# Political, economic and cultural factors influencing HTA: Comparison between South Africa and other regions

Jani Mueller

CMeRC

# Outline

- Factors influencing policy-making?/HTA
- Examples from other countries

# Introduction

Pharmacometrics and pharmacoeconomic modelling →

bridge the gap between efficacy (Phase III) data and effectiveness outcomes.

Pharmacoeconomic cost-effectiveness & HTA →

decision making during medicines development, licencing, market access, pricing and reimbursement.

→ pharmacoeconomics has become an integral part of decision making in healthcare.

# Criteria for decision-making

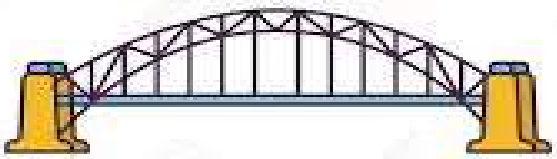
1. General relevance (disease severity, target population, burden of disease
2. Safety
3. Efficacy
4. Effectiveness
5. Economic and financial impact
6. Impact on Equity
7. Social/Ethical impact (social and cultural context)
8. Organizational impact (system capacity)

# EUnetHTA Handbook

- Only producing good quality information and analysis does not imply the HTA is successful"
- "Different actions and strategies should be considered and carried out as an integrated plan"

*SCIENCE*

Patient wishes
Industry claims
Provider preferences
Evidence on safety, effectiveness, etc



*DECISION*

Macro: marketing, reimbursement,
Meso: adoption/purchase
Micro: clinical practice

# Factors influencing policy-making

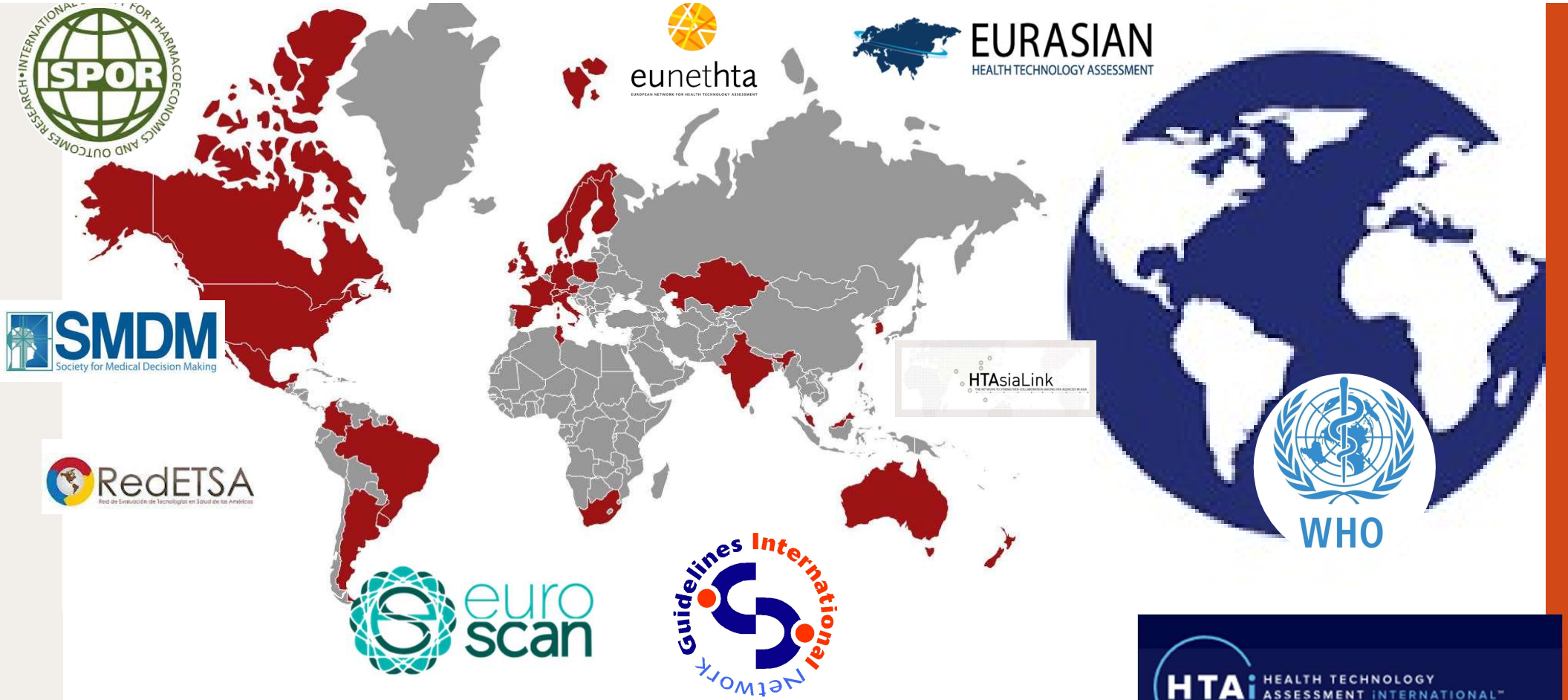

Source: : 2005. adapted. Davies. Evidence-base policy at the cabinet office

# Factors influencing HTA set-up

- Orientation of national and regional policies
- Decision-making traditions concerning scientific and technological innovation
- Financial situation and priorities
- Health system factors
- Attitudes of policy makers concerning evidence-based working
- Political and societal acceptance of ethical standards in health care
- Education level of general public
- Culture of the country and sub-groups favorable to change
- Education & Training capacities

# Challenges towards HTA in many countries

- Political instability
- Corruption
- Lack of institutional and human capacity
- Fragmented healthcare system
- Poor communication between researchers and policy-makers
- Lack of knowledge of and expertise in HTA
- Lack of commitment of policy makers
- No tradition of use of evidence in policy making (ideology)
- Lack of governance in HTA
- Data quality, availability and sharing
- Finances




# HTA: international

# Dimensions of HTA programs/agencies

| Structure | Processes | Results | Product impact | Final outcomes |
|---|---|---|---|---|
| • Mandate – Target-population | Process management: | Screening on the horizon | Acceptance of the agency's products: | Impact on the health status |
| • Principles/Values | • HR management | HTA products (complete): | • Awareness | Impact on the healthcare system: |
| • Governance | • Financial management | • Description | • Attitude | • Overall |
| • Contract relationship | • Project management | • Quality | • Satisfaction | • Economic/Costs system |
| • Colaborative relationships | • Strategy/Planning | • Cost | Use of HTA products: | • Equitability |
| • Final resources | • Evaluation and/or research | • Opportunity | Symbolic | • Sustainability |
| • Human resources/ personnel | • Comunications | • Relevance | • Conceptual – change in awareness, knowledge, attitude in relation to technology | |
| • Comitttee/Structures/ Functions | HTA processes: | Recommendations/ Appraisals/Others: | • Instrumental – changes in policy or practice | |
| • Organizational structure | • HTA priority-setting and selection | • Research transference or capacity development events/products | Impact on technology: | |
| • Data/Information systems | • Formulation of HTA issues | | • Innovation or adaptation | |
| • Target-population | • Comissioning and follow-up | | • Research and development | |
| • Sources of requests | • Data collection and analysis | | • Obsolescence/ Replacement | |
| | • Decisions/Recommendations | | | |
| | • Report preparation and revision | | | |
| | • Research disclosure/transfer | | | |
| | • Appeals | | | |

Source: 2003 Hailey. Elements of Effectiveness of HTA programs

# Profile of a few HTA organizations

| HTA organization | Technology assessed | Begin operations | Type of organization | Funding | Organization in-charge of appraisal | Role | Organization in-charge of overall decision |
|---|---|---|---|---|---|---|---|
| PBAC | Medications | 1953 | Gover | Government | PBAC | Consultative | MoH |
| TLV | Medications | 1987 | Governmental | Government | TLV | Regulatory | TLV |
| CADTH | Medications/devices/procedures | 1989 | Quasigovernmental | Government | CADTH | Consultative | MoH |
| AHRQ | Medications/devices/procedures | 2003 | Governmental | Government | CMS | Consultative | CMS |
| IQWIG | Medications/devices/procedures | 2004 | Private | Government & private sector | G-BA | Regulatory | G-BA |
| HAS | Medical and surgical procedures/Medication/devices/biologic tests | 2005 | Independent public body | Government & private sector | HAS | Consultative | MoH |
| CENETEC | Medications/devices/procedures | 2004 | Governmental | | CENETEC | Consultative | MoH |
| CONITEC | Medications/healthcare products/procedures | 2011 | Governmental | Government | CONITEC | Consultative | MoH |
| IETS | Medication/devices/diagnostic tests/procedures | 2012 | Public-private | Government & private sector | IETS | Consultative | MoH; private sector |
| CMeRC | Medications/devices/interventions/procedures | 2005 | Pubic-academic | Government & private | CMeRC | Consultative | MoH |

# Priority-setting criteria for selection of technologies to be assessed

| Criteria | SBU | CADTH | AHRQ | IQWIG* | HAS | CONITEC | CMeRC |
|---|---|---|---|---|---|---|---|
| Clinical impact | x | x | x | | x | | x |
| Economic impact | x | x | x | | x | | |
| Burden of disease | x | x | x | | x | x | x |
| Budget impact | x | x | x | | | | x |
| Expected level of interest | | | x | | | x | x |
| Existing evidence | | x | x | | | x | |
| Ethical, legal or social implications | x | | | | | | |
| Technology of controversial nature | x | | x | | | | |
| Existing alternatives | | x | | x | | | |
| High likelihood that results will affect decision making | | | x | | | | |

PBAC: does not define medications to be assessed. Reviews submission of new medication
IQWIG: considers nature and severity of the disease, magnitude of therapeutic benefits, profile of side effects, convenience of use.
HAS: impact in organizing healthcare, action planned by applicant of assessment
CENETEC, IETS – could not be identified

# Decentralized systems

# HTA in Canada

National processes:

- CADTH
  - Non-oncology health technologies for all public (CDR)
  - pCODR
  - Oncology health technologies for all public

Provincial processes:

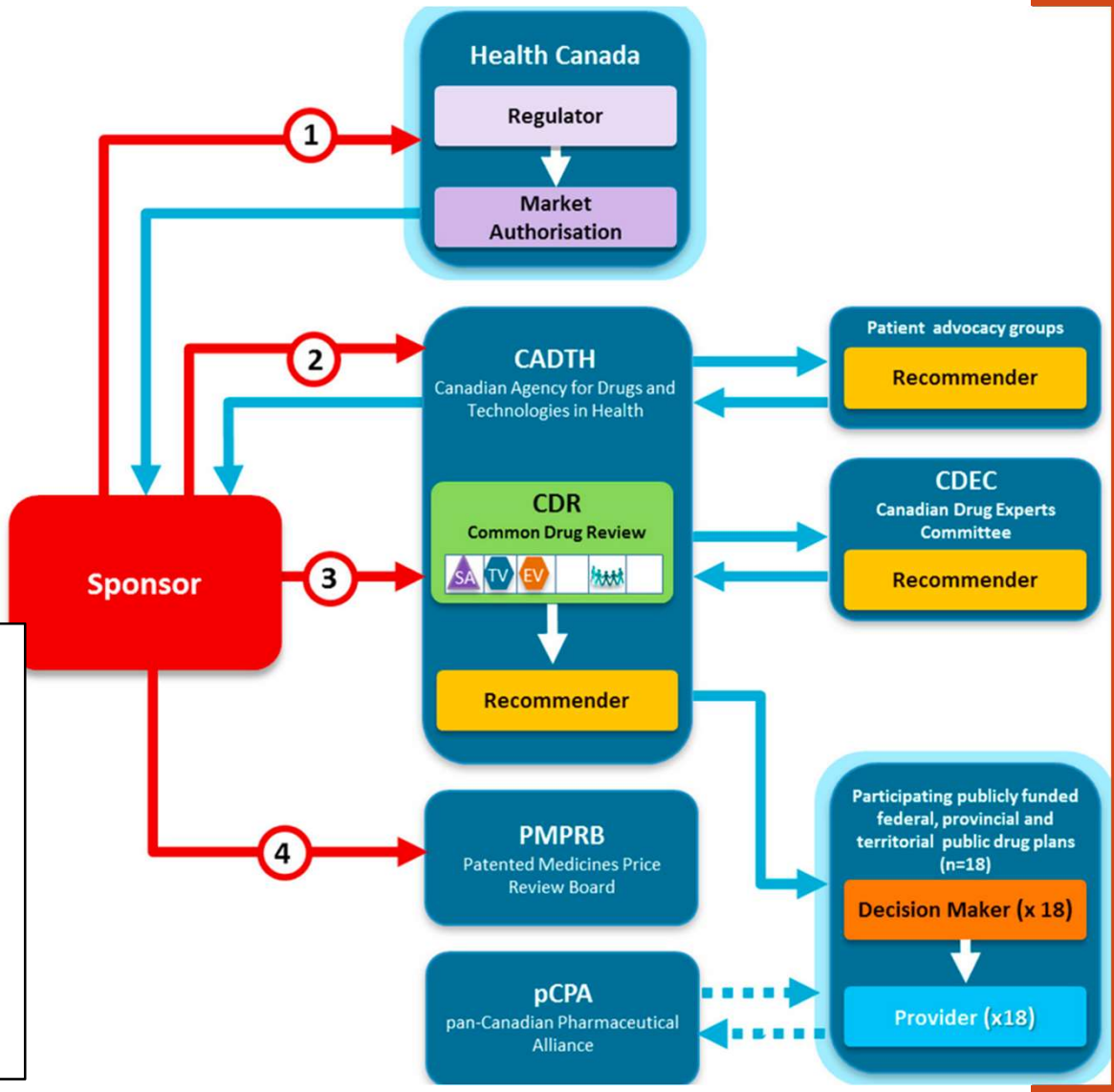
- Quebec – INESSS (30 day feedback)

  All health technologies for Quebec
- Ontario – Ontario Public Drug Programs
- British Columbia – “Your Voice” program

# HTA in Canada

CDEC:
- List/
- List with clinical criteria and/or requirements/
- Do not list/
- Do not list at the price submitted

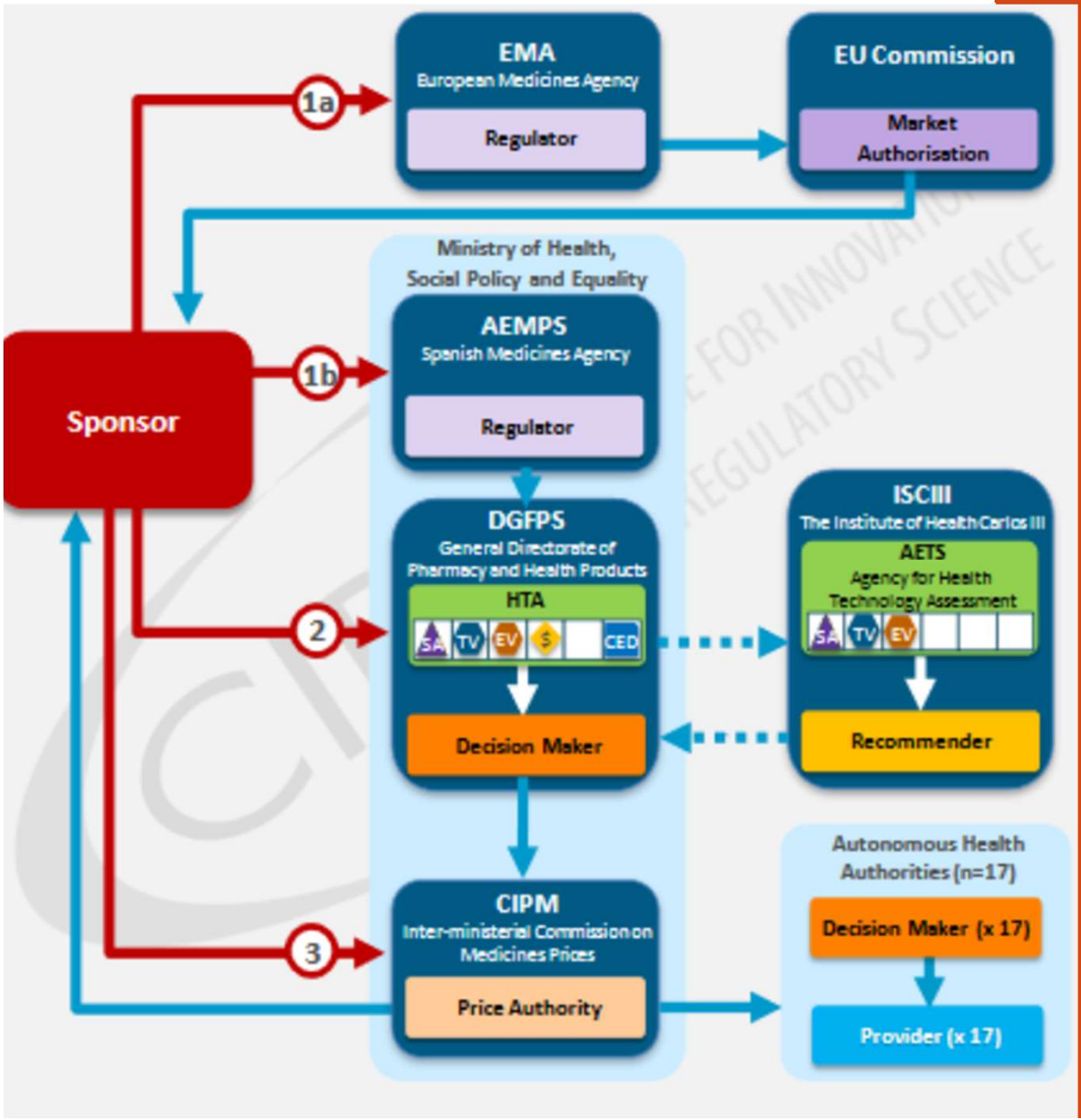
Provincial reviews:
- Some reconsider national review and make further recommendation to provinces (local priorities, practices, budgets)
- Negotiations on price/criteria of drugs
  - Joint negotiations through pCPA (except QC)
  - Individual provincial negotiations



# Spain

DGFPS - > summary dossier

AETS – recommendations not mandatory nor binding
Proposes and develops guidelines related to healthcare.
ISCIII – collaborate with regional authorities
HTA reports -> DGFPS
DGFPS -> initiates procedure for pricing and reimbursement



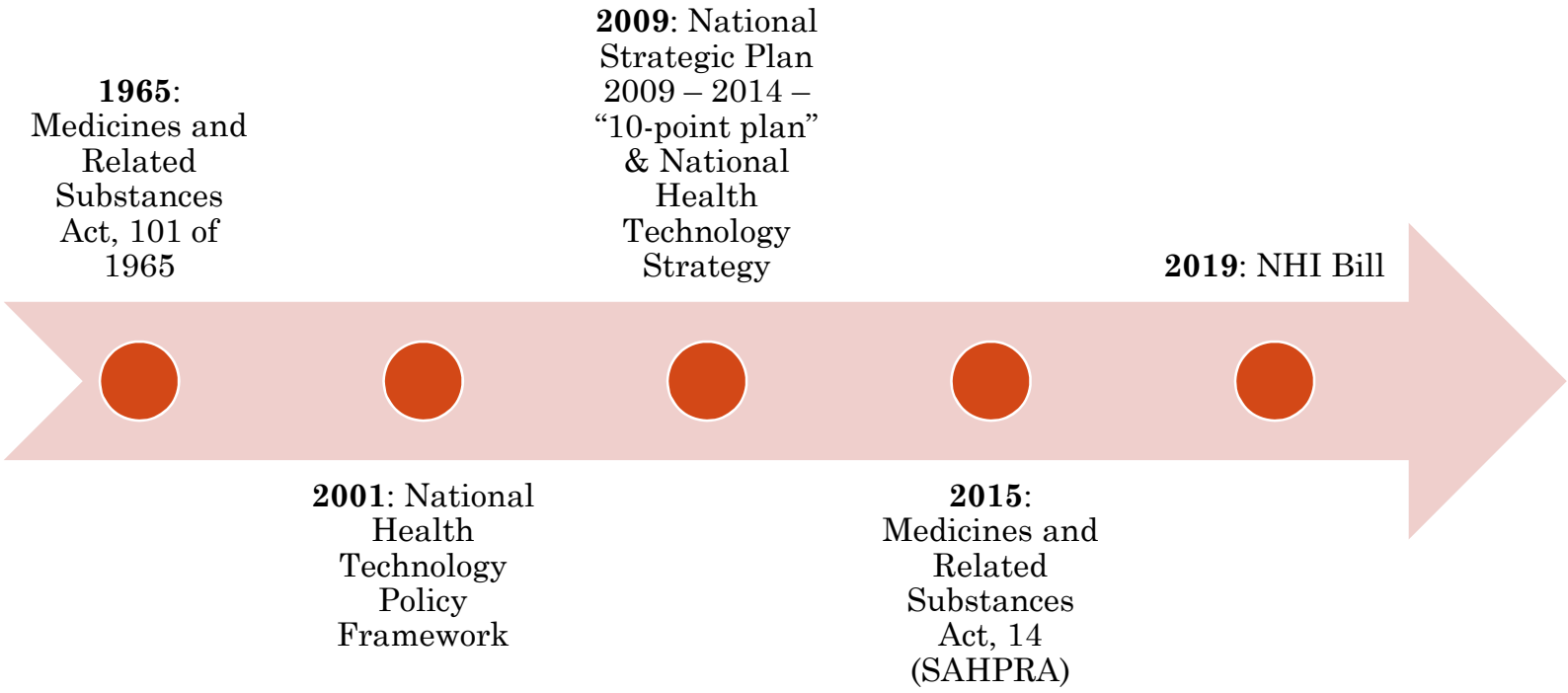
# Considerations in developing HTA

- Advocacy of key individuals – Mexico
- Critical mass of experts – Brazil
- Pressures from outside - World Bank
- Internal pressures - costs, inefficiency, technological pressures, public demands, stakeholder concerns, **national health insurance**
- Organization of the health care system - most efficient with one system and one national agency (but doesn't work all the time)

# To establish a HTA program

- Interest and commitment from government policy makers
- Ability and willingness to commit public funds to HTA
- Support from important stakeholders
- Scientific capability
- Training program
- Consideration of workable options - eg national agency, network, coordinating agency
- A coherent and effective health policy structure - regulation, payment, etc.
- If HTA Agency(ies) then what kind?

# HTA in South Africa



# HTA in South Africa

**NHI Bill**

*" The Ministerial Advisory Committee on Health Technology Assessment for ……. to advise the Minister …… will regularly review the range of health interventions and technology by using the best available evidence on cost -effectiveness, allocative, productive and technical efficiency and Health Technology Assessment."*

# Thank you

**dbmueller7@yahoo.de**