

The Role of HTA in the price regulation of new drugs: the Brazilian experience

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HTA and Pricing

- ❖ **The great majority of new drugs does not show clinical benefits over the best treatment available**
- ❖ **High budget impact of new drugs but no value for money**
- ❖ **Growing use of HTA to assess the value of new drugs and to help pricing decisions**
- ❖ **In some countries pharmaceuticals are classified according to the benefit to the treatment (France, Canada, Brazil)**

International experience

- ❖ **France: 67% of the drugs evaluated did not add anything to the treatment (1981 and 2003)**
- ❖ **Sweden: 58% with no additional benefit (1987-2000)**
- ❖ **USA: 77% considered as mee-too drugs (1998-2002)**
- ❖ **Canada: only 5,9% of the new drugs were considered to bring significant clinical benefit over the current treatment (1990-2003)**

What is an innovative drug?

- New process?**
- New mechanism of action?**
- New molecule?**

**patented medicine=really
innovative medicine in terms of
the benefit for the treatment?**

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**

Economic regulation and economic evaluation of new technologies

- ❖ **Branch of the Brazilian Health Surveillance Agency (ANVISA)**
- ❖ **Responsible for HTA to support pricing decisions**
- ❖ **Participation in the National Commission that gives the recommendation to the Minister about which technologies should be paid by the Public Health System**
- ❖ **Dissemination strategies**
- ❖ **Budget impact analysis**
- ❖ **International cooperation**

Evidence Based Price Regulation

- ❖ **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 characteristics of the model

- ❖ Fourth hurdle (besides efficacy, safety and quality) before marketing approval**
- ❖ Application of HTA to define the ceiling prices for new drugs**
- ❖ Does not allow that mee-too drugs be more expensive than the best treatment option (85% of the cases)**
- ❖ Not only limited to the Public Health System (SUS), since around 75% of the market is private**

Challenges

- ❖ **Lack of head-to-head studies**
 - **Should we accept indirect comparisons?**
- ❖ **Studies against the wrong comparator**
 - **Should we demand new clinical trials?**
- ❖ **Surrogate end-points**
 - **Should we accept them for pricing decisions?**

Reimbursement Decisions

- ❖ **The National Commission for Technology Incorporation (CITEC) is responsible for making the recommendation to the Minister of Health, who makes the final call about which technologies should be paid by the Public Health System**
- ❖ **The Commission has 5 members, 3 from the Ministry of Health and 2 from the agencies (ANVISA and the Agency that regulates the health private sector-ANS)**
- ❖ **The recommendation is based on a HTA report**
- ❖ **4 votes are needed to approve a recommendation**
- ❖ **Budget impact analysis is required**

Dissemination

- ❖ **Two important publications:**
 - *Brazilian Bulletin of Health Technology Assessment (BRATS)*
 - *Health and Economics*
- ❖ **The main goal is to help decision-makers making informed decisions**
- ❖ **BRATS is published every 3 months**
- ❖ **8 issues have been published so far**
- ❖ **The Bulletin has around 22.000 subscribers, in more than 30 countries**
- ❖ *Health and Economics* had its first edition last month, with great acceptance
- ❖ **Both are available at www.anvisa.gov.br (publicações - boletins eletrônicos)**

Working in Collaboration

- ❖ **Joint projects on economic evaluation (Argentina, Cuba)**
- ❖ **Anvisa has been asked to offer training programs on HTA, Regulation and Pricing (Colombia, Uruguai, Cuba, Cabo Verde, Moçambique)**
- ❖ **HTAi group of developing countries**
- ❖ **Project to strengthen HTA in the MERCOSUL region**
- ❖ **Working group on Economic Regulation in the PAHO region**
- ❖ **Department of Science and Technology (Ministry of Health) is member of the INAHTA**

An Invitation

- ❖ **Rio de Janeiro will host the 2011 HTAi meeting**
- ❖ **It will be the first time that a Latin-American country hosts this meeting**
- ❖ **The theme will be “HTA and Health Systems Sustainability”**

We are looking forward to seeing you!