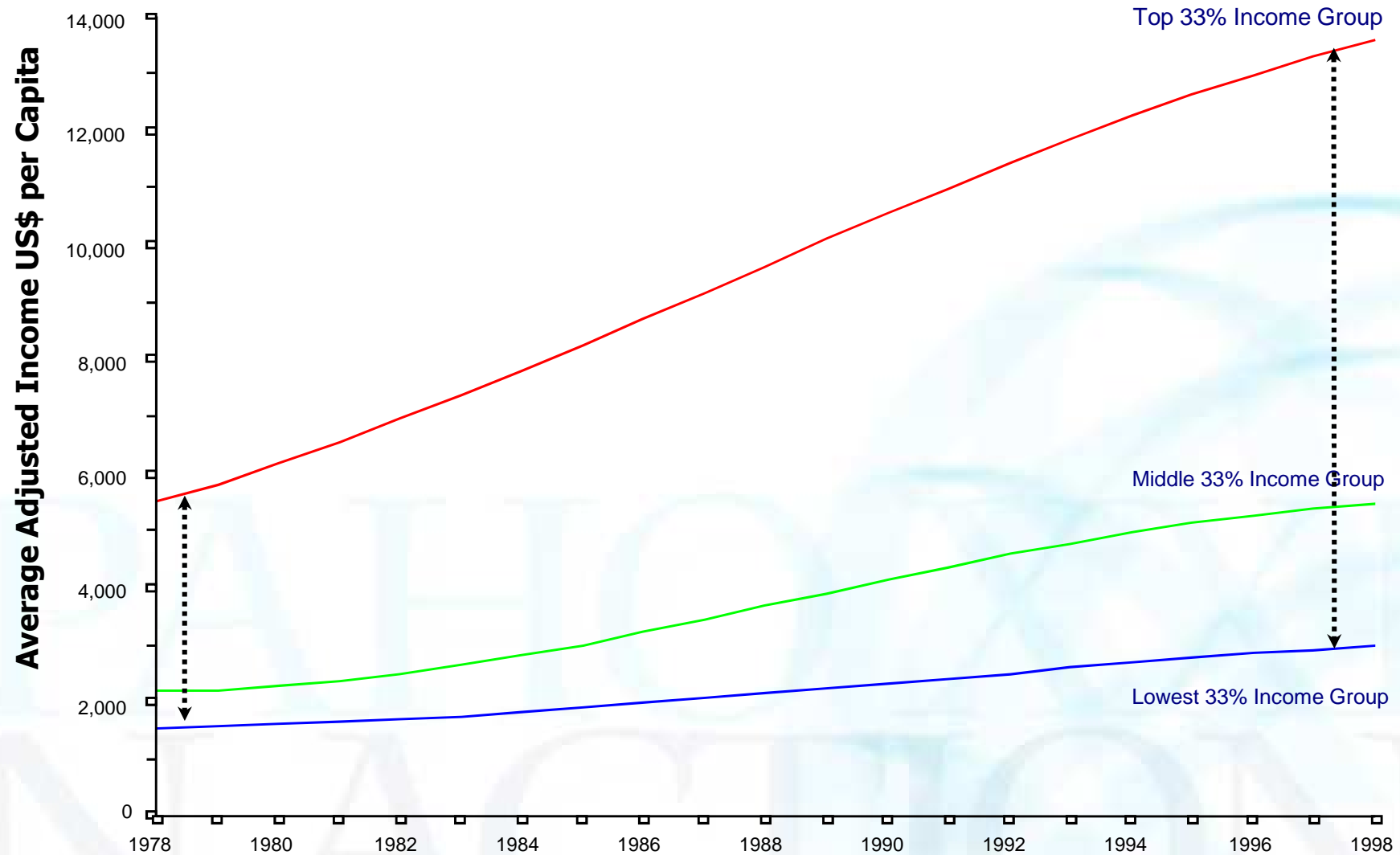
### Adapting Global Strategies to the Regional Context

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# Outline

- Overview of Health Situation: Advances and Inequities
- Challenges in Access to Medicines and Biologicals
- Medicines in the Global and Regional Health Agendas: Opportunities;
- Goals and Objectives of the PAHO Project in Medicines and Biologicals
  - Responding to Countries Needs
  - Innovative Modalities of Cooperation
  - Strengthening Regional Foro
  - Using knowledge and Evidence
  - Strategic Management

# Economic Advances in the Americas



# Improvement in health in the Americas 1980 - 2010

Indicator	1980–1985	1990–1995	2005–2010
Life expectancy at birth (years)	68.8	71.1	74.9
Infant mortality (per 1,000 live births)	37.8	22.5	16.5

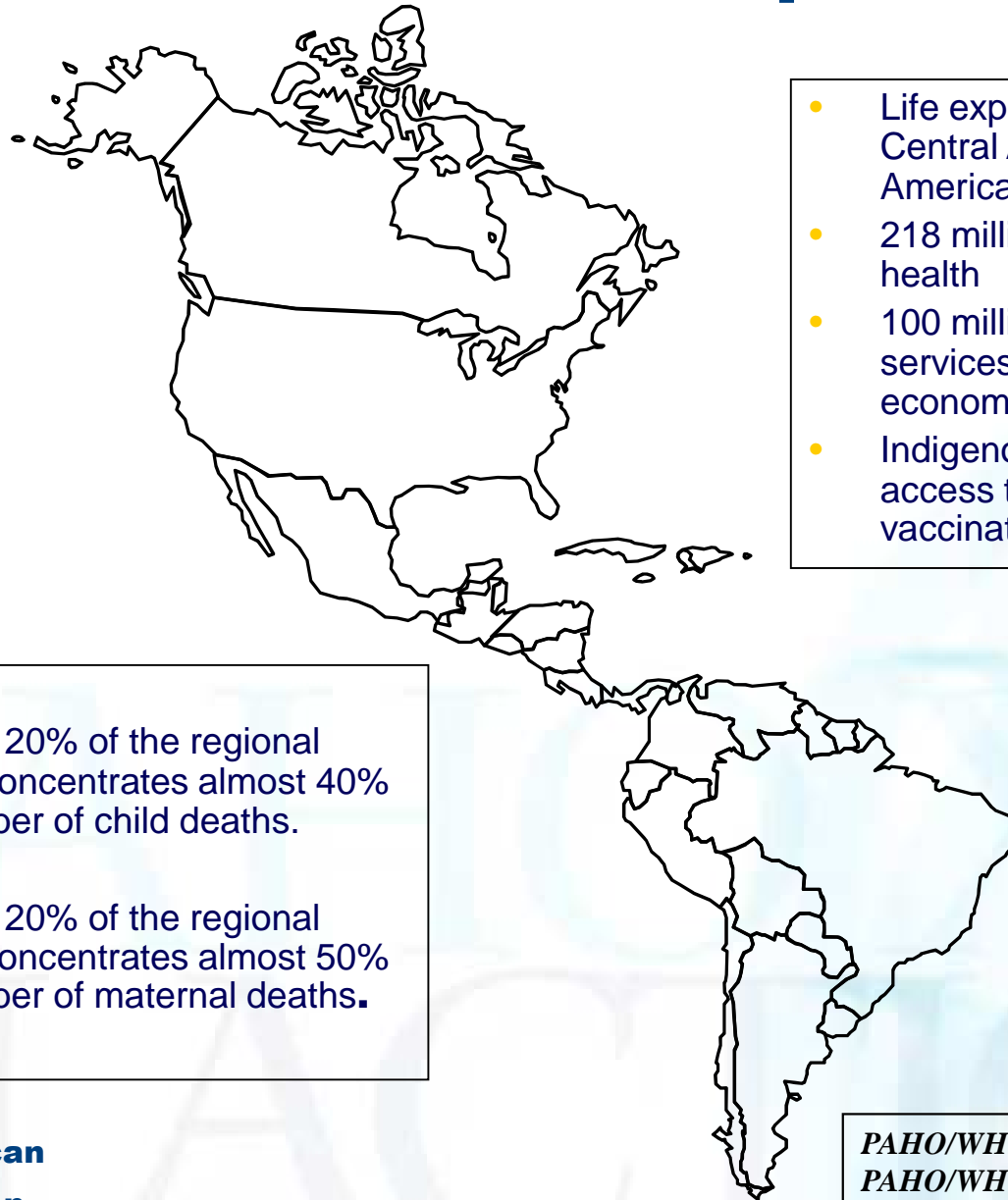
  

Indicator	1980–1984	1990–1994	2000–2004
Mortality from communicable diseases (rate/100,000 inhabitants)	109	62.8	55.9
Mortality from diseases of the circulatory system (rate/100,000 inhabitants)	280	256.2	229.2

Indicator	1980	1990	2005
Immunization coverage (%): DPT3	45	76.8	93
Access to sanitation services (%)	59	66	84
Nurses per 10,000 inhabitants	23.1	37.9	30

# Persistence in Health Inequalities



- Life expectancy ranges from 68.8 in Central America to 77.9 in North America
- 218 million lack social security in health
- 100 million lack access to health services due to geographical and economic barriers
- Indigenous populations register lower access to health services, including vaccination

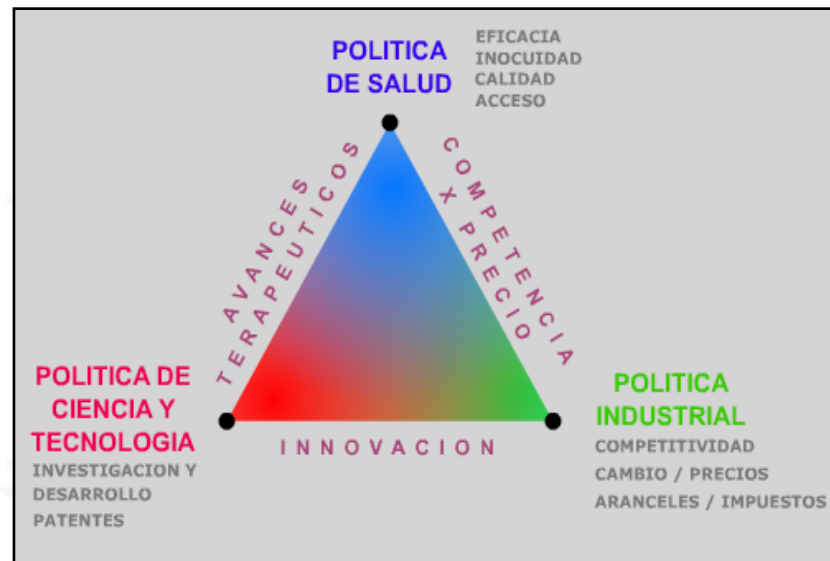
- The poorest 20% of the regional population concentrates almost 40% of total number of child deaths.
- The poorest 20% of the regional population concentrates almost 50% of total number of maternal deaths.

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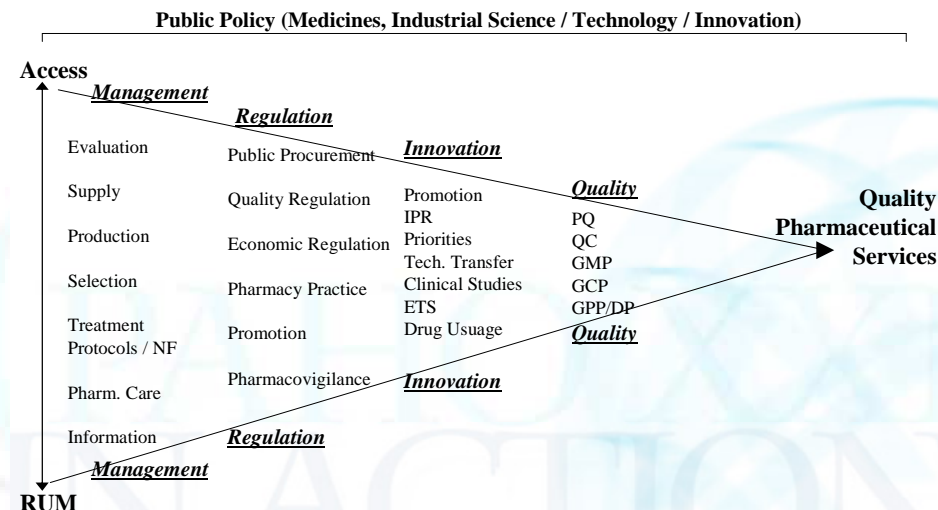
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# Policy Challenges in the Americas

- 65% of countries reporting have a medicines policy, only 40% have an implementation plan
- Only 56% of Medicines Policies are considered to be integrated with National Health Policy: need for integration with industrial and science / technology policy
- Inadequate focus on organization of pharmaceutical services and links with the Renewed Primary Health Care Initiative
- Policy implementation and financing focused on procurement and supply management, and not on Universal Access.



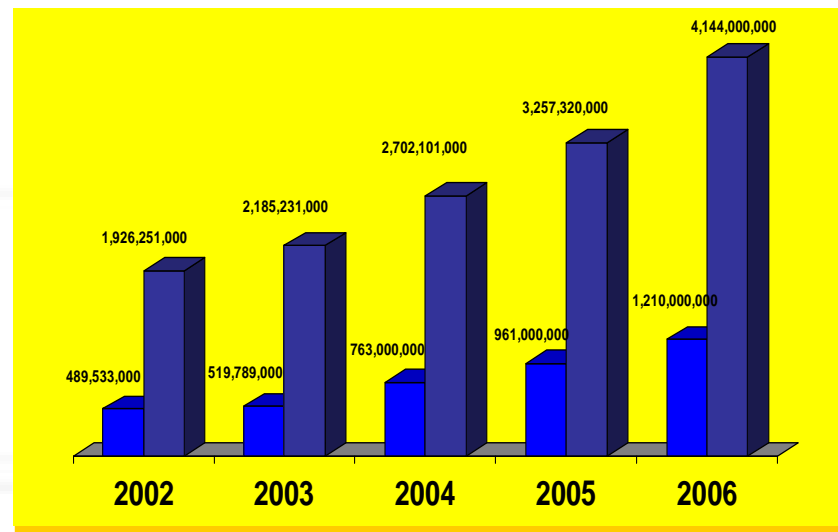
*Interfaces in Pharmaceutical Policy, Tobar. F.*



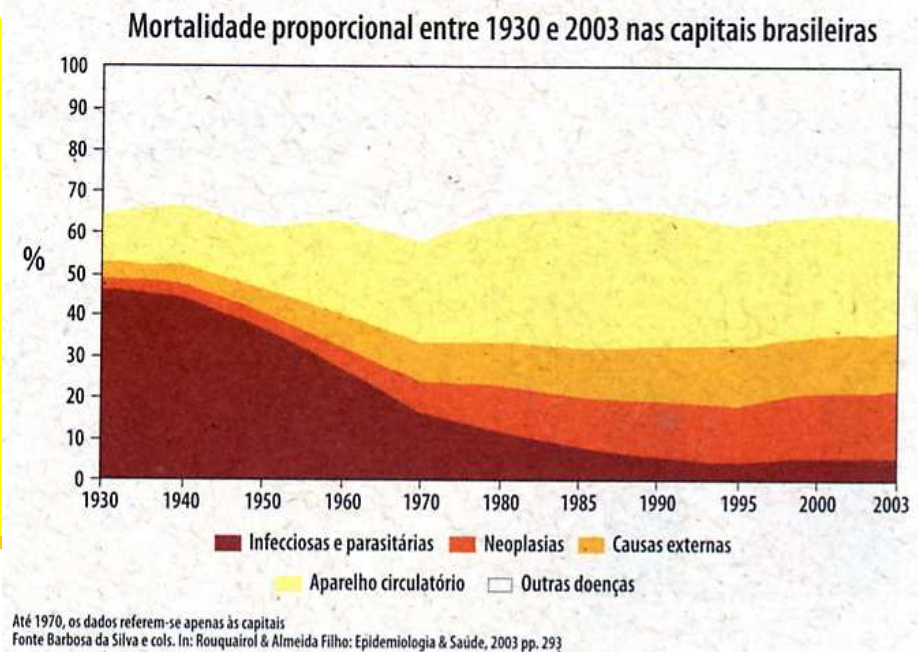
*Integration of Pharmaceutical Services, 2008 PAHO Brazil.*

# Challenges in Access in the Americas (1)

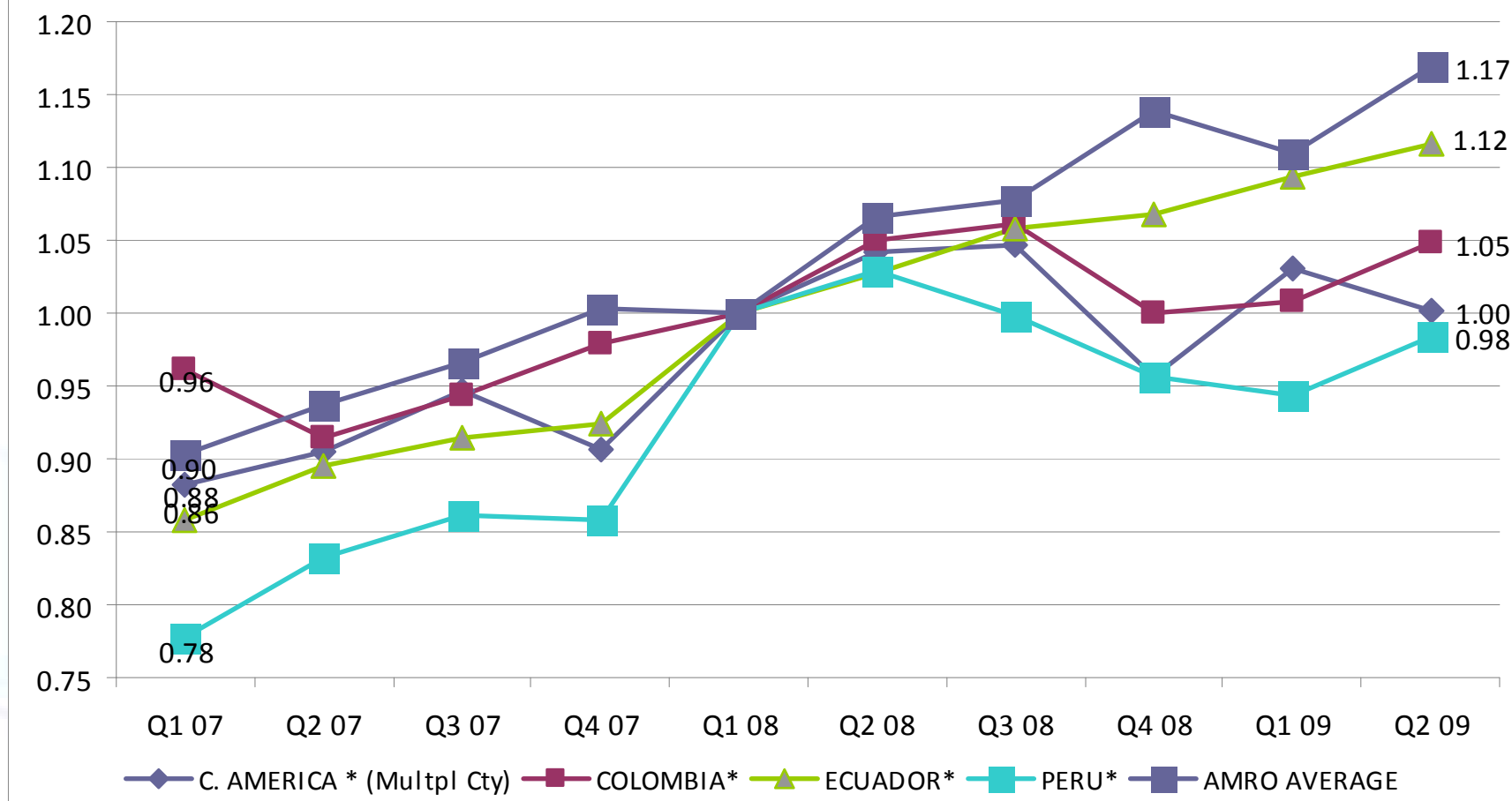
- Continued prevalence of neglected tropical and other priority diseases while prevalence of chronic degenerative disease increase rapidly.
- Proliferation of new medicines and biologicals of unproven value within markets and health systems (ANVISA > 16,000 products registered).
- Increases in health expenditures due to incorporation of new technologies, increased access and changes in the epidemiological profile.
- Persistent inequities in access to medicines, poor and vulnerable populations.



*Increase in Medicines Expenditure, Brazil 2002 – 2006. in Reales*

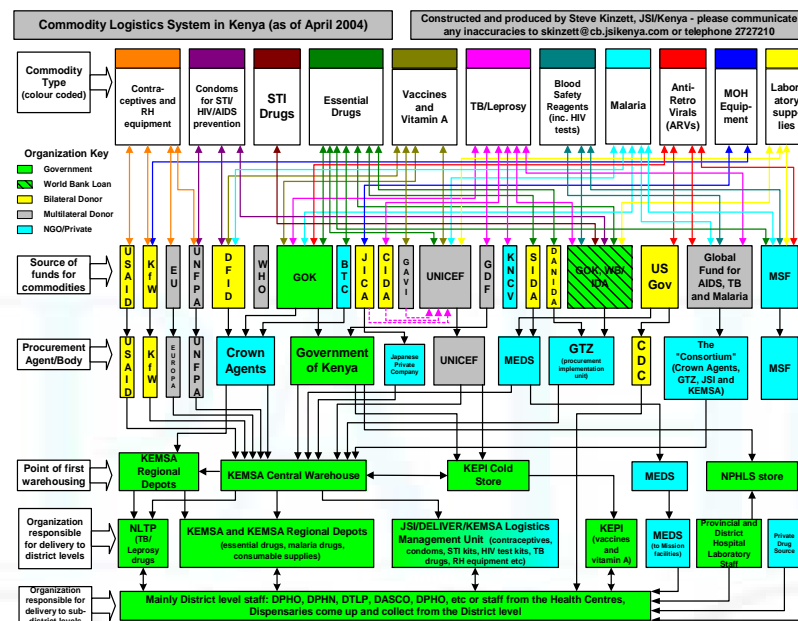


# Pharmaceutical expenditure lower middle income countries AMRO (Evolution on Q1 08)

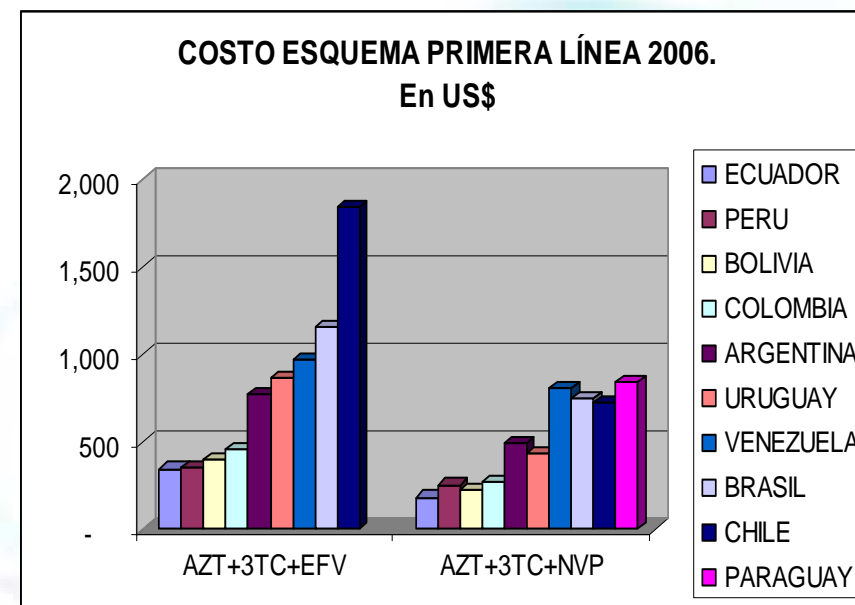


## Challenges in Access in the Americas (2)

- Fragmentation and Segmentation of systems ensuring access
- Sustainable financing and pricing systems based on principles of equity
- Lack of social protection and access: insurance systems inadequately developed
- Proliferation of bilateral trade agreements with TRIPS+ provisions

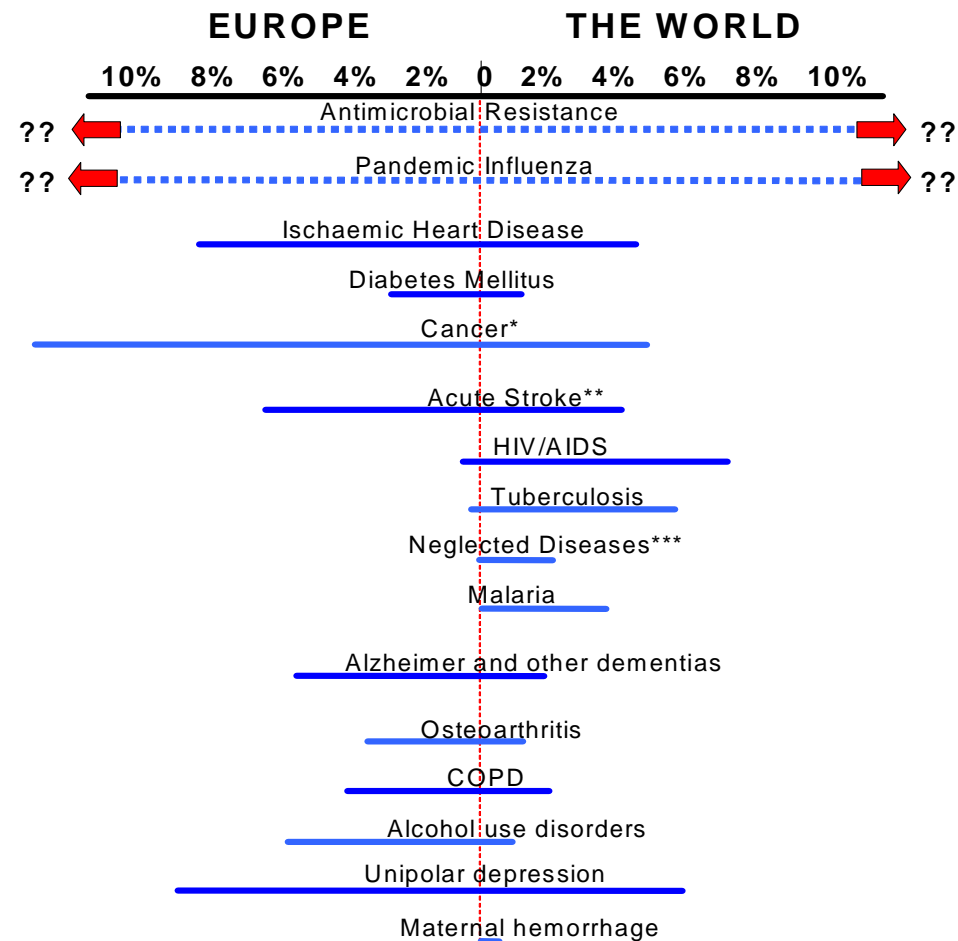


Analysis of Supply Systems, Kenya 2004.



Pricing Disparities in ARVs, Americas, 2006

# Linking Access with Innovation

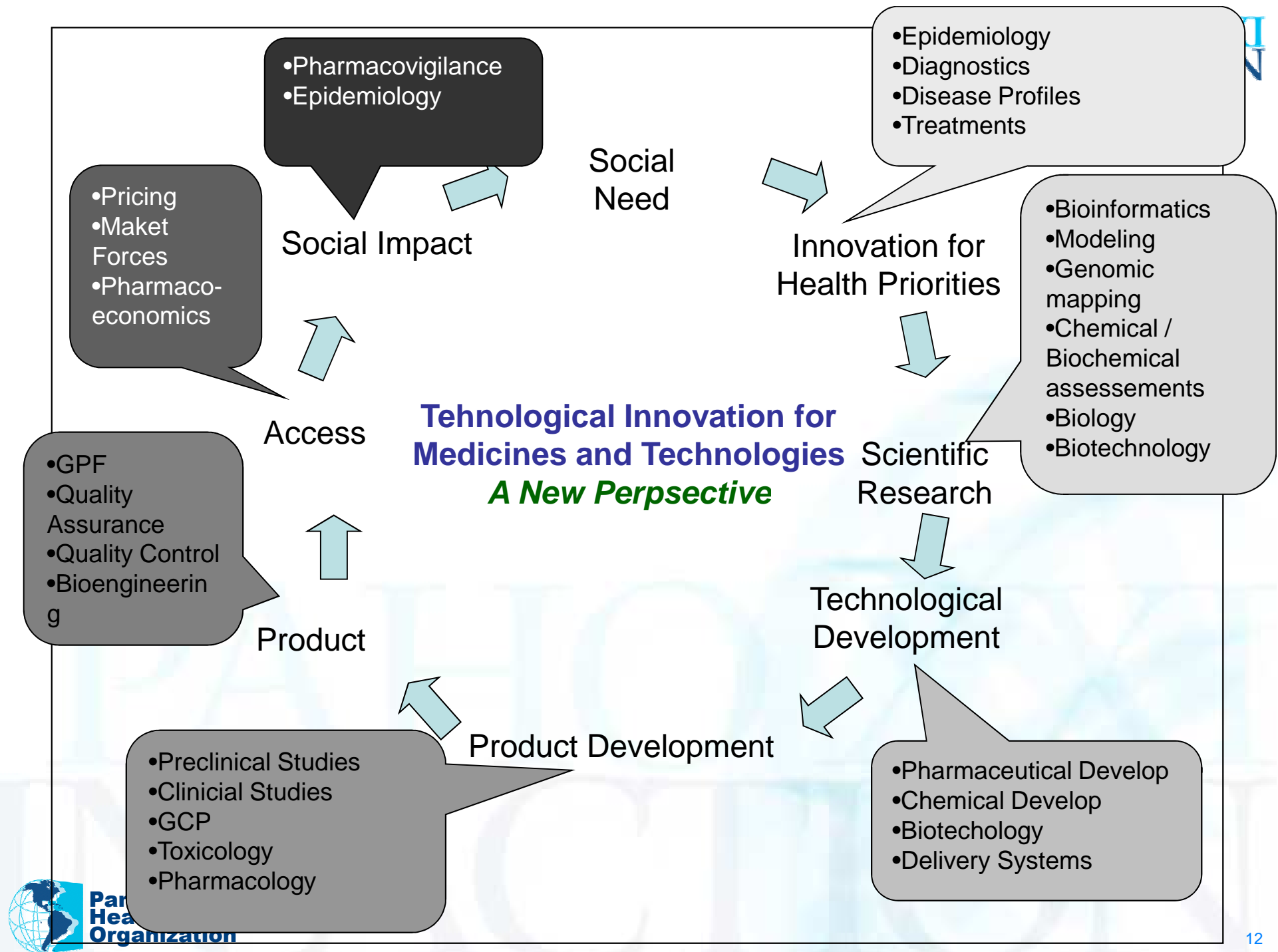


\* Includes bladder, breast, cervical, colon, uterine, lung liver, mouth, oesophageal, ovarian, pancreatic, prostate, stomach cancer and leukemias, melanomas, lymphatic cancers and myelomas

\*\* "Cerebrovascular disease"

\*\*\* Chagas disease, Dengue, Leishmaniasis, lymphatic filariasis, Onchocerciasis, Schistosomiasis, Trypanosomiasis

*Source: WHO. Priority Medicines for Europe and the World. 2004*

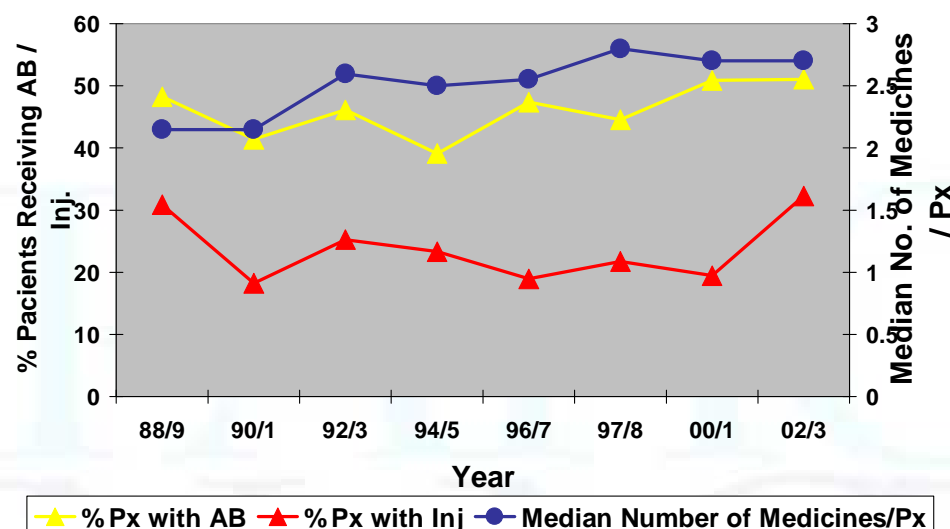


# Challenges in Quality in the Americas

- Even though more than 65% of the countries in LAC (85% in LA) have a regulatory authority, most still have inadequate capacity in product assessment and regulation
- Decentralization in larger countries v ensuring regulatory functions in smaller
- Application of differing standards in GMP, impeding harmonization (Central America WHO1975, MERCOSUR 1999).
- Application of different standards regulating generic medicines resulting in fragmentation of generics markets
- Lack of HR technical capacity for effective regulation and implementation of basic functions:
  - Market Authorization and Licensing;
  - Inspection;
  - Quality Control;
  - Pharmacovigilance;
  - Monitoring and evaluation of Clinical Studies
- Proliferation of new technologies and in particular biotechnologies, including biosimiliars.
- Incorporating international norms in national regulatory processes: balancing harmonization criteria (PANDHR, ICH), international norms (WHO, PQ) with national interests.
- Regulation of the promotional activities of the pharmaceutical industry

# Challenges in Rational Use

- 92% of countries have updated Essential Medicines Lists, however the number of medicines considered 'essential' varies from 346 to over 650!
- While 76% of countries have a national formulary, only 56% have treatment protocols
- Health professional training in rational use of medicines is low: less than 50% of health professionals are trained in EML, use of the National Formulary or Treatment Protocols
- One country (Brazil) has an official National Strategy for the Promotion of the Rational Use of Medicines

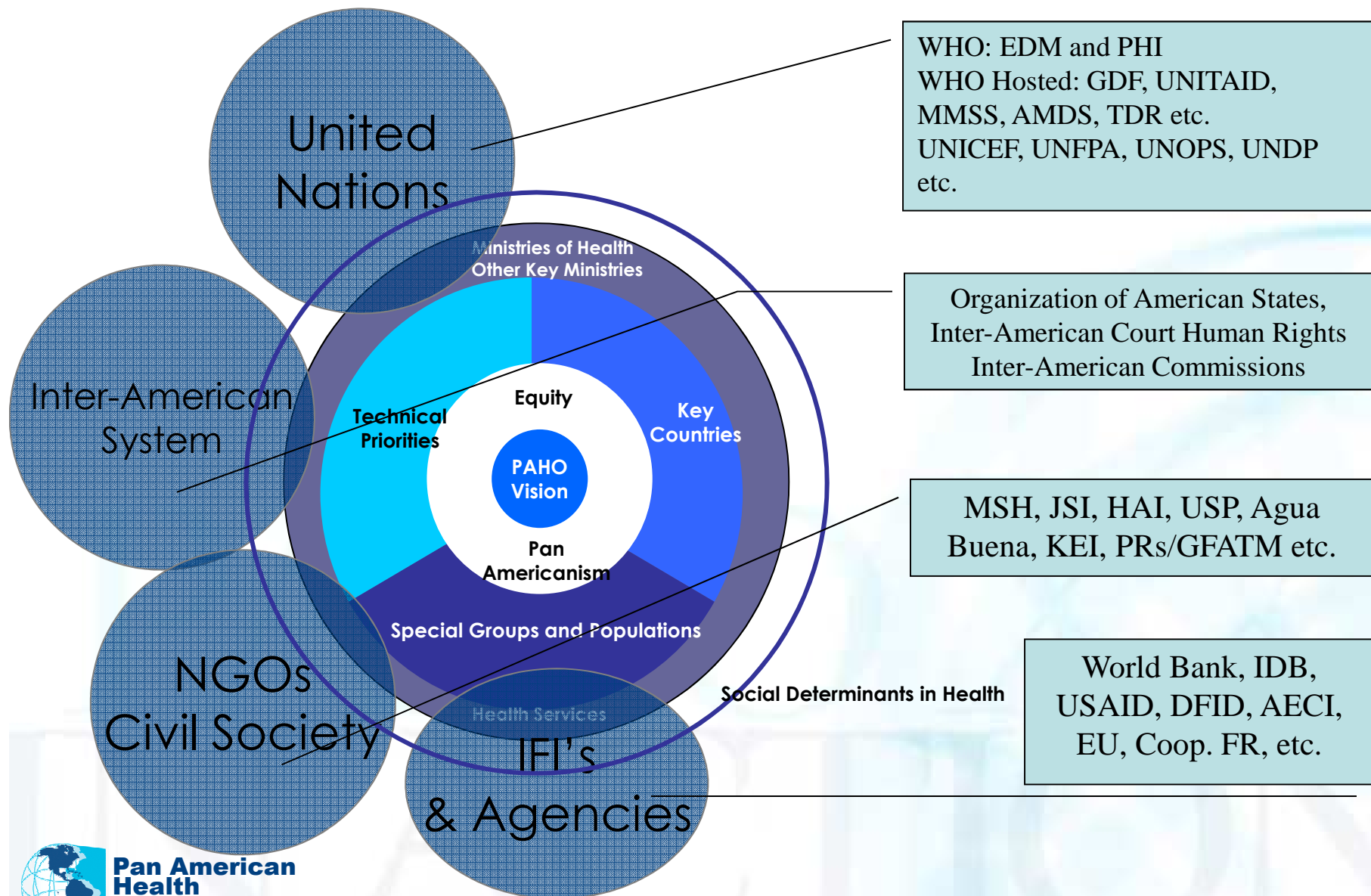


Use of Medicines 1990 – 2003 WHO / PSM Data base

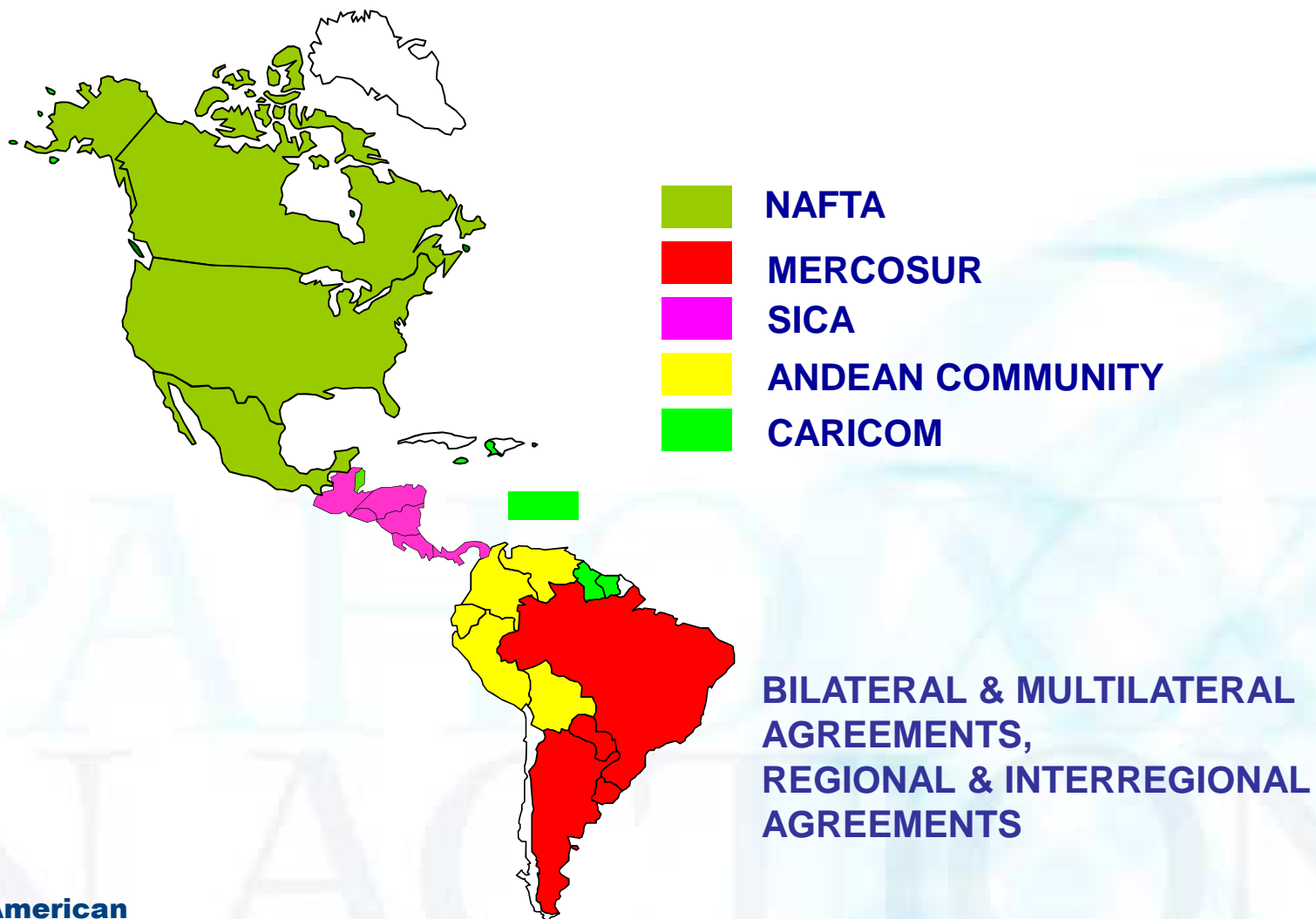


AIS-LAC: Acceptability of Generics, El Salvador April 2006.

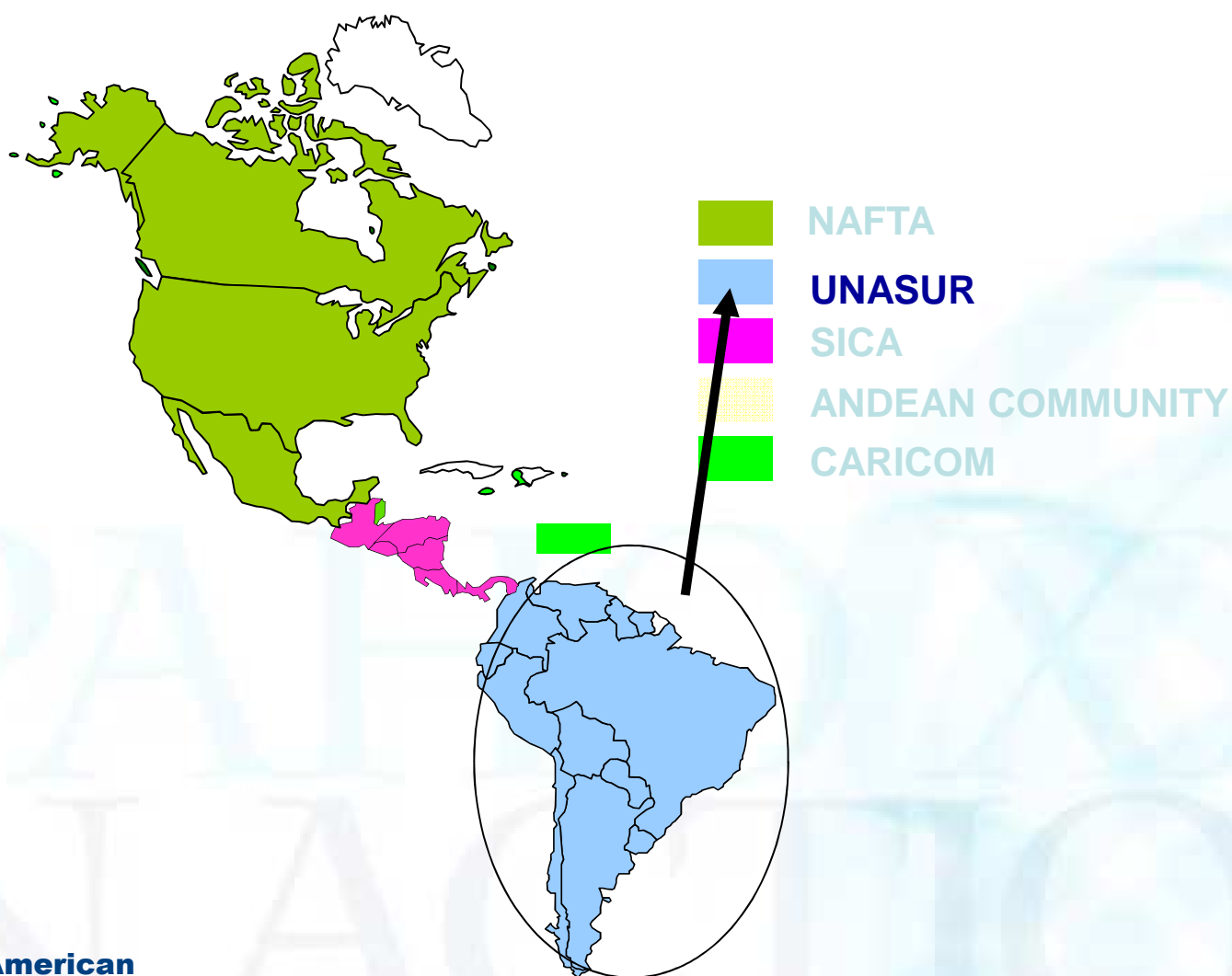
# Stakeholders in the Americas (1)



## Stakeholders in the Americas (2)



## Integration in the Americas (2)



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# (1) Medicines and Biologicals in the Global and Regional Health Agenda

## Global and Regional Mandates

1. Millennium Development Goals
2. XI WHO Medium Term Strategic Plan (2008-2015);
3. Health Agenda for the Americas (2008 – 2017)
4. PAHO Strategic Plan (2008-2012);
5. WHO Core Functions
6. PAHO 5 Organizational Change Objectives

## WHO / PAHO Resolutions (selected)

- WHO Medicines Strategy (WHA54.11)
- Ensuring accessibility of essential medicines (WHA55.14)
- Global strategy and plan of action on public health, innovation and intellectual property (WHA 61.21)
- Access to Medicines (CD45.R7)
- Public Health, Health Research, Production, and Access to Essential Medicines (CD47.R7)
- Public Health, Innovation and Intellectual Property (WHA61.21): a regional perspective (CD48.R15)

# The Interface with the Global and Regional Health Agendas (1)

- Millennium Development Goals (MDGs)
  - 6 of the eight MDGs, 7 of the sixteen targets, and 18 of the 48 indicators relate directly to health.
  - Target 17: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.

*'Generic Medicines are only available in 34.9% of facilities, and on average cost 250% more than the International Reference Price'*

*Source: UN; Delivering on the Global Partnerships for Achieving The MDGs, 2008*

# The Interface with the Global and Regional Health Agendas (2)

- WHO MTSP 2008 – 2013 (SO11) and the MDGs
  - Access can be achieved through the development of comprehensive policies
  - Supply requires political commitment and capacity building, as well as targeted efforts within markets
  - Developing the evidence base in norms and standards
  - Linking Public Health, Innovation and Intellectual property

# The Interface with the Global and Regional Health Agendas (3)

## Health Agenda in the Americas

- Strengthening the National Health Authority
- Tackling Health Determinants
- Increasing Social Protection and Access to Quality Health Services
- Diminishing Health Inequalities among Countries and Inequities within Them
- Reducing the Risk and Burden of Disease
- Strengthening the Management and Development of Health Workers
- Harnessing Knowledge, Science and Technology
- Strengthening Health Security

## PAHO SP 2008 – 2012 (SO11)

Equitable Access to essential medical products and technologies of assured quality, safety and efficacy, and on their sound and cost-effective use.

# Continuity versus Change; WHO Medicines Strategy 2008 - 2012

- Essential medicines for renewed primary health care
- Public health, innovation and intellectual property
- Building regulatory capacity
- WHO / UN prequalification of priority medicines
- Combating counterfeit medicines
- A health systems approach to medicine supply
- Promoting the rational use of medicines
- Traditional medicine
- Evidence and information for medicine policies
- Working within one WHO, supporting regions & countries

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# Goals and Objectives: PAHO Project in Medicines and Biologicals 2008 - 2012

- Goal:
  - Equitable Access to essential medical products and technologies of assured quality, safety and efficacy, and cost effectiveness, and on their sound and cost-effective use.
- Objectives:
  - RER12.1 Comprehensive national policies on access, quality and rational use
  - RER12.2 Implementation of international norms, standards and guidelines for safety, quality, efficacy and cost effectiveness
  - RER12.3 Evidence base for cost effective use

# (1) Responding to Countries Needs

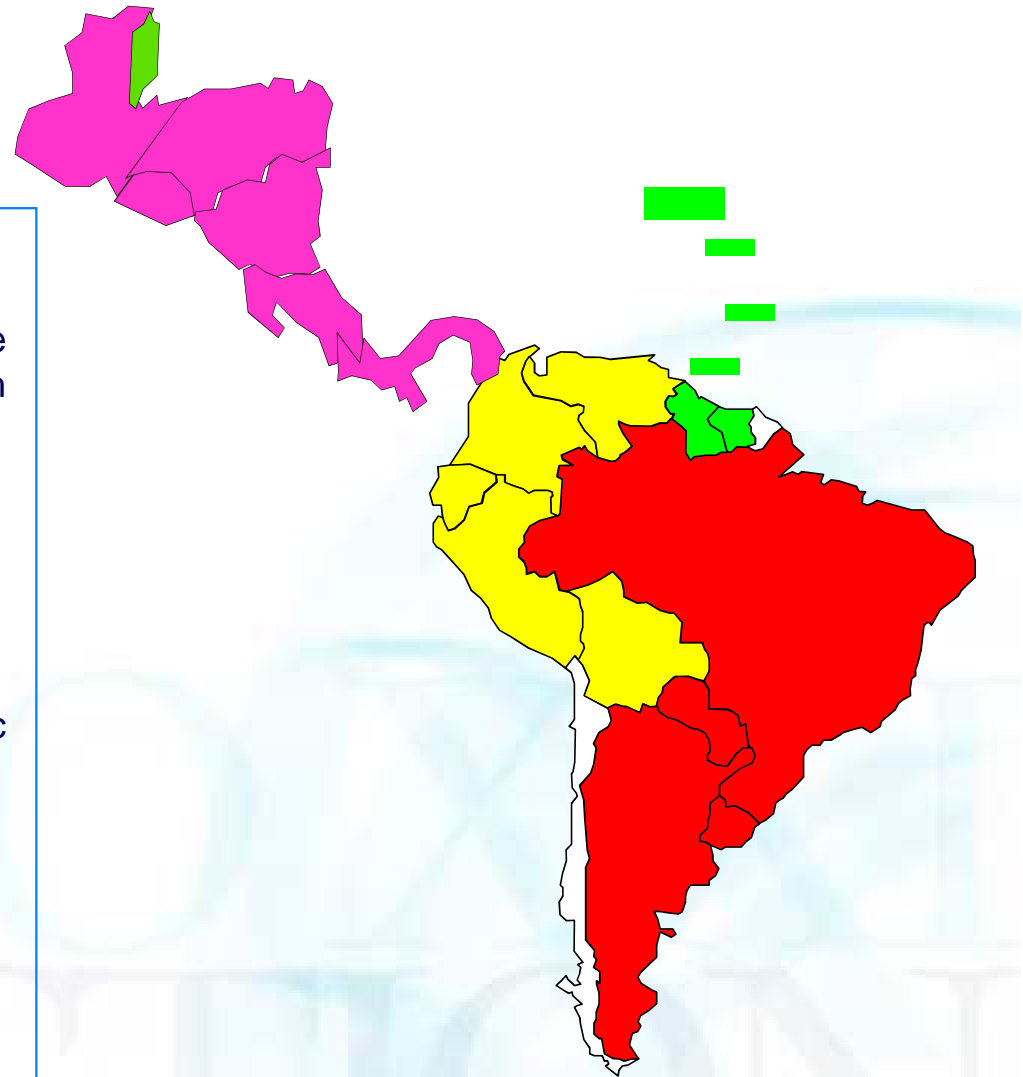
- Policy
  - Addressing Social Exclusion and promoting Access as a Human Right
  - **Updating policies and prioritizing implementation plans**
  - Integration with Health, Science/Innovation and Industrial policies
  - Organization of services through the PHC Strategy
  - Incorporation of research priorities into policy
  - Promotion of Good Governance and Transparency in Implementation
  
- Access and Innovation
  - **Implementing and Integrating the Regional Perspective of the Global Strategy and Plan of Action in Public Health, Innovation and Intellectual Property**
  - Promoting the concept of Integrated Supply Systems
  - Promoting concepts of equity in strengthening financing systems
  - Access to medicines by pooling risk and resources (insurance)
  - Strategies to promote and rationalize access to High Cost medicines
  - Technical guidance on traditional medicines
  - Access to controlled medicines

# (1) Responding to Countries Needs

- Quality and Regulation
  - Strengthening core functions of NRAs
  - Strengthening PANDHR, with increased country participation
  - Development of regional norms through PANDHR WGs
  - Mainstreaming quality in supply management, including PQ
  - Strengthening the regional network of OMCLs
  - Supporting countries in global initiatives (ICH, ICDRA).
  
- Rational Use
  - Development of a Regional Strategy
  - Strengthening Committees responsible for EML, Formulary and Protocol development
  - Develop national and regional Pharmacovigilance networks
  - Capacity building strategy for health professionals

## (2) Innovative Modalities of Cooperation

- Strengthening integration through sub-regional projects / initiatives
- Promoting inter-country cooperation at the sub-regional level, as well as South-South cooperation
- Mainstreaming with the Health Systems Strengthening Approach, PHC, and other priority areas (HIV, TB, NTDs).
- Bringing countries together through the use of information technology
- Promoting self assessments with strategic interventions and support facilitated by PAHO
- Identify and mobilize new Collaborating Centers, partners and experts
- Defining links with global initiatives: TDR, ICH, UNITAID etc.



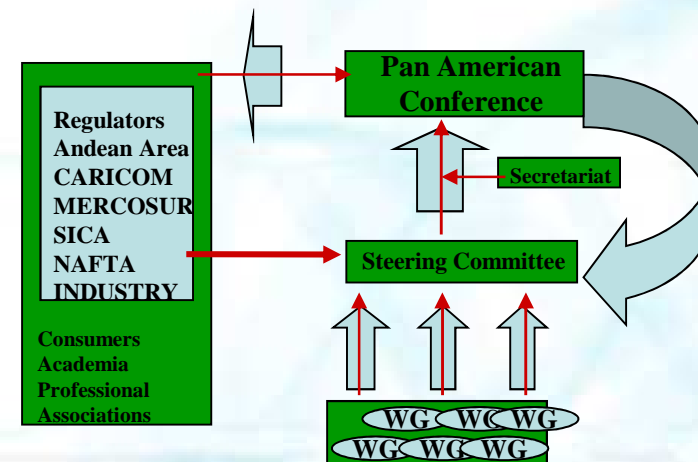
*Subregional Cooperation projects PAHO 2007*

### (3) Strengthening Regional Foro:

- PANDRH and the Informal Forum of Regulatory Agencies in the Americas
- PAHO Strategic Fund, Access to Strategic Public Health Supplies
- The Regional Platform for Innovation in Health
- Interagency Pharmaceutical Coordination Mechanism for the Americas (proposed)



PAHO Strategic Fund website:  
[www.paho.org/fondoestrategico](http://www.paho.org/fondoestrategico)



*Pan American Network for Drug  
Regulatory Harmonization / Structure  
2008*

## (4) Using Knowledge and Evidence

- Defining priority actions in countries based on monitoring of country indicators
- Databases and IKM strategies with evidence, tools and guidelines to guide actions (access studies, Level I and II, HAI studies).
- Defining sub-regional and regional interventions based on existing evidence
- Promoting research in priority areas and best practices

Reference	Indicator
<b>Nuevo 6</b>	National Plan or Strategy for the promotion of the rational use of medicines
06_01	National EML updated in the last 5 years
07_1	EML committee
06_02	National STG produced by MOH for major conditions
06_04	National or Reference Formulary updated in the last 5 years
06_05	EML and STG as part of the basic curricula in most health training institutions
<b>Nuevo 7</b>	Pharmaceutical service model defined for PHC
06_07	Public or nationally funded medicines information centre for dispensers, prescribers and consumers

*Sample Core Indicators to prioritize country interventions  
Rational Use , 2008*

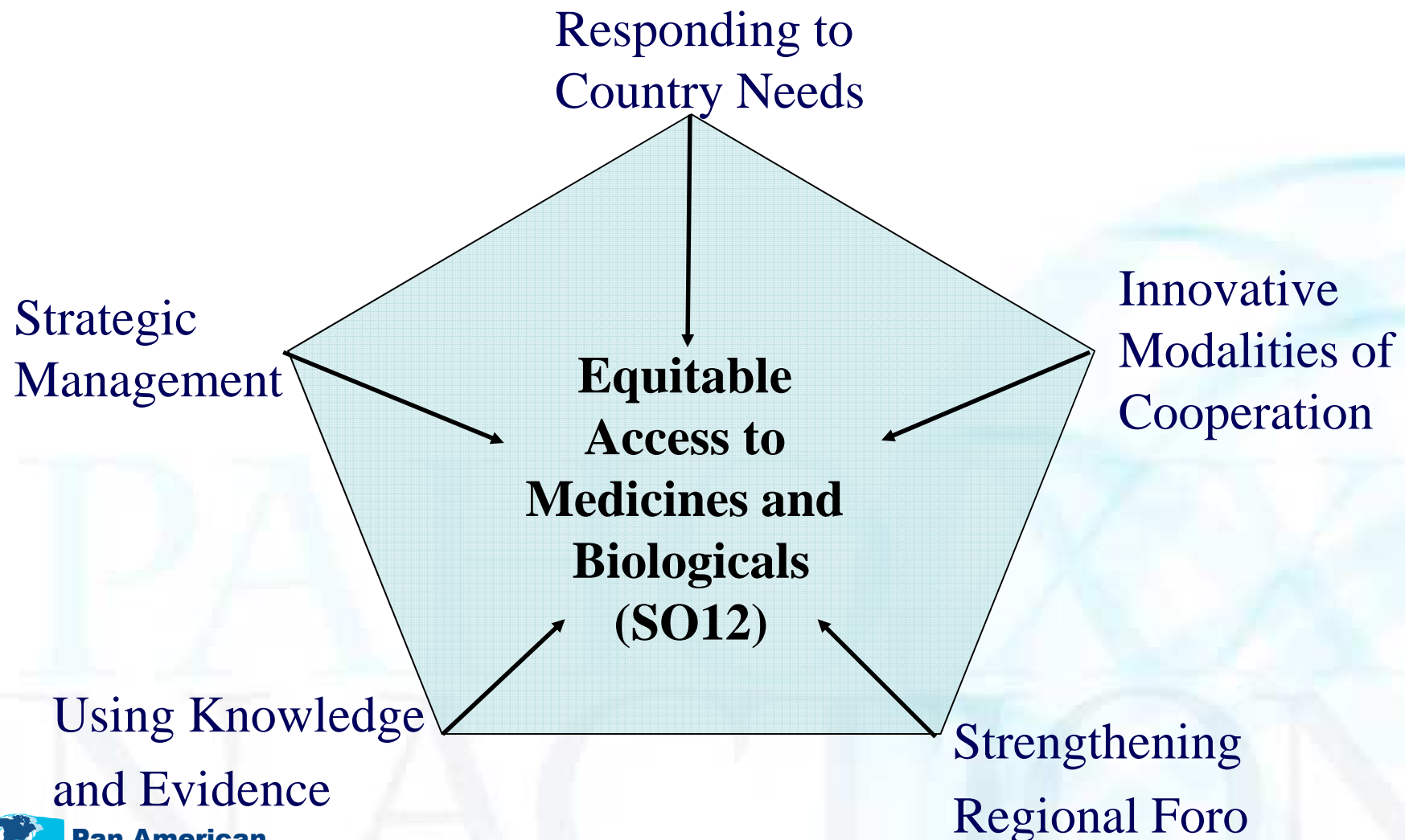


*Sample resources evidence base: PAHO / BIREME 2008*

## (5) Strategic Management Practices

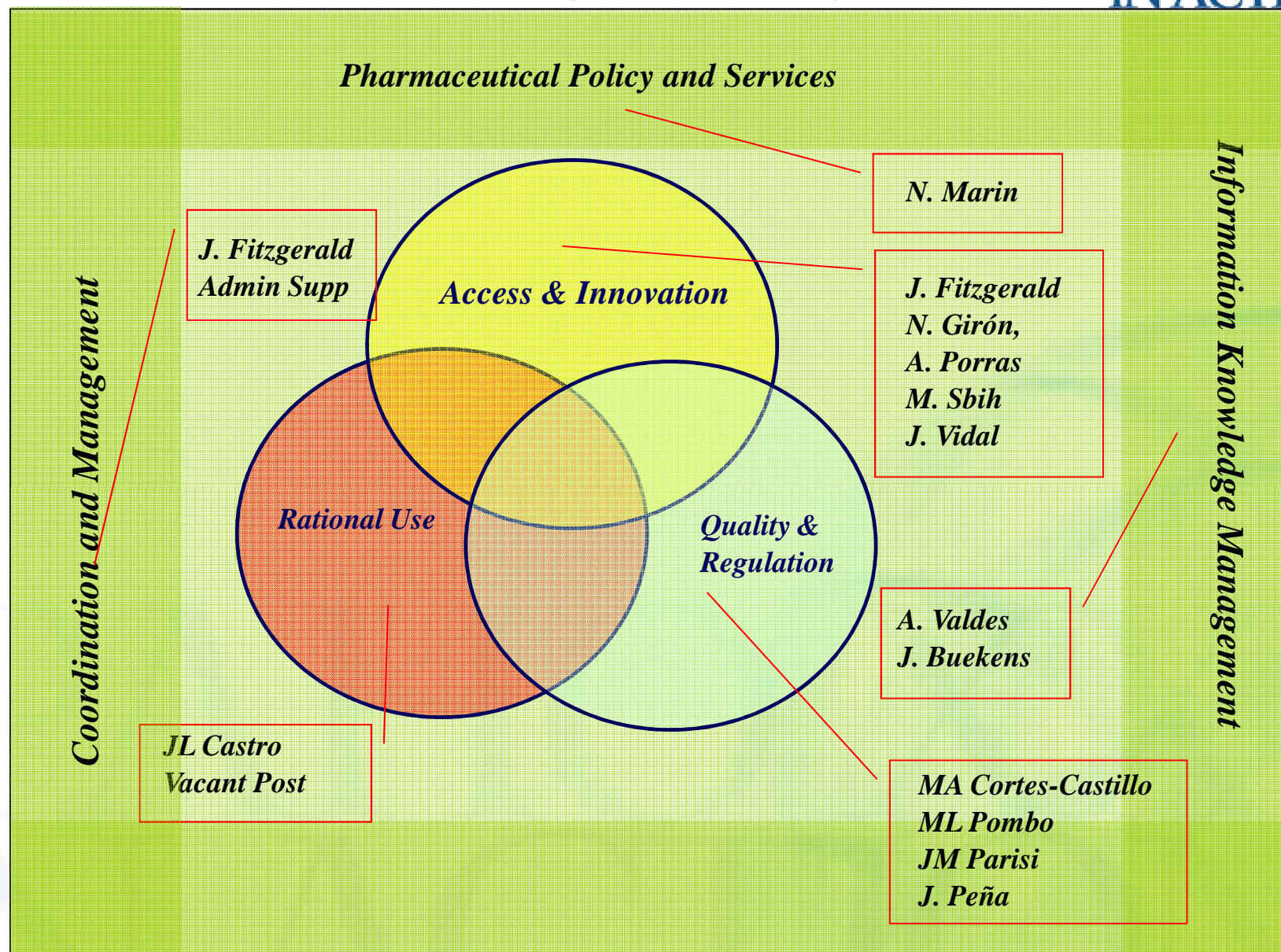
- Strategic development of partnerships and alliances based on the interests and priorities defined with the PAHO SP 2008 - 2012
- Linking SO 12 objectives with internal planning processes
- Linking planning with monitoring and evaluation
- Team work in key issues (PHC, Supply Systems, Policy, IP and Innovation, Neglected Disease etc).
- Internal communication and coordination mechanisms (inter-project, inter-programmatic)
- Knowing who is who, and developing external communication and connectivity capacity: Web, webcasts, list-serves, sharepoint. Etc
- Continuing the alignment with WHO
- Developing resource databases on experts
- Evaluating and mobilizing Collaborating Centers
- Resource mobilization: based on priorities and not availability

# A Comprehensive Approach



# PAHO Medicines & Biologicals Project:

PAHO XXI  
IN ACTION





*Thanks!*

*Contact: [fitzgerj@paho.org](mailto:fitzgerj@paho.org)*

