HTA or REFERENCE PRICING?
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The Future of Pharmaceutical Cost Controls in Latin America

Workshop
For distribution to ISPOR Latin America attendees

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Today’s workshop will focus on exploring cost-containment strategies, and the extent to which lessons can be learned from regionally-relevant markets.

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2. Brazil  
3. Mexico                                                                 |
| 12:45 – 12:55 | Evolving Landscapes                          | 1. New Method Adoption  
2. Case: Colombia                                                        |
| 12:55 – 13:15 | Regionalisation                              | 1. Regional Efficiencies  
2. Government Opportunities  
3. Pharmaceutical Opportunities  
4. Questions                                                              |
The objective of this workshop is to explore the future development of two high-potential cost-containment mechanisms: reference pricing and HTA.

**OVERALL OBJECTIVE**

To explore the future development of two high-potential cost-containment mechanisms, reference pricing and HTA, currently being leveraged in assorted forms by various Latin American countries.

**WORKSHOP GOALS**

- To better understand the current landscape of reference pricing and HTA in Latin America
- To evaluate the trade-offs associated with reference pricing versus HTA
- To explore the potential future centralisation of these processes throughout the Latin American region
The current Latin American healthcare coverage environment is evolving at varied rates, with BRA and MEX leading the region in coverage of high-cost therapies.

**LATIN AMERICAN ENVIRONMENT**

**BREADTH vs. QUALITY OF COVERAGE**

- **Social insurance in MEX provides half of the population with access high-cost molecules; the other half of the population has very limited coverage.**

- **BRA covers many high-cost therapies, but consists of a tougher reimbursement environment with regards to oncology therapy coverage.**

- **Although extremely fragmented the system in ARG covers a broad portion of the population and provides access to some innovative therapies.**

**BRA**

**MEX**

**COL**

**ARG**

SOURCE: ISA Proprietary Research
Relative to other emerging regions, BRA, MEX, and ARG lift the regional access environment for Latin America.

**SELECT EMERGING MARKETS**

**TARGETED THERAPY REIMBURSEMENT EXAMPLES**

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<th>SUTENT</th>
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*Not exhaustive

Source: ISA Proprietary Research
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**Agenda**

1. **Introduction & Objectives**
   - 1. Introduction
   - 2. Meeting Objectives

2. **HTA and Reference Pricing Examples**
   - 1. Current Pricing Landscape
   - 2. Brazil
   - 3. Mexico

3. **Evolving Landscapes**
   - 1. New Method Adoption
   - 2. Case: Colombia

4. **Regionalisation**
   - 1. Regional Efficiencies
   - 2. Government Opportunities
   - 3. Pharmaceutical Opportunities
   - 4. Questions
Historically, the lack of government coverage and price controls on pharmaceuticals has created a high price tolerance throughout the region.

RESULTING HIGH PRICES
COVERAGE & PRICING CONTROLS

LIMITED COVERAGE \times \text{LIMITED PRICE CONTROLS} = \text{HIGH PRICES}

In countries like MEX, before the creation of Seguro Popular the majority of the population paid OOP for pharmaceuticals

Historically, COL has been allowed for the introduction of high priced agents into their environment and not controlled pharmaceutical pricing

The creation of a strategy to provide their product to those that can afford it throughout LatAm has created pricing that only the “top of the pyramid” can afford
Looking at various primary care products, Colombia is by far the most expensive market with South Africa, India, and Algeria on the lower end.

VARIATION FROM AVG PRICE:
PRIMARY CARE, 08Q4-09Q3

Pricing for PCP products in Latin America has historically been higher than other emerging markets due to lack of pricing controls and the knowledge that some volume of patients will be able to afford the product.

Unlike in Latin America, strong price controls in the European emerging markets have allowed for lower overall pricing of primary care products.

Source: ISA Proprietary Research

Note: Pricing data reflects list price, not net price
For specialty brands, Latin American countries (except Mexico) tend to exhibit high pricing, most likely due to lack of reimbursement.

Lack of reimbursement and expected small levels of utilisation have created a need for high pricing of specialty products in Latin America.

Source: ISA Proprietary Research

Note: Pricing data reflects list price, not net price
Historically, countries have utilised a combination of mechanisms to ensure they can provide comprehensive coverage within their budget limitations.

**COST-CONTAINMENT MECHANISMS**

**AT-LAUNCH**

- **COST-PLUS PRICING**
  
  Countries like CHN, have historically utilised cost-plus pricing for reimbursed products, providing little room for rewarding the product’s additive value.

- **THERAPEUTIC REFERENCE PRICING**
  
  Therapeutic reference pricing is often applicable to generics or biosimilars, but innovative products often get grouped with products that provide diminished clinical value.

- **INTERNATIONAL REFERENCE PRICING**
  
  International reference pricing has served many markets, like TUR, to lower pharmaceutical prices, but it creates an environment where country priorities, needs and product value are not evaluated.

- **HTA EVALUATION**
  
  Although HTA evaluations can offer a justification for lowered pricing needs, the resources necessary to conduct these evaluations are often limiting.

Source: ISA Proprietary Research
Most Latin American markets are beginning to explore how to reward the value of innovative drugs while making them affordable to their population.

HEALTHCARE EVOLUTION

COVERAGE vs. PRICE CONTROLS

UNIVERSAL COVERAGE → BUDGET DEFICIT / CONSTRAINTS → POSITIVE LIST ESTABLISHED → HTA GUIDELINES CREATED

REFERENCE PRICING INTRODUCTION → HTA EVOLUTION

Recent changes towards providing universal coverage have created financial challenges for the market and led to the need for new policies for healthcare regulation.

BRA and MEX are still developing their healthcare legislations, but policies are more developed than in most Latin American countries.

Source: ISA Proprietary Research
In BRA, a dual system composed of reference pricing and HTA is currently utilised to ensure affordable pricing for the Brazilian population.

**BRA PRICING & REIMBURSEMENT**
**CURRENT PROCESS**

CITEC is tasked with the HTA evaluation of all new pharmaceuticals pursuing national reimbursement and must provide the MS with an inclusion or exclusion recommendation.

The Ministerio da Saúde takes CITEC’s recommendation and upon analysing the budget-impact makes a final decision on the product’s reimbursement inclusion.

CMED first judges a product based on its level of innovation and if deemed innovative, will then employ international reference pricing to arrive at the list price in BRA.

Source: ISA Proprietary Research
The use of international reference pricing to set the list price and an HTA assessment to justify additional discounts, has resulted in high price discounts in BRA.

### Brazil Case Study

#### REIMBURSEMENT DISCOUNT EXAMPLES

**GLIVEC & MABTHERA**

<table>
<thead>
<tr>
<th>SUS PRICE DISCOUNT</th>
<th>RATIONALE</th>
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<tbody>
<tr>
<td>50%</td>
<td>• GLIVEC will be centrally procured and will see approximately a 10% volume increase</td>
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<td>• GLIVEC is a strategic product for the Brazilian government and is coming up on its patent expiration in 2012 and could be facing generic competition</td>
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<td>• 80% of GLIVEC’s sales in Brazil come through the SUS system</td>
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Prior to inclusion in the SUS reimbursement list, GLIVEC was the most requested drug through legal injunctions.

• President, Dilma Rousseff, was diagnosed with cancer and utilised MABTHERA as part of her treatment.

• The political pressures and Roche’s presence in Brazil led to the addition of rituximab to the NHL protocol and SUS tables.

Source: ISA Proprietary Research
Although examples of successful negotiation exist for the BRA government, many drugs never make it through the process due to CITEC’s limited resources.

CITEC’s ability to appraise drugs is improving, but in the last five years only 87 drugs have received a decision, which leaves many more waiting for public access.

Source: TABELA DE DELIBERAÇÕES DA CITEC
In a similar fashion to BRA, MEX conducts reference pricing to obtain the product’s list price, but reimbursement often results in decentralised evaluations.

MEX PRICING & REIMBURSEMENT
CURRENT PROCESS

List pricing regulations are weak in MEX, and although reference pricing may be utilised the markets referenced tend to be markets where the product has the highest sales.

No centralised HTA system is currently in place and many decisions and evaluations take place independently depending on the coverage program in question.

Source: ISA Proprietary Research
CENETEC is an HTA organisation in MEX, but its reports and evaluations are not directly linked to the reimbursement decisions taking place in MEX.

**AREAS OF FOCUS**

1. **MEDICAL EQUIPMENT PLANNING**
2. **HEALTH TECHNOLOGY ASSESSMENT**
3. **E-HEALTH**

Historically, CENETEC has focused much of its effort on medical equipment, but since its creation has expanded into other areas of assessment.

Although CENETEC’s role within the MEX healthcare system remains small, its influence is consistently evolving and its collaborative nature should provide a good example for other Latin American countries.
International reference pricing is an evolving price control strategy being adopted by most emerging markets as they further their development.

REFERENCE PRICING
BRICT MARKETS

LAUNCH REFERENCE
REIMBURSEMENT REFERENCE
INFORMAL REFERENCE
INFORMAL REIMBURSEMENT REFERENCE
POSIBLE FUTURE REFERENCE

Source: ISA Proprietary Research
High-pricing in LatAm has often led to financing difficulties, but as markets evolve their coverage landscape and utilise HTA assessments, reimbursement will improve.

**SUMMARY**

- Historically, **Latin American** countries have had **extremely high pricing** for primary care and specialty products
- The **evolving coverage landscape** and increasing **need to provide access** to high-cost medicines has led to a **need to contain costs**
- **Cost containment** can take **many forms**, but throughout Latin America clear examples of **reference pricing** and **early HTA** development exist
- **BRA** utilises **reference pricing** to set the **initial list price**, but also requires an **HTA evaluation** to occur before a product can obtain **public reimbursement**
- In **MEX**, similar to BRA, **reference pricing** has **sometimes** been employed to set the product’s initial price, but **additional negotiations ensue** with each of the country’s payers
- Organisations like, **CITEC and CENETEC**, are **still developing**, but their trials and errors can prove **useful lessons for other Latin American countries** initiating their journey towards HTA incorporation

Source: ISA Proprietary Research
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Colombia’s health reforms focused on several aspects of health system improvement, however the most significant effect will be for the POS update.

Source: ISA Proprietary Research
Colombia’s health reforms focused on several aspects of health system improvement, however the most significant effect will be for the POS update.

**HEALTH REFORM**

- PREVENTION-FOCUS
- REGIONAL MONITORING
- AGENCY RESTRUCTURING

**POS UPDATE**

*How do we accomplish our goals cost-effectively?*

- HTA ADOPTION
- REFERENCE PRICING
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Governments are in a position to forge cooperative relationships, however the nature of these relationships must be carefully considered.

**EVIDENCE NETWORKS**

- **OBJECTIVE:**
  - To share knowledge and evidence for clinical and economic assessment by payers throughout the region

- **TRADE-OFF:**
  - Automatic acceptance of decisions from other payers / agencies / governments could result in inequitable access

**REGIONAL REF. PRICING**

- **OBJECTIVE:**
  - To limit public pricing of pharmaceuticals to that of other countries in the region

- **TRADE-OFF:**
  - May result in a pricing spiral for the region, creating a non-innovation friendly environment

**REGIONAL BIOSIMILAR PATHWAY**

- **OBJECTIVE:**
  - To expedite the approval of and access to lower-cost specialty drug options

- **TRADE-OFF:**
  - Attaining cost-effectiveness for ‘lower-cost’ biosimilars may still not be achievable

Source: ISA Proprietary Research
The pharmaceutical industry can help promote regional solidarity in an effort to improve access through their own collaborative initiatives.

**EVIDENCE NETWORKS**

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  - To share knowledge and evidence for clinical and economic assessment by payers throughout the region

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**LOCAL INVESTMENT**

- **OBJECTIVE:**
  - To foster economic and domestic industry development to improve government relations

- **TRADE-OFF:**
  - May lead to intellectual property risk and poor government reciprocation

**PORTFOLIO OPTIONS**

- **OBJECTIVE:**
  - To provide price concessions on products critical to public health

- **TRADE-OFF:**
  - Upside for remainder of portfolio may be limited for the manufacturer and government, alike

Source: ISA Proprietary Research
If you would like a copy of these slides, please contact us.

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