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Access to High Cost Medicines: Examples from the Americas

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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 and/or rare 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

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High Cost Medicines: A question of Innovation?

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- Market driven R&D is not responding to needs in innovation for health technologies for rare or neglected diseases.
- The degree of value-added?
- Universal Access and the rights based approach, with legal enforcement. However, criteria and processes not defined.
- Public health perspective calls for access to new health technologies, incorporated in a sustainable manner, with clear therapeutic benefits:
  - comparable to existing treatments
  - linked with reimbursement and pricing

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Global Strategy and Plan of Action on Public Health , Innovation, and Intellectual Property (2008)

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- **Element 1.** Prioritizing research and development needs
- **Element 2**. Promoting research and development
- **Element 3.** Building and improving innovative capacity
- **Element 4.** Transfer of technology
- **Element 5.** Application and management of intellectual property to contribute to innovation and promote public health
- **Element 6.** Improving delivery and access
- **Element 7.** Promoting sustainable financing mechanisms
- **Element 8.** Establishing monitoring and reporting systems

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Regional Mandate in the Americas - CD48R15

- CD48.R15: Public Health, Innovation and Intellectual Property: A Regional Perspective. Road map to regional implementation of GSPA (October 08).

"(b) strengthen relations and collaboration among key stakeholders, from different sectors (public, private, academic, industrial, and scientific), that can play a role in the implementation of the global strategy in accordance with the agreed parts of the plan of action;

(d) improve cooperation among countries and, where applicable, within subregional integration organizations, in order to promote technology transfer and foster research and technological innovation among countries."

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Strategies to Promote Access to High Cost Medicines

- Development of integrated policies to promote access
- Promote the management of Intellectual Property from the public health perspective
- Develop capacity in HTA as a means to assess innovation; build processes and methods for incorporating health technologies in health systems
- Apply selective financing mechanisms to new health technologies
- Regulation and negotiation of prices
- Strategic management of public sector procurement
- Promote and regulate the rational use of medicines

Acceso a Medicamentos de Alto Costo, OPS 2009.

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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

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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, cost-plus etc.)
  - medicines financing (selective financing, adjusting co-payment modalities).

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Management of 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).

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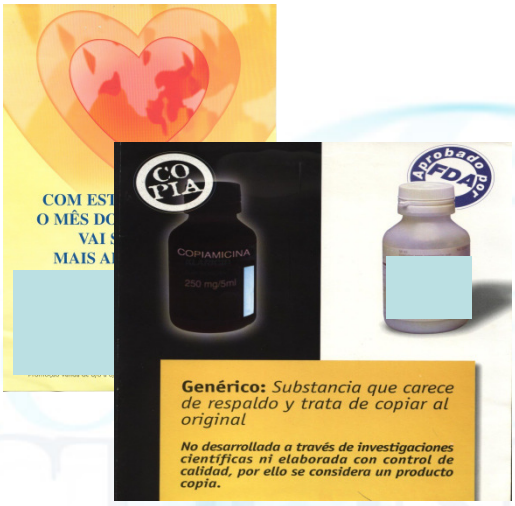
Promote and Regulate Rational Use

- 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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Negotiation and Regulation of Medicine Prices

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- Identify the government's capacity to negotiate prices for products under market exclusivity based on its purchasing power
- Develop transparency mechanisms (e.g. databases) to evaluate and disseminate medicine pricing information for products with market exclusivity as well as for multi-source products
- Evaluate options for the price regulation of high-cost and limited-source medicines

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Price Regulation: why?

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- New medicine development and production is concentrated in a small number of manufacturers
- Patents that provide protection from competition
- Informational asymmetry

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Price Regulation: how?

- Reference based pricing
- International reference pricing
- Performance based pricing
- Differential pricing
- Profit control
- Cost-plus approach

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An example of a Pharmaceutical Pricing Policy in the Region of the Americas: the experience of the Brazilian Health Regulatory Agency (ANVISA)

ANVISA

- Brazilian Health Regulatory Agency, founded in 1999
- Office of Economic Regulation in 2000
- Office of Economic Evaluation of New Technologies created in 2003, to support pricing decisions
- Responsible for health and economic regulation
- In the case of pharmaceuticals, the Agency is responsible for the safety and efficacy evaluation, and for the pricing decision
- The decisions are made in different units

Pricing Decisions

- Price Regulation Policies are defined by the Pharmaceutical Price Council (CMED), formed by 5 Ministries (Health, Finance, Justice, Industry and Civil House)
- The Minister of Health is the President of the Council
- ANVISA is the Executive Secretariat: decides on prices of new drugs, which can be reviewed by the Council
- The Office of Economic Evaluation of New Technologies is responsible for performing the assessment of new drugs

HTA and Pricing

- The majority of new drugs does not show significant clinical benefits over the best treatment available
- High budget impact of new drugs
- Growing use of HTA to assess the value of new drugs and to help pricing decisions
- In 2004 a new Resolution was approved by the Brazilian Pharmaceuticals Price Regulation Board (CMED) and HTA started being used in the pricing decisions

Price regulation of new drugs in Brazil - criteria evolution

- In the early stage of the regulation, patented medicines had their prices out of the control
- Afterwards these prices were limited by the average of prices in 5 reference countries
- In 2004, important changes were made in the regulatory framework, with the application of health technology assessment to the pricing decisions: evidence based price regulation policy

Evidence Based Price Regulation

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- New pharmaceuticals (new chemical entities) are classified according to their benefits over the comparators, and their ceiling prices are defined based on a rapid HTA (3 months)
- If the new drug has no benefit over the chosen comparator (best treatment), then it is classified as a Category 2 drug, and their ceiling price is defined based on cost-minimization analysis
- If the new drug is considered to be better than the comparator (Category 1), then a premium price is allowed, but this price cannot be higher than the lowest price among 9 reference countries
- This analysis is prior to the drug launch

Main steps

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- Economic dossier submitted by industry
- Rapid HTA: literature review, choose of the right comparator, economic evaluation
- A report is produced and then discussed at the Executive Secretariat meeting
- Marketing approval (deadline: 3 months after submission)

Results

- Between 2004 and 2011, 193 new chemical entities were evaluated by the Office of Economic Evaluation of New Technologies
- 178 products were classified as category II drugs and 15 were classified as category I (less than 8% of the total)
- The Evidence-based pricing policy has led to significant price reductions since 2004

Results (2)

- In March 2010 the Office of Economic Regulation published a study about all the patented drugs in Brazil, a total of 96 products
- The study showed that the Evidence-based pricing policy had a strong influence over the prices
- Among the 63 patented drugs that were in the market before the policy approval, only 13% have their lowest price in Brazil, considering the reference countries
- Among the 33 patented drugs evaluated after the policy approval, 52% have their lowest price in Brazil

HTA, Regulation and Pricing

- Drug regulatory agencies have usually assessed the quality, safety and efficacy of drugs
- The Brazilian approach has introduced the comparative efficacy as a fourth regulatory hurdle before marketing approval
- HTA is applied to support a regulatory decision
- This policy does not allow that me-too drugs be more expensive than the best treatment option
- Not only limited to the Public Health System (SUS), since 65-70% of the market are private

Challenges

- High out-of-pocket expenses in the Region

- What should we do when the best comparator is not approved for the same indication (off label)?

Ex: Bevacizumab (Avastin) x Ranibizumab (Lucentis) for AMD

- 3 mg of Lucentis costs US$ 2000
- 3 mg of Avastin costs US$ 20

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A new Agenda for the Region

- Pan American Meeting on Economic Evaluation of Pharmaceuticals, with the participation of 23 countries of the Region
- HTA Network of the Americas (RedETSA)
- Development of the capacity to use HTA to support pricing and reimbursement decisions
- Regional price database

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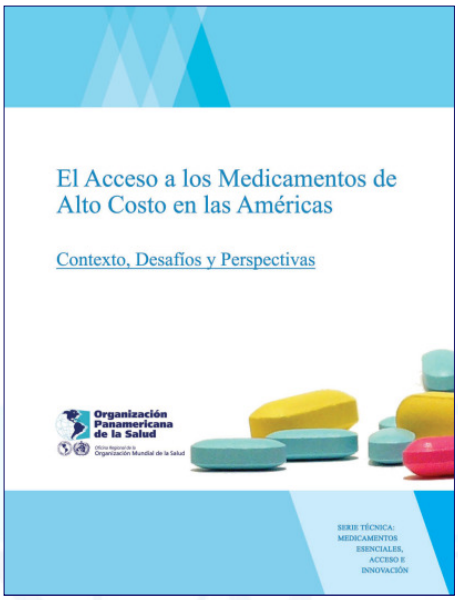

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