From the launch until the payers

Without this price approval process, the company can’t sell the product on the Brazilian market, even for the private market.

International impact on Brazilian market pricing

The product pricing process in Brazil takes as reference the following countries prices, excluding taxes:

- Australia
- Canada
- Spain
- USA
- UK
- France
- Greece
- Italy
- New Zealand
- Portugal
- Product origin country

The reference price will be the lowest price from this group of countries.
Flow for Incorporating Technologies in the Unique Health System (SUS) and the Supplementary Health System

1. Referral Ministry of health secretaries and programs
2. Referral
3. Technical support AD HOC
4. Revision
5. Technical scientific appraisal
6. Recommendation
7. Referral
8. Referral
9. Referral

CITEC (Technology incorporation commission)
MADS (Medical strategic action commission)
DECIT (MoH Science and technology department)
ANS (National Supplementary Health Agency)

LAW 12.401
28_APRIL DE_2011

• Changes Law 8.080
• New rules for Therapeutic assistance and Health Technology incorporation for the public health care
• Fixed timeline for deliberation – 180 days
• Public consultation
• Cost effectiveness

Obrigada!
gabriela.tannus@axta.bio.br

Visit ISPOR booth at HTAi 2001!

PHARMACOECONOMICS IN BRAZIL: REGULATORY TRENDS AND FUTURE PERSPECTIVES
Health plan beneficiaries, according to coverage, Brazil – September, 2010

Medical hospitalar assistance

Number of health plan beneficiaries

Health plans:
- Revenues
- Expenditures

(A) Revenues: R$ 65,543,669,146
(B) + (C) Expenditures: R$ 64,798,058,680

Administrative: R$ 10,830,920,617

Medical hospitalar: R$ 53,967,129,027

Private Brazilian market: stakeholders

Health plans:
- Hospitals
- Doctors and other health professionals
- Health plan
- Insurance
- Pharmaceuticals
- Inputs

Current scenario: rising health care costs

- Increasing administrative costs
- Ageing population
- Chronic diseases
- Health technologies

Main types of Chronic Diseases, with and without health plan assistance - Brazil - 2009

<table>
<thead>
<tr>
<th>Chronic disease</th>
<th>With health plan</th>
<th>Without health plan</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>19,132,403</td>
<td>19,132,403</td>
<td>83%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>5,298,422</td>
<td>7,845,234</td>
<td>44%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1,383,821</td>
<td>1,383,821</td>
<td>82%</td>
</tr>
<tr>
<td>Coronary heart</td>
<td>1,383,821</td>
<td>1,383,821</td>
<td>82%</td>
</tr>
<tr>
<td>Congestive heart</td>
<td>1,383,821</td>
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<td>Congestive heart</td>
<td>1,383,821</td>
<td>1,383,821</td>
<td>82%</td>
</tr>
<tr>
<td>Cancer</td>
<td>831,857</td>
<td>831,857</td>
<td>70%</td>
</tr>
</tbody>
</table>

Ageing population

Age pyramid of the Brazilian population, by sex - 2009

Age pyramid of health plan beneficiaries, by sex - September, 2010
Health technologies

- Procedures / Technical
- Equipments / exams
- Prosthesis and devices
- Medicines

INTEGRATION PROGRESS
TECHNICAL/SPECIALIZED ANALYSIS

FINANCIAL/ECONOMIC EVALUATION

- Contributions of health plans
- Pricing references by tables
- Contributions of health plans
- Pricing references by tables

Health technologies – coverture and incorporation

- ANVISA
- ANS
- Regulatory institutions

Name | Description | Cost | Availability | Guidelines | References
--- | --- | --- | --- | --- | ---

Health technologies – criteria for reimbursement

- MEDICAL SOCIETIES
- PRIVATE MARKET
- ANVISA

Health technologies – regulatory criteria

- HEATH PLANS
- ANVISA
- ANS
- Technical audit specialist

Reflections of health technologies

- ANVISA
- ANS
- Technical audit specialist

Reflections of private Brazilian market

- The supplier stimulates demand for procedures, especially those new and / or high technology?
- A new technology available is quickly assimilated?

Reflections of private Brazilian market

- Is there any gap between technological advances and quality of health care?
- Marketing of the technology encourages the inappropriate use / waste of technology?
- The problems faced within the judiciary favor the misuse and waste of health technologies?
- The asymmetry of information contributes to the incorporation of technology?
Reflections of private Brazilian market

• In health care, a new technology replaces the previous or is cumulative?
• There are conflicts of interest between those requesting and who performs the procedures?
• Are induced by product/supplier/manufacturer?
• Regarding access to technology, there are differences and/or regional barriers in a country of continental dimensions like Brazil?

Decreasing in recent years

• The predominant model in Brazil to pay providers of services (fee for service) are viable in the medium and long term?
• New payment models are applicable in Brazil?

Maybe

Many of the questions raised can be answered by the use of tools

• Pharmacoeconomics and health economics

Private Brazilian market: stakeholders

• Companies
• Providers
• Health plans
• Beneficiaries
• Suppliers

• Hospitals
• Doctors and other health professionals
• Health plan
• Insurance
• Pharmaceuticals
• Inputs

Current scenario: rising health care costs

• We’re all together!

Risk sharing

• Companies
• Providers
• Health plans
• Suppliers
• Beneficiaries

• Packages
• Daily global
• Capitation
• Pharmaceuticals
• Inputs

Risk sharing: possible factors inducing
Risk Sharing

Barriers to be overcome: the perspective of the payer

- Uncertainty about the budgetary impact;
- Concerns about evidence and use;
- Concerns / doubts about the implementation: Spending time, effort and funding;
- Collecting data -> information and decision making.

Barriers to be overcome: the perspective of pharmaceutical industry

- Short-term gain worth the long term?
- Investors will accept the financial risk?
- Difficulty in measuring investment results.

Barriers to be overcome: the perspective of both

- Drugs that require hard data to demonstrate results;
- Outcomes that depend on multiple factors;
- The results depend heavily on patient effort;
- Concern about the neglect of the patient and physician;
- The coverage of the health plans is not uniform.

Risk Sharing: final considerations

- Outcomes must be measurable;
- Determine the responsibilities of actors;
- Audit;
- Set goals that can be tracked;
- Warranty against poor performance;
- Pharmacoeconomics and health economics;
- Preserving the innovative investment;
- Protect the payer of innovations that do not deliver value to the patient.
Pay for Performance

- Pay for performance is based on critical measurements, for which a provider’s performance is compared with a reference standard. And it is this comparison that determines their remuneration.
- Bauman [USA, 2006]
- USA - part of the reform of the health system has recently approved components of pay for performance

Pay for Performance

- Reality or myth? Discussing the uncertainties
  - Pay for performance will end with the current systems of pay?
  - There are risks of limiting the power of decision of the doctor?
  - It is synonymous with cost reduction?
  - Where is the EBM? The evidence is important?

  - Who should take the process of change?
  - How to make the process transparent?
  - The focus on patient / client is a utopia?

Pay for Performance

- Five major commercial plans operating in Massachusetts during 2001-2003 period.
- 4 million enrollees
- 5,350 primary care physicians
- >90% of practicing PCP
- Overall, P4P contracts were not associated with greater improvement in quality compared with a secular trend.
- Financial incentive probably was not large enough to lead to a change in practice.

Pay for Performance

- The key point of the model is not directly improve the gain of the physician / provider or reducing care costs, but improve the quality of health care of patients or clients.

Pay for Performance

- To whom and how much to pay for performance?
  - Incentives should be sufficient to compensate for the effort
  - Must constitute a substantial portion of all revenue.
    - USA: 2-9% (M. Rosenthal, 2007)
    - UK: 25 to 30% (depending on the indicators achieved) (T Doran, 2006)
  - Who should receive the incentives?
    - health professionals
    - professional groups
    - institutions

Pay for Performance

- … incentives lead to an improvement in the documentation of procedures the patient had no impact on quality of care (Roski J. 2003)

Conclusions: Good quality of care for hypertension was stable or improving before pay for performance was introduced. Pay for performance had no discernible effects on processes of care or on hypertension related clinical outcomes. Generous financial incentives, as designed in the UK pay for performance policy, may not be sufficient to improve quality of care and outcomes for hypertension and other common chronic conditions.

In summary, we can say that the pay for performance:
- Favors incentives based on quality of care and not to stimulate the volume of services provided and/or complexity
- Encouraging continual improvement in efficiency (processes) and effectiveness (results)
- The distribution of financial results is through milestones achieved.

In Brazil, we are prepared? Facing challenges
- Indicators
- Reference standards
- Acceptable deviations

The pay for performance seems to be an interesting alternative, however, the customization of a Brazilian model is complex. We understand that the opportunity to experience not to be missed.

The Brazilian Experience
The Health System and HTA in one of the BRIC countries

Stephen Stefani, MD
190 million people
40 million covered by private health insurance
Health Ministry budget: US$ 25 billion

GPD per capita
US$ 8,304,00
< 4% of GIP is invested in healthcare

40 million covered by private health insurance
50% of all spent money

Who’s fault?

Benefit Design
• Same list of benefits to all the Companies
• No changes of the certificate of coverage
• No exclusion of any kind of disease
• Reduce of non-covered time
• Fee regulated by the Government
• Reimbursement to the Public System (SUS)
Private System

Benefit Design

• No co-insurance
• No co-payment
• Self referrals
• No obligations to cover
  – drugs for outpatients
  – Experimental treatments
  – Off label (OT)
  – Cosmetic treatments

• Once the technology is approved by Ministry of Health
• Fee for service
• Based on the spread between Factory Price (PF) and Maximum Price to the Consumer (PMC) of drugs and devices

Public System

• SUS (Unified Health System)
• Guarantee by the Constitution
• “HMO like” with a pre defined budget (by disease)
• Special program to high cost drugs
List of Exceptional Drugs

- Regulated by Ministry of Health – MH (Port GM nº 2.577 / 06)
- National Evidence Based Guideline
- Paid by the MH and logistics control by local government (State and City)
- Report case by case to MH

Trends in HTI in Brazil

- 2 Poster at ISPOR Congress Praga
- Submissions to CITEC 2003 – 2010
- Time to answer: 24 months
- Only 27% had been answered
- No clear definitions of the process

Cost-effective definition

<table>
<thead>
<tr>
<th>Country</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUA</td>
<td>US$ 50.000/Qaly</td>
</tr>
<tr>
<td>United Kingdom (NICE)</td>
<td>US$ 60.000/Qaly</td>
</tr>
<tr>
<td>Brazil</td>
<td>?</td>
</tr>
</tbody>
</table>

The World Health Organisation (WHO) defines the threshold for cost-effectiveness as being less than 3X the gross domestic product (GDP) per head.

- **Cost effective**
  - Interventions that gain each year of healthy life (e.g. disability adjusted life year [DALY] averted) at a cost less than GDP per head (i.e. less than US$ 30,000 per head) are defined as very cost effective.
  - Interventions averting each DALY at a cost between one and three times GDP per head (US$ 30,000 – US$ 90,000) are defined as cost-effective.

- **Not cost effective**
  - The remainder (>US$90,000 per QALY) is defined as not cost-effective.

78% of the judges understand that social justice justify decisions that violate contracts.
83.7% of judges with less than 40 years old understand that they can judged against the law in favor of social justice

References: IPEA – Institute of Political and Economical Analysis

Treating the symptoms
Jul 15th 2004   -The Economist

SINCE governments first started to get worried about rising health costs in the 1970s and 1980s, they have tried time and again to check expenditure. The methods have varied from one country to another, and have developed from the crude to the more sophisticated. But all the attempts have one thing in common: any initial success has eventually been reversed by the pressure for higher spending in systems that remain wasteful.
And the future?

Publicada no DOU do dia 29/abril/2011, que altera a Lei no 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do SUS.

"The greatest danger in times of turbulence is not the turbulence; it is to act with yesterday’s logic.” 

Peter Drucker