Access to High Cost Medicines

In the Americas:

Context, Challenges and Perspectives

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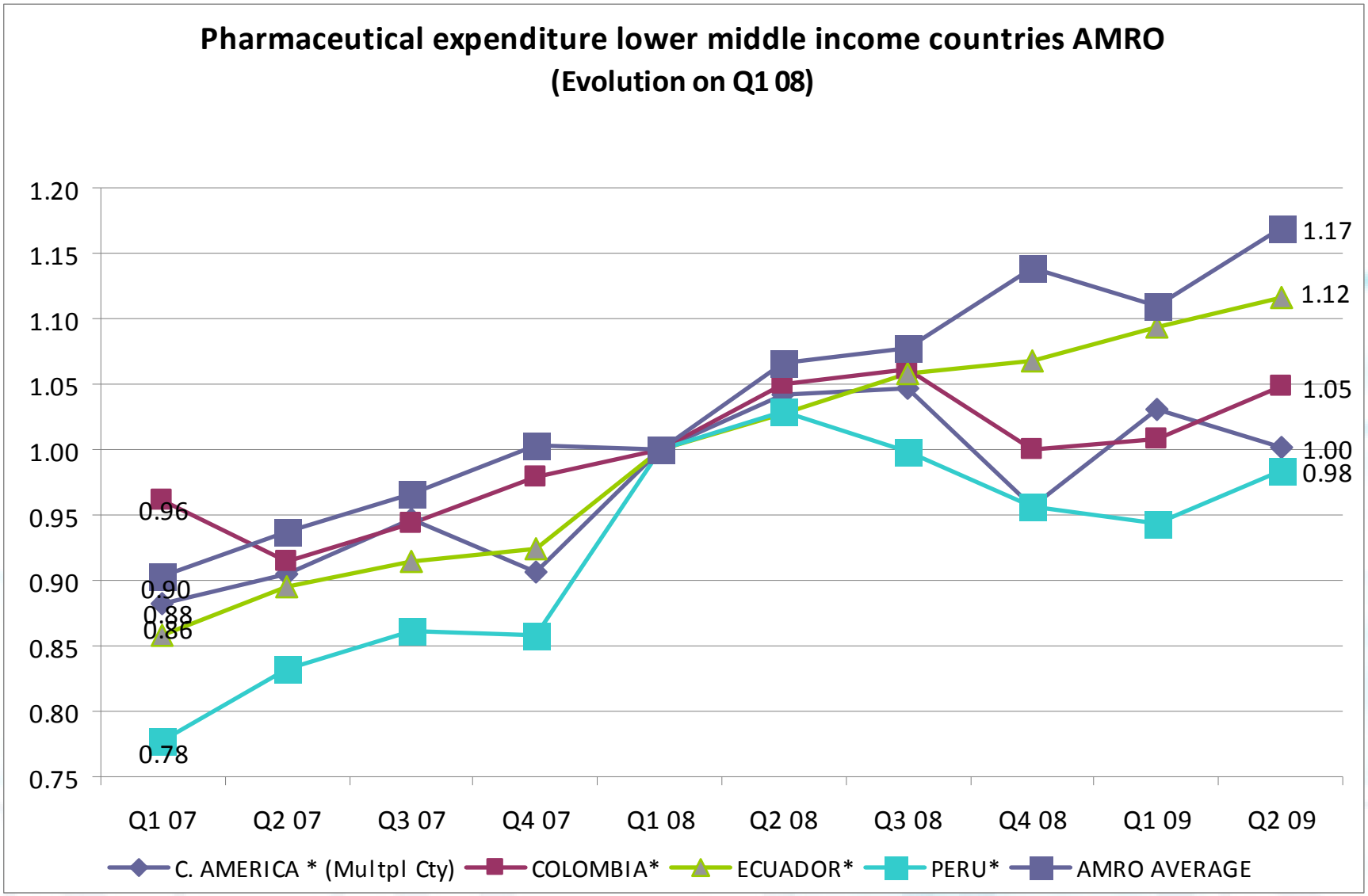
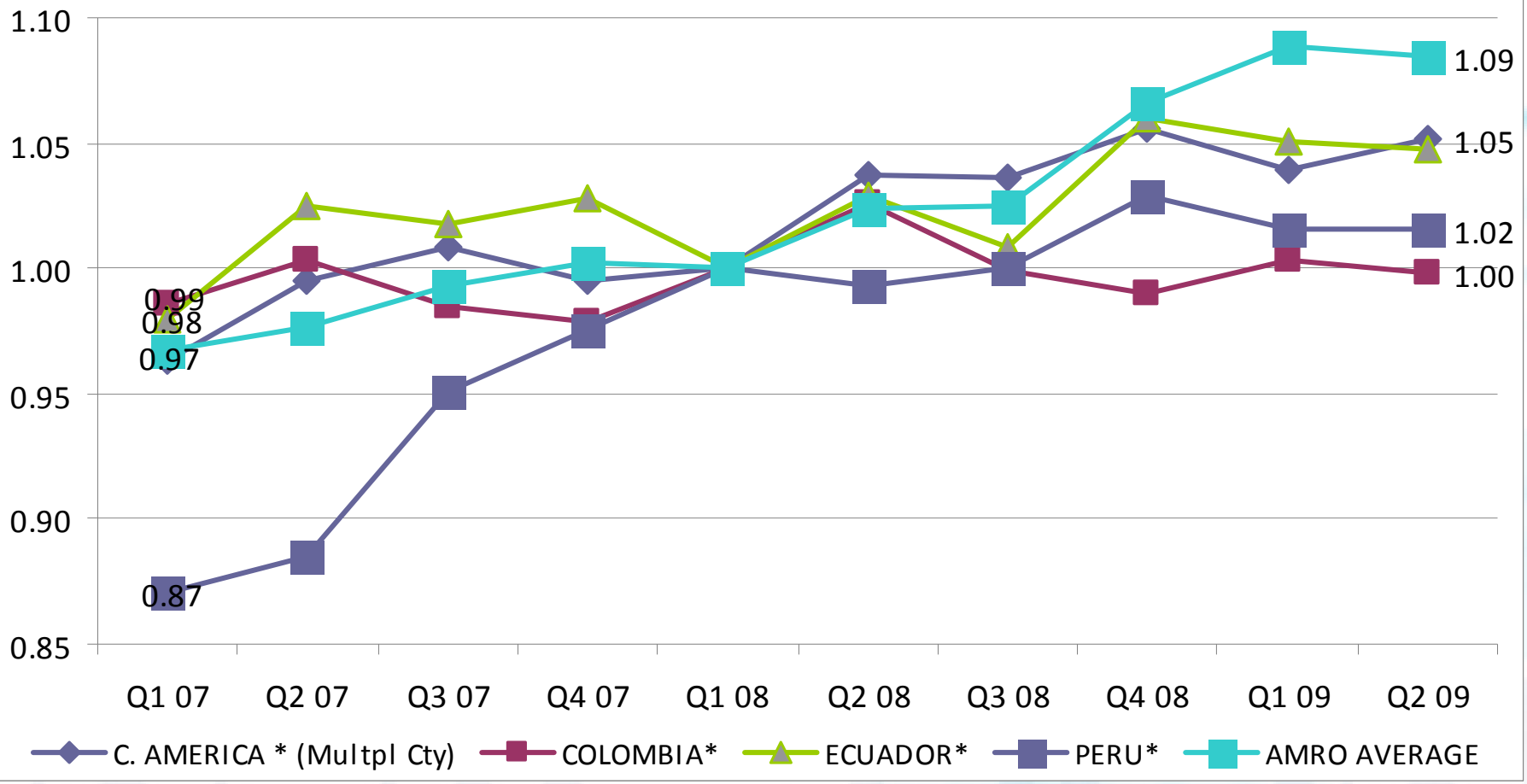
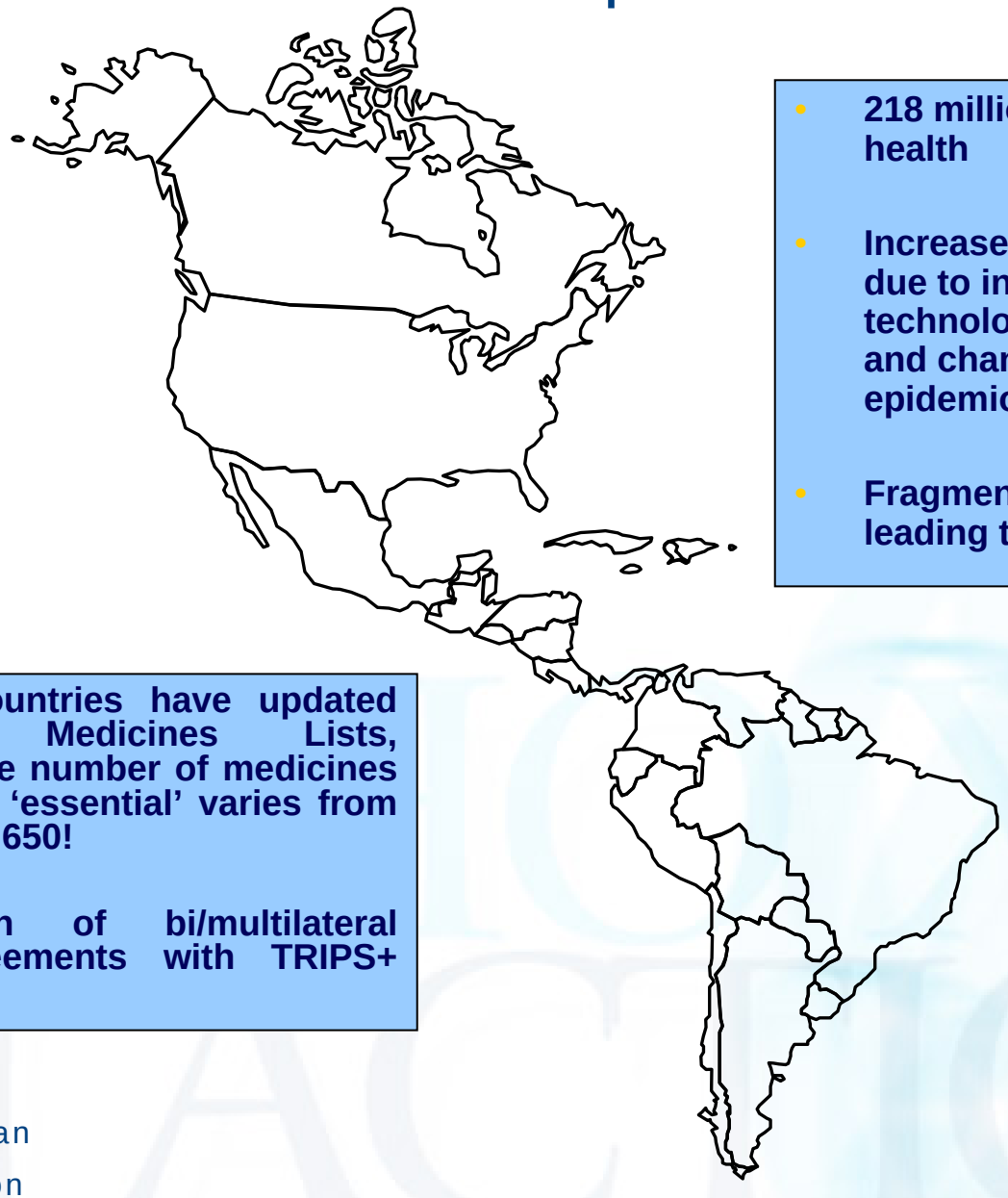
Pharmaceutical expenditure lower middle income countries AMRO
(Evolution on Q1 08)



Price per IMS Standard Unit (lower middle income countries) AMRO
(Evolution on Q1 08)



Persistent Health Inequalities



- **218 million lack social security in health**
- **Increases in health expenditures due to incorporation of new technologies, increased access and changes in the epidemiological profile**
- **Fragmentation and segmentation leading to persistent inequities**

- **92% of countries have updated Essential Medicines Lists, however the number of medicines considered 'essential' varies from 346 to over 650!**
- **Proliferation of bi/multilateral trade agreements with TRIPS+ provisions**

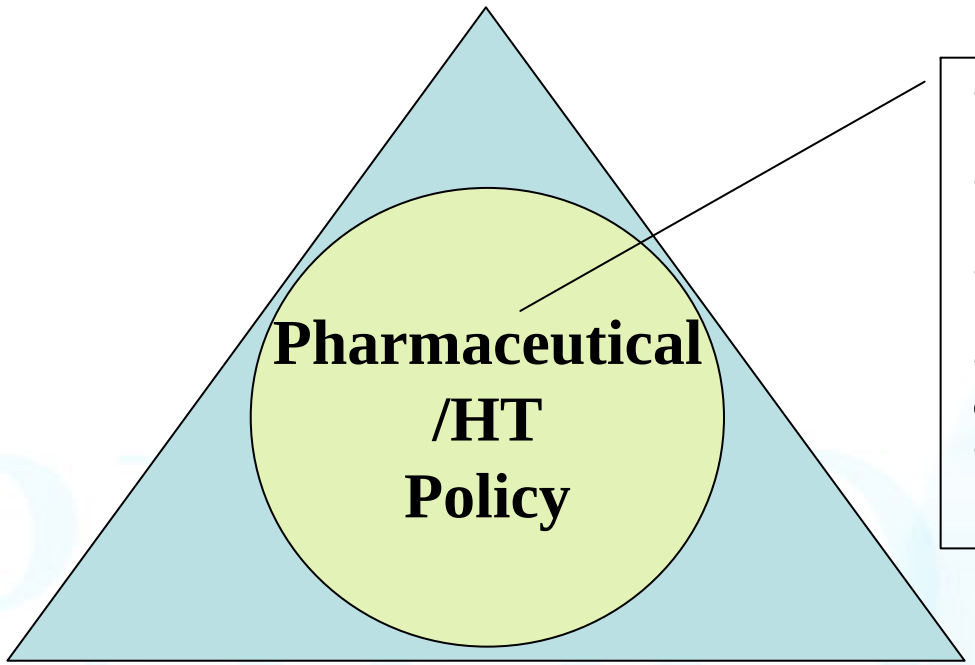
Characteristics of High Cost Medicines

- No universal definition
- Conceptual elements of the approach are similar:
  - Essential medicines, limited or single source (exclusivity)
  - Specialized medicines for specific diseases, associated with costly and complex health interventions
  - Long term chronic disease care and management
- Representing an ever increasing (absolute and relative) portion of pharmaceutical expenditure

A question of Innovation?

- Market driven R&D is not responding to needs in innovation for health technologies.
- The degree of value-added…..? The evidence base….?
- Public health perspective calls for clear therapeutic benefits and/or lower cost:
  - Comparable to existing treatments
  - Based on needs of the society

Innovation in Pharmaceutical/HT Policy



- Defining innovation strategies based on public health needs
- Promotion of mechanisms for R&D and knowledge transfer
- Increase capacity in the production chain
- Ensuring inter-ministerial coordination
- Public Health management of IP

Management of IP and Public Health

- Ensuring that TRIPS flexibilities are incorporated within national legislation and regulatory framework (reaffirmed by the DOHA declaration).

- Improving quality of patents being granted:
  - Health sector participation in the process of patent approval (Anuencia Previa, Brazil)
  - Avoiding unjustified patent perpetuation *(evergreening)*
  - Proof of improved efficacy (India)
  - Improving process: validity assumption, transparency, review mechanisms

- Assessment of impact of IP on access to medicines

Evaluation and Incorporation of New Health Technologies

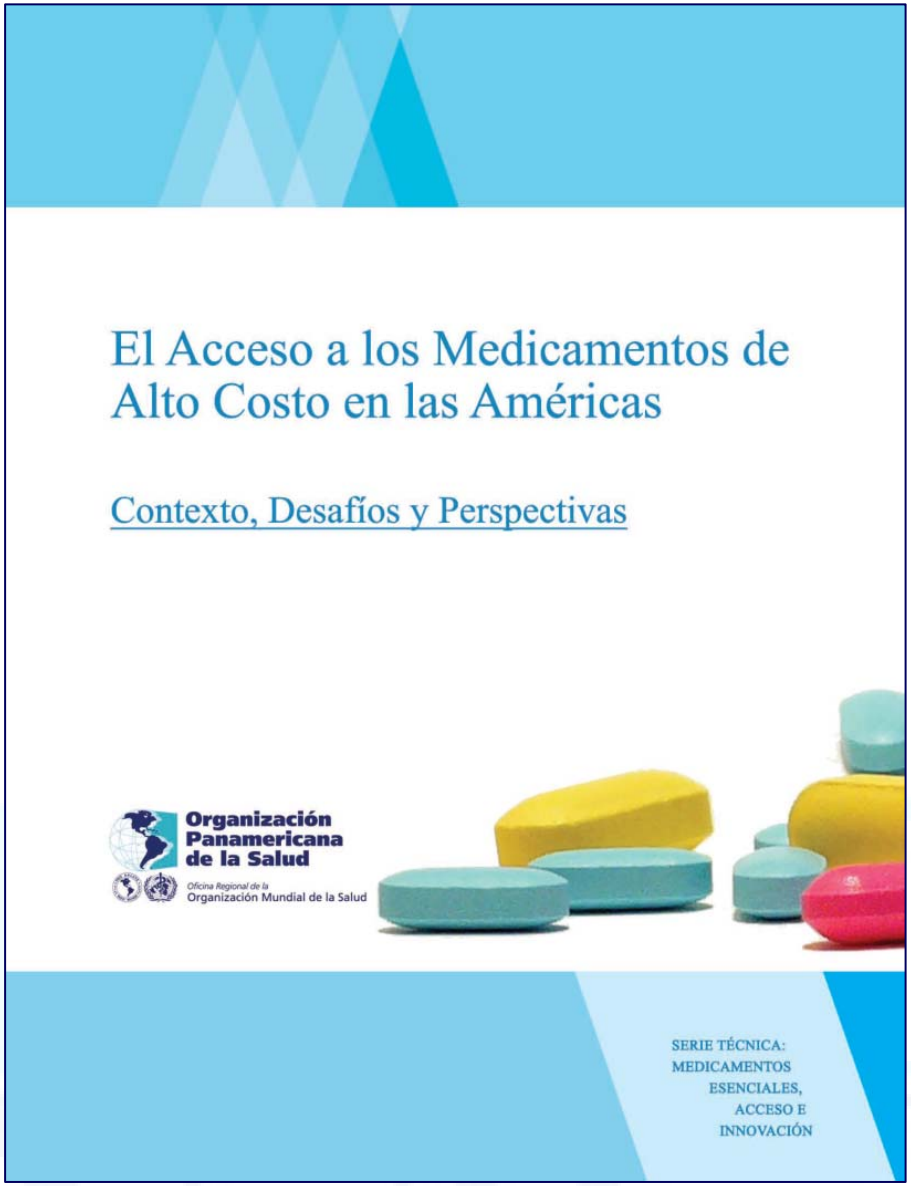
- Establish a regulatory procedure for evaluation of newer health technologies and medicines.
- Strengthen national and regional capacity to conduct economic assessment/impact studies
- Using evidence for the decision making process / incorporation within the health system
- Linking assessment results with:
  - processes for price regulation (value added, price referencing)
  - medicines financing (selective financing, adjusting co-payment modalities).

Managing Public Procurement

- Pricing data through public pricing data systems (generic and single/limited source)
- Centralized negotiations for High Cost Medicines
- Consolidate public sector demand
- Negotiate by therapeutic schemes (not by individual medicine)
- Evaluate options through international mechanisms (PAHO Revolving Fund for Vaccines, PAHO Strategic Fund).

Promote and Regulate Rational Use

- Strict application of treatment protocols and guidelines for high cost medicines
- Promote incentives for rational prescribing: eliminate perverse incentives
- Training of prescribers and pharmacists supported with independent and reliable information



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