

INSTITUTIONALIZING HTA IN BRAZIL: A COMPARATIVE ANALYSIS WITH THE UK, CANADA AND AUSTRALIA

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OBJECTIVES AND METHODS

Objectives: The aim of this study was to compare the use of HTA for decision-making regarding technology reimbursement in Brazil with its use in these three countries.

Methods : Scientific literature on HTA was reviewed on the Medline, Lilacs and Scielo databases, on the sites of HTA agencies from the four countries, and on the INAHTA and HTAi sites.

AUSTRALIA

- Departments of the MoH that develop or commission the HTA.
- Since 1993, economic evaluations are prerequisites for the incorporation of drugs into the public sector.
- Drugs: PBAC (Pharmaceutical Benefit Advisory Committee) → PBPA (Pharmaceutical Benefit Pricing Authority) → Health Minister → if > AU\$ 5 million (Finance Minister) → if > AU\$ 10 million (Cabinet Council) → PBS (Pharmaceutical Benefits Scheme).
- Since 1998, devices are evaluated regarding their cost-effectiveness by MSAC (Medicare Services Advisory Committee).
- ASERNIP-S evaluates surgical techniques and advises the MSAC.

CANADA

- HTA developed by agencies from provinces.
- 1 national agency and 8 in the provinces, diverse forms of funding.
- The 1st body created was in Quebec in 1988 – AETMIS
- Coordination and promotion conducted by a national agency, the Canadian Agency for Drugs and Technologies in Health (CADTH), founded in 1989.
- CADTH is composed of three areas (HTA, CDR and COMPUS) and it provides impartial information to decision-makers.
- PMPRB (Patented Medicine Prices Review Board), created in 1987, regulates the prices of patented drugs, based on treatment costs or on the price average from 7 countries.

THE UNITED KINGDOM

- In 1999, NICE was created.
- 3 Centres: Public Health Excellence; Health Technology Evaluation; and Clinical Practice.
- NICE recommendations are emitted in the form of mandatory guidances for the NHS (National Health Service).
- NICE: ~460 employees, ~3,000 experts, 2 out of 3 assessments are for drugs, £60 million per year.
- There is still no assessment regarding the exclusion of technologies that are not cost-effective.
- A centralized decision-making process sometimes it does not reflect the reality in the provinces.
- PPRS of the MoH negotiates drug prices.

BRAZIL

- **ANVISA:** In 2003, altered the law regarding the registration of medical devices and drugs, making it mandatory to present economic information in order to allow for registration; and also in 2003, the creation of the Office of the Economic Evaluation of New Technologies (GERAE);
- **CMED:** In 2000, an interministerial organ was created for the economic regulation of drugs, the Board for the Regulation of the Drug Market (CMED), which, since 2004, is using economic evaluation concepts to establish new drug prices (Cat I – the lowest price in nine countries and Cat II – treatment cost).

BRAZIL

- **SCTIE/MINISTRY OF HEALTH:**
- **DECIT (Department of Science and Technology):**
 - HTA area instituted in 2005.
 - Activities: develop methodological guides; train health managers and professionals; coordinate a collaborative network; create and implement the National Policy for HTA; international cooperation; promote research; do internally rapid reviews.
 - Team: 20 professionals
 - US\$ 12 million and 490 HTA studies.

BRAZIL

- **CITEC** (Comission for the Incorporation of Technology at the Ministry of Health):
 - Instituted in 2006;
 - Makes recommendations to the Health Minister;
 - Focuses on incorporating new drugs, despite, having the mission to analyze the entire life cycle of technologies.
 - New Federal Law: Creating CNIT (National Comission for the Incorporation of Tecnhnology in the Health System) – effects in november 2011.

COMPARATIVE ANALYSIS

- Regarding the formal structure, Canada and the United Kingdom created independent national institutions, while Australia and Brazil adopted a model of creating areas within the Ministry of Health itself. In spite of this difference, HTA activities and drug price definition, in all countries, are conducted by different areas/organs.
- In Australia, Canada and the United Kingdom, the incorporation of drugs in the health systems follow similar steps: health technology assessment (scientific and economic) and price of reimbursement definition.

COMPARATIVE ANALYSIS

- In Brazil, after license approval, the economic area of the National Health Surveillance Agency (ANVISA) produces economic evaluations of drugs and then the Board for the Regulation of the Drug Market (CMED) defines their prices for the market and allows commercialization.
- After that, technologies with a request for incorporation into the public health system pass through another stage of evaluation (HTA) conducted by the Department of Science and Technology (DECIT) of the MoH, which sends its recommendations to the Commission for Health Technology Incorporation of the MoH (CITEC) regarding the incorporation of the drug into the public sector.

COMPARATIVE ANALYSIS

- In Australia, the United Kingdom and Brazil, HTA and the incorporation of new technologies into the public health system are processes that are directly linked to and promoted by the central government, differing from Canada, where HTA agencies perform the function of advising the health authorities.
- For medical devices, none of the four countries has institutions that are dedicated to price regulation.

CONCLUSION

In Brazil, an overlapping of governmental responsibilities and activities in health technology assessment is apparent and indicates the need to reform the current institutional model by creating an independent HTA institute that would be able to concentrate actions and human resources, aiming to optimize financial resources and capacity building in the HTA field.



THANK YOU!
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