



Application of Health Technology Assessment in Decision-Making

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Agenda

- **Application of HTA and health economics and outcomes research information in reimbursement**
 - An overview of HTA practices in
 - United Kingdom
 - United States of America
 - Canada
- **Key trends**

Increasing HTA World-wide

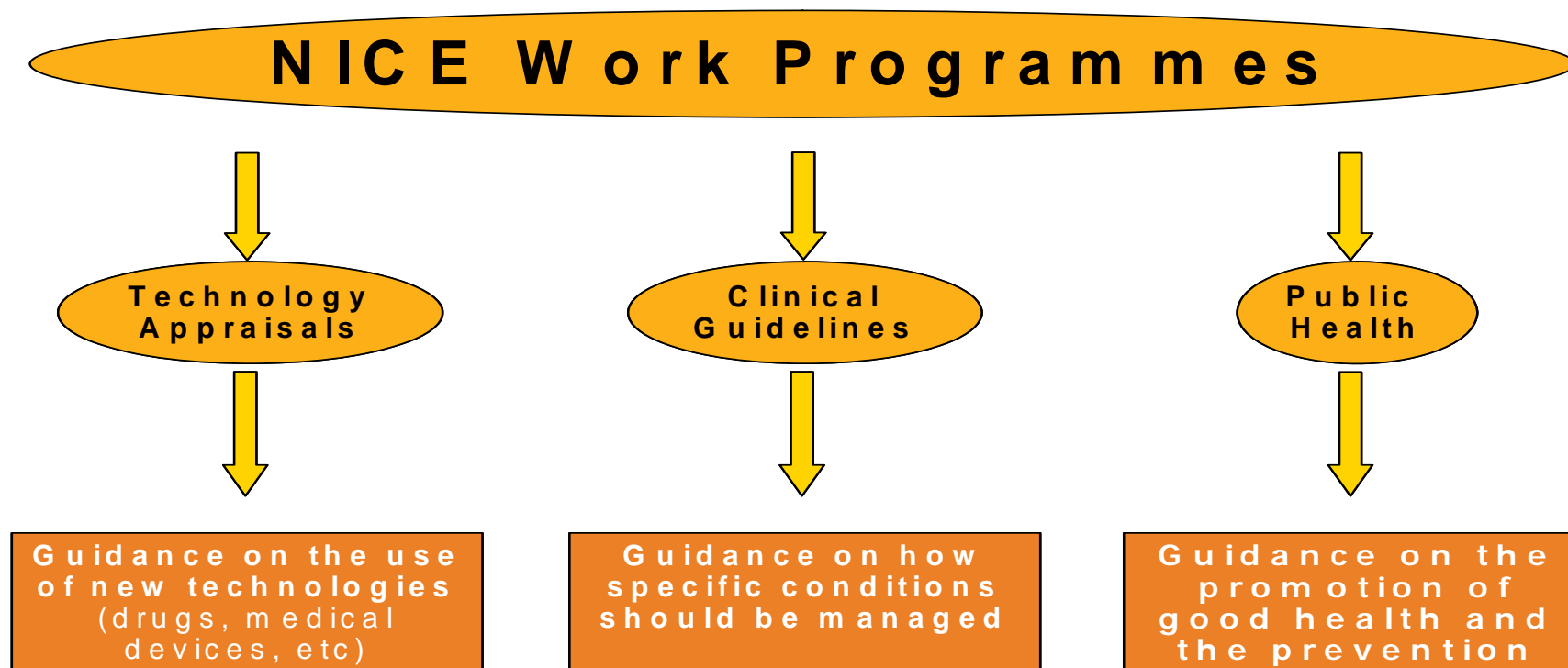
2009 Status

“Established”	“Emerging”	“Not Yet in 2009”
Australia (PBAC, 2002) Canada (CADTH, 2006) England (NICE, 1999) New Zealand (PHRAMAC 1993) Sweden (LFN, 2003) Scotland (SMC, 2002)	France Korea Germany (IQWiG, 2004) Netherlands Spain Taiwan Turkey USA	China Japan Italy Switzerland Russia



National Institute for Health and Clinical Excellence (NICE)

- Established as a Special Health Authority in April 1999
- Covers England & Wales only
- Annual budget in 2006-2007 = £28.7m





NICE Prioritization Criteria

- Population
 - The larger the population, the more important a technology is for evaluation
- Disease severity
 - e.g., takes into account of life expectancy;
- Resource impact
 - Potential resource impact of guidance including cost of implementing guidance, including any additional services, facilities or staff requirements
- Claimed therapeutic benefits
 - Extent to which a new technology claims measurable therapeutic benefit over currently availability NHS treatments

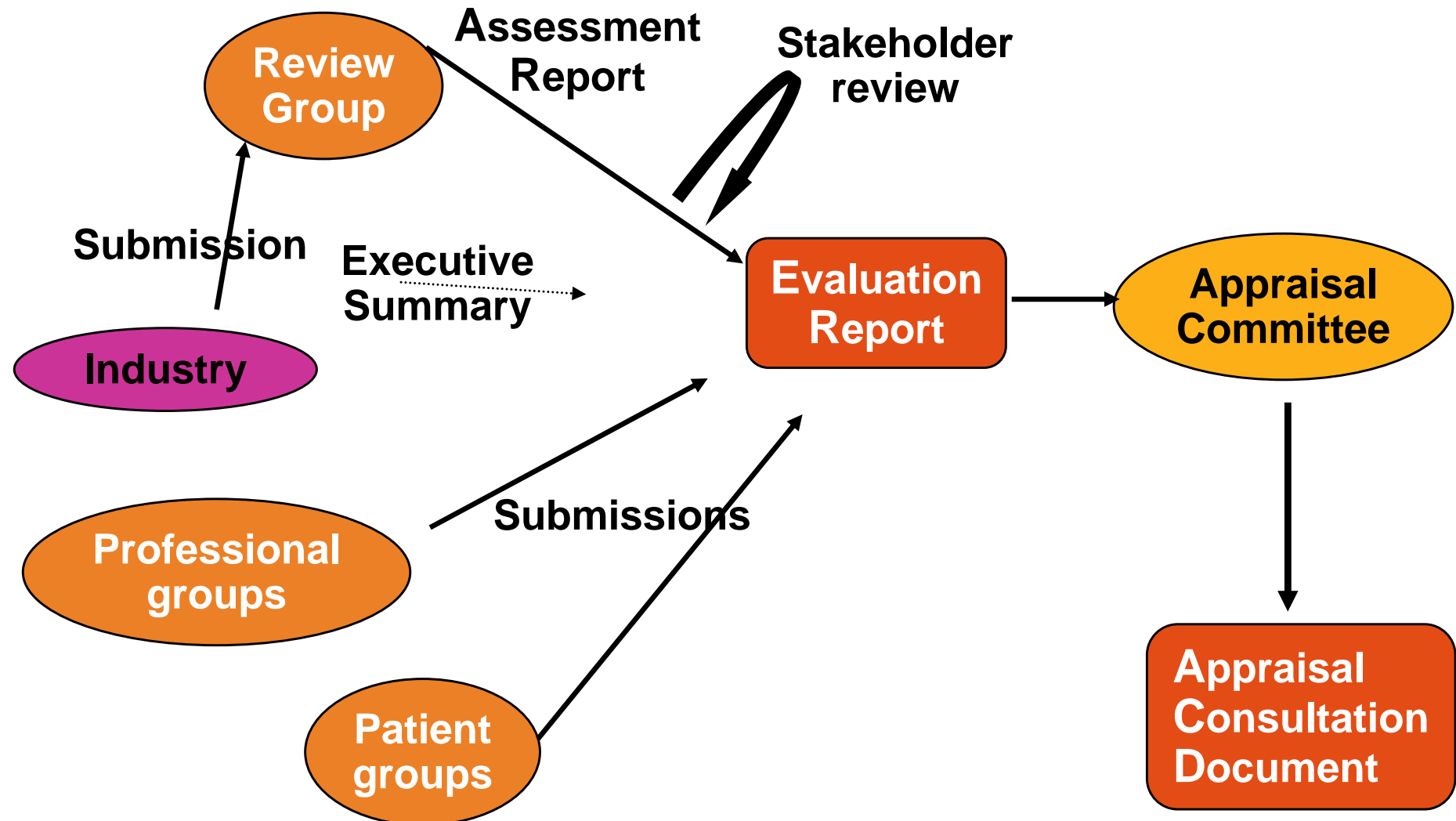


Two Routes for Technology Appraisal

- Multiple technology appraisal (MTA)
 - MTA examines a disease area or a class of drugs and contain either new evidence gathered after the launch of a drug or include a new economic modeling
 - Based on input from a broad range of stakeholders, with emphasis on the Assessment Group
- Single technology appraisal (STA)
 - Developed to provide early guidance for new drugs targeting a single indication, as well as for new indications for drugs already on the market
 - More streamlined process than MTA
 - Greater emphasis on the submission evidence from manufacturers



Overview of NICE Process-Stakeholder Involvement





NICE: Decisions

- Unconditional reimbursement
- Reimbursement conditional on future research
- Reimbursement conditional on particular patient characteristics
- Unconditional refusal to reimburse
- Opportunity for appeal
- Decisions are reviewed in future

NICE Recommendation	Number (total=117)*	%
Yes	27	23%
Yes, with major restrictions	38	32%
Yes, with minor restrictions	30	26%
No	22	19%

*Raftery J, Review of NICE's recommendation, 1999-2005. BMJ 2006; 332:1266-8.



How NICE says it Makes Decisions...

- 6.2.6.10 Below a most plausible ICER of £20,000/QALY, judgements about the acceptability of a technology as an effective use of NHS resources are based primarily on the cost-effectiveness estimate. Above a most plausible ICER of £20,000/QALY, judgements about the acceptability of the technology as an effective use of NHS resources are more likely to make more explicit reference to factors including:
- the degree of uncertainty surrounding the calculation of ICERs
 - the innovative nature of the technology
 - the particular features of the condition and population receiving the technology
 - where appropriate, the wider societal costs and benefits.
- 6.2.6.11 Above an ICER of £30,000/QALY, the case for supporting the technology on these factors has to be increasingly strong. The reasoning for the Committee's decision will be explained, with

From Dr. Mark Sculpher's presentation.
National Institute for Clinical Excellence (NICE). *Guide to the Methods of Technology Appraisal*.
London: NICE, 2004.

Evidence on Impact of NICE Decision on the National Health Services



What's the evidence that NICE guidance has been implemented?
Results from a national evaluation using time series analysis, audit of patients' notes, and interviews

Trevor A Sheldon, Nicky Cullum, Diane Dawson, Annette Lankshear, Karin Lowson, Ian Watt, Peter West, Dianne Wright, John Wright

BMJ VOLUME 329 30 OCTOBER 2004

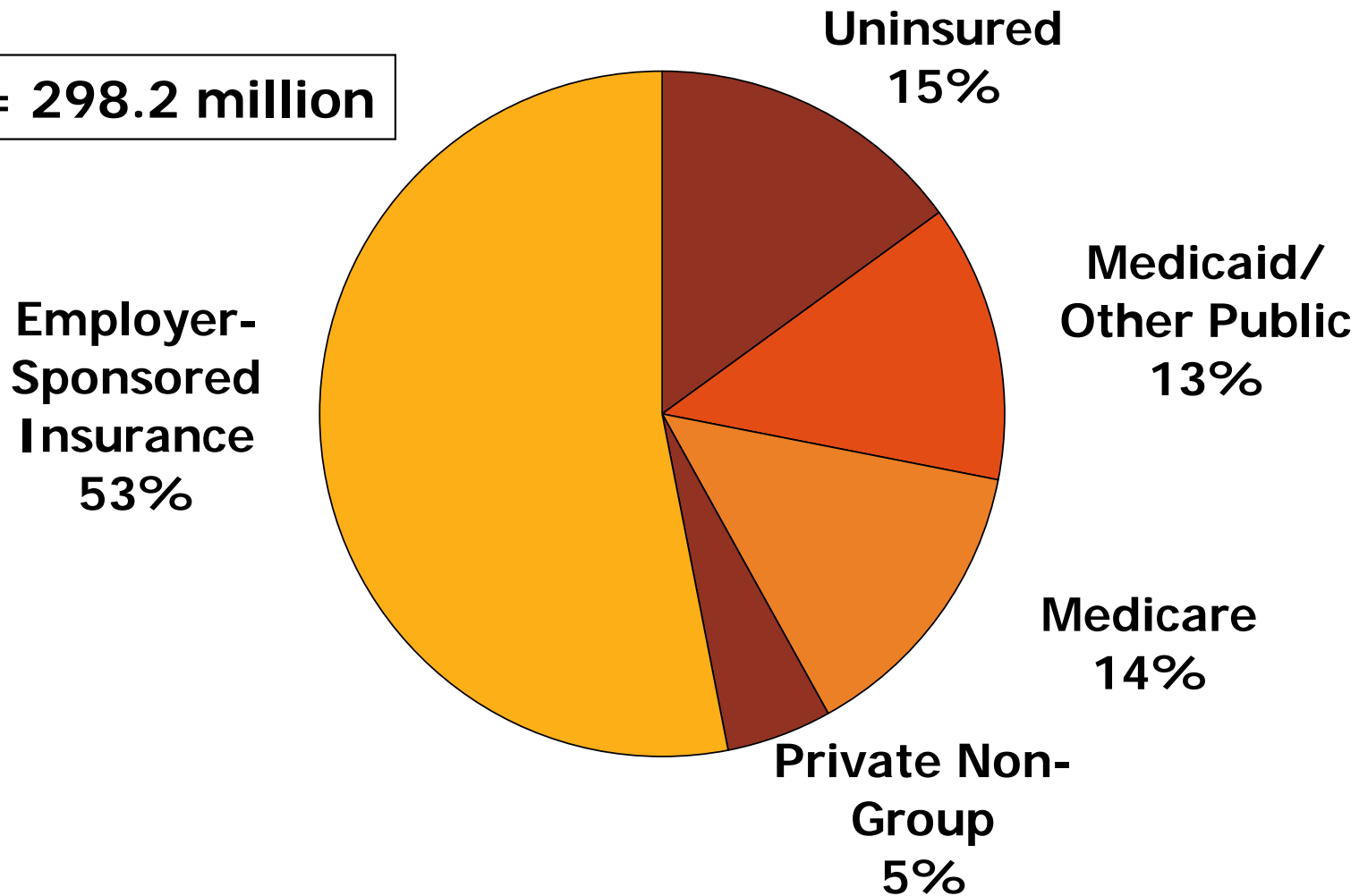
Conclusions Implementation of NICE guidance has been variable. Guidance seems more likely to be adopted when there is strong professional support, a stable and convincing evidence base, and no increased or unfunded costs...

Sheldon TA et al. What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews. BMJ 2004;329:999.



Health Insurance Coverage in the U.S., 2007

Total = 298.2 million



NOTE: Medicare includes those over age 65. Medicaid/Other Public includes Medicaid, SCHIP, other state programs, and military-related coverage. Those enrolled in both Medicare and Medicaid (1.7% of total population) are shown as Medicare beneficiaries.

Commission on Medicaid and the Uninsured/Urban Institute analysis of March 2008 CPS



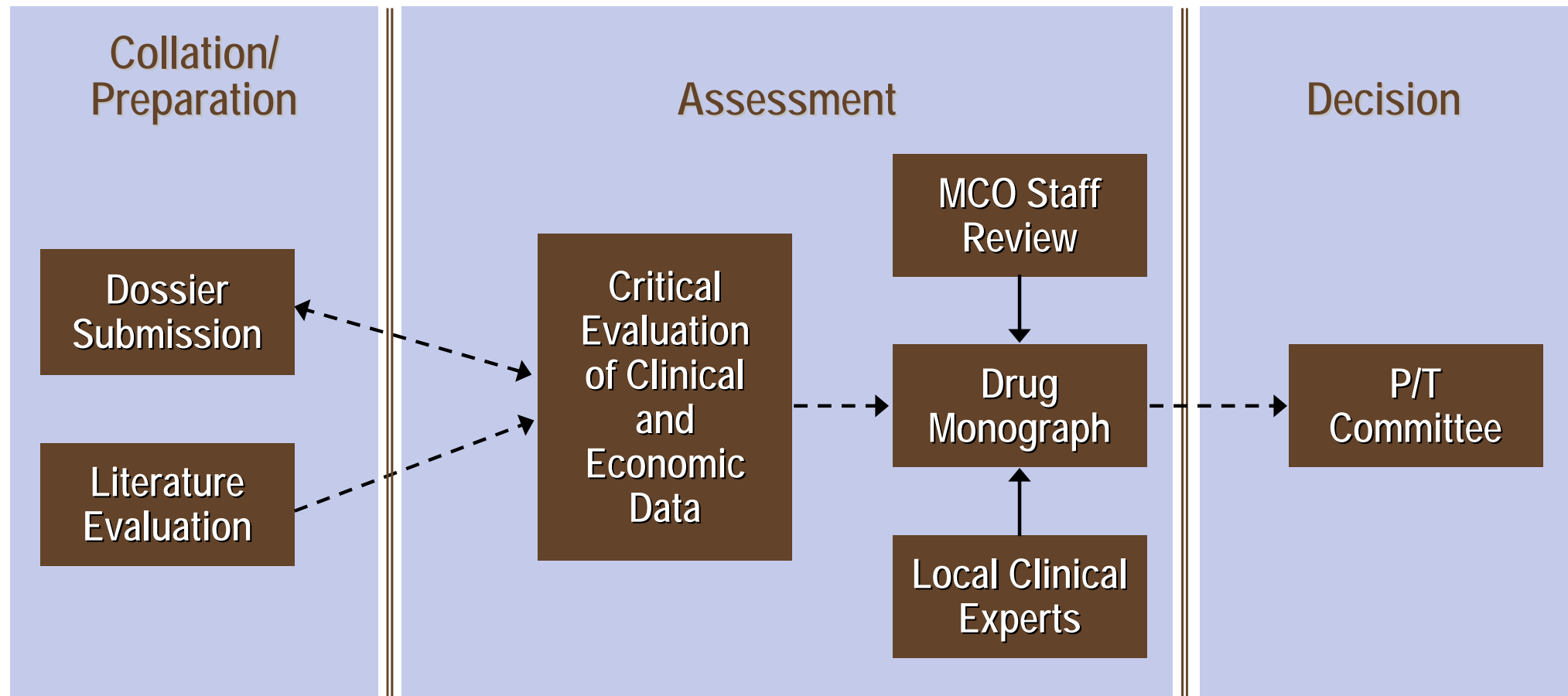
HTA in US: Public Sector

	Objective	Methods	Use
<p>AHRQ Effective Health Care Program</p> <p>Jean Slutsky, Director, Center for Outcomes and Evidence</p>	<ul style="list-style-type: none">Conducts comparative research addressing the needs of Medicare, Medicaid, and SCHIP	<ul style="list-style-type: none">Synthesizes existing evidence to understand relative safety, risks, and effectivenessGenerates new evidence through rapid turnaround research	<ul style="list-style-type: none">Distributed to payers and public; the government cannot:<ul style="list-style-type: none">Develop clinical guidelinesHowever, private organizations may use information for coverage decisions
<p>Drug Effectiveness Review Project</p> <p>Mark Gibson, Deputy Director, Oregon Health and Science Univ.</p>	<ul style="list-style-type: none">Generates evidence for local decision makers, primarily state Medicaid agencies	<ul style="list-style-type: none">Conducts systematic reviews of safety and efficacy between drugs in the same class	<ul style="list-style-type: none">Supports Medicaid preferred drug list (PDL) decisionsIncorporated into <i>Consumer Reports</i> Best Buy Drugs Program



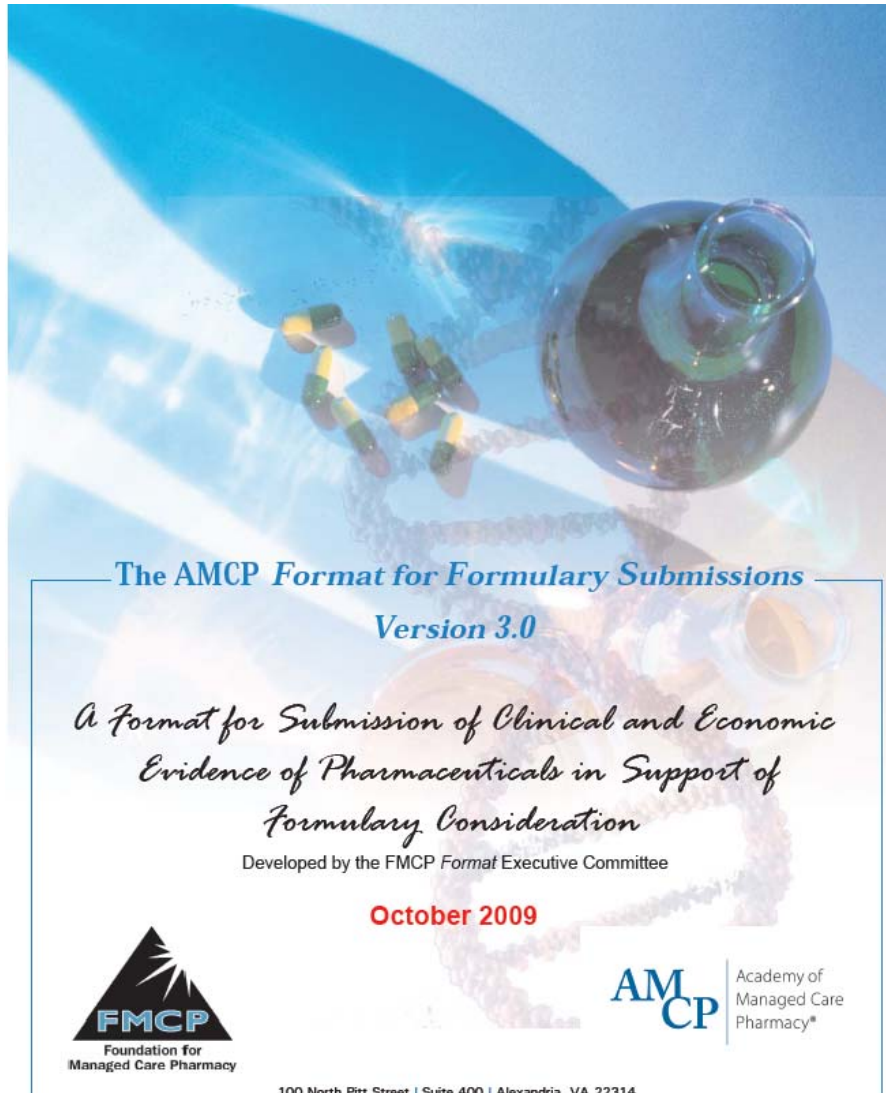
HTA in US: Private Sector

Managed Care Process for Selecting Formulary Drugs



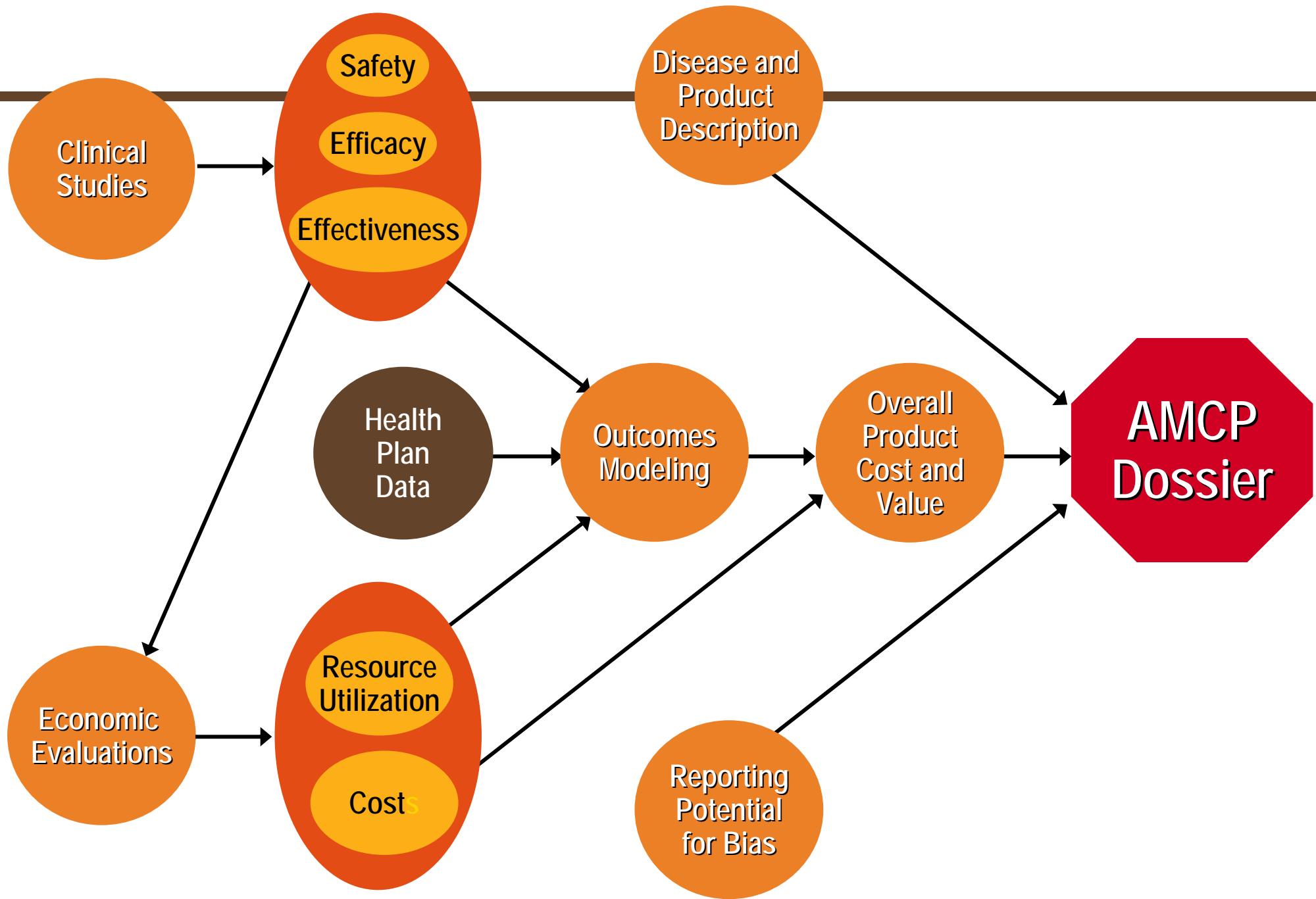


AMCP Format for Formulary Submission



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- **AMCP Endorses a Standard Format for the Submission of Clinical and Economic Information of Pharmaceutical Products – October 2000**
- **FMCP supports the Format**
 - Revisions (v2.1)-April 2005
 - Revisions (v 3.0)-Oct 2009
 - Format Executive Committee
- **Education and Training**
 - FMCP supports programs to educate managed care pharmacists about the Format and use of evidence in formulary decision-making
 - > 45 programs and >1400 attendees



HTA in US: Future



- Under the American Recovery and Reinvestment Act (ARRA)
 - **Channeled through AHRQ/National Institute of Health (NIH)/Health and Human Services (HHS)**
 - **Includes \$1.1 billion in comparative effectiveness research:**
 - NIH: \$400; AHRQ: \$300 million; HHS: \$400 million
 - **Priority to studies that can be conducted quickly**
 - **Establishes Federal Coordinating Council for CER**
- Use of funding
 - **“Conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items and services and procedures...and encourages the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data.”**

Canadian Agency for Drugs and Technologies in Health (CADTH)



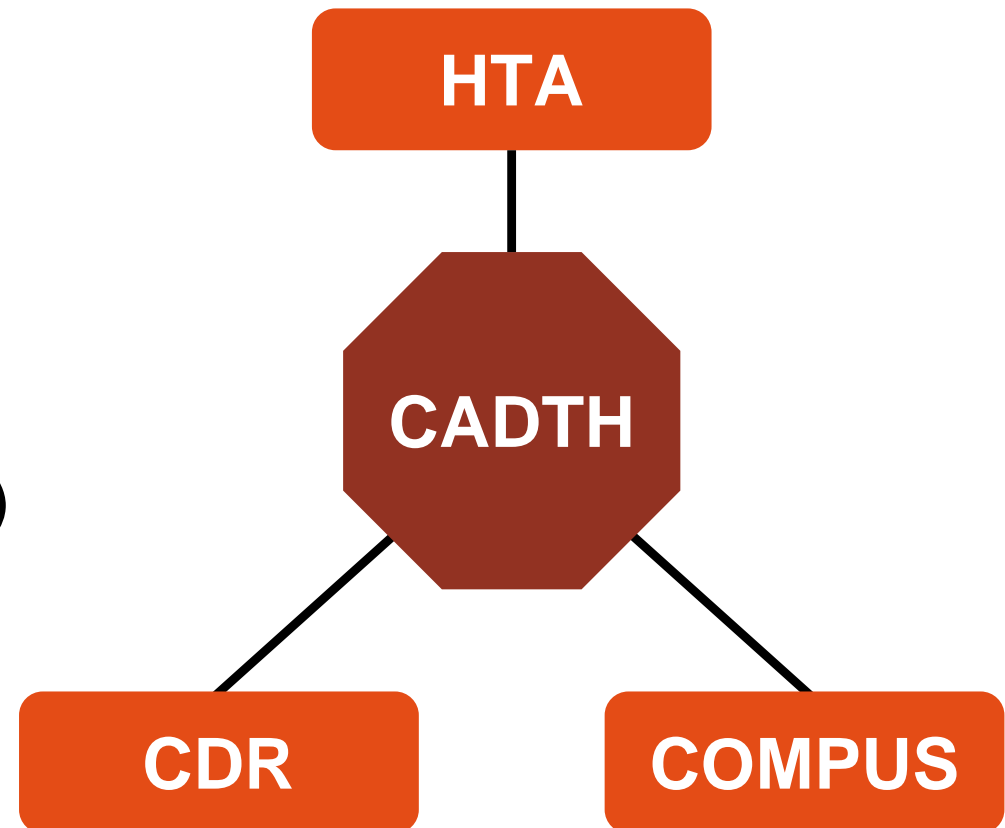
- Independent, incorporated, not-for-profit agency
- Founded in 1989
- Funded by the Canadian federal, provincial, and territorial (F/P/T) governments
 - *“We need a more coordinated approach across the country to ensure that all Canadians are benefiting from the advances being made in health technology”* (Perrin Beatty, Minister of National Health and Welfare, 1989)



CADTH's Objectives

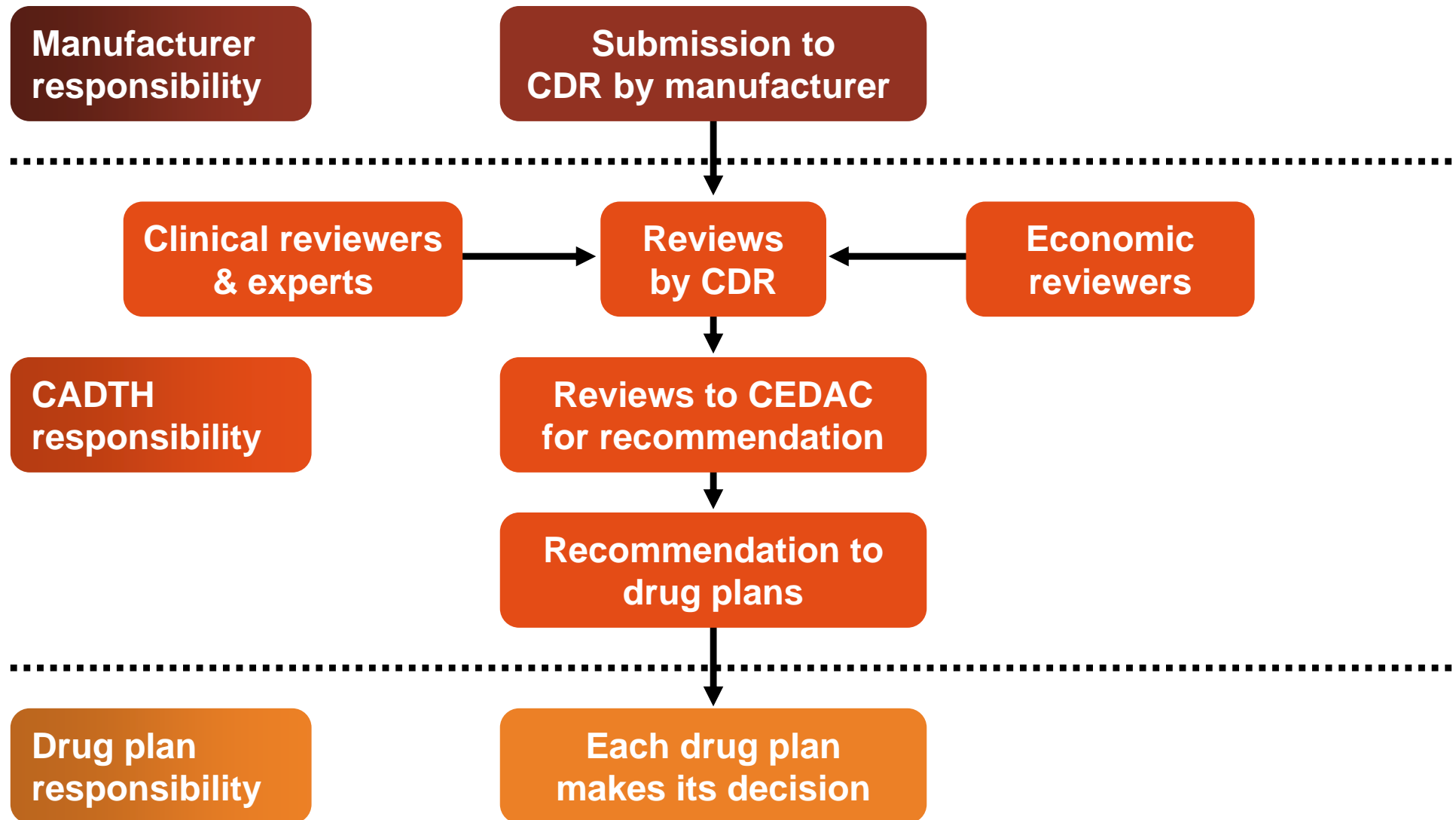
CADTH's three core programs

- HTA (Health Technology Assessment)
- CDR (Common Drug Review)
- COMPUS (Canadian Optimal Medication Prescribing and Utilization Service)





CDR Process



Mike Tierney (CADTH) presentation on May 4, 2008 at the PhRMA-ISPOR Symposium, entitled "Evolving Evidence Requirements from a payer's perspective: Canada"

<http://cadth.ca/index.php/en/home>

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HTA Objectives

- **Overarching objectives of HTA systems**
 - **Inform coverage decisions**
 - **Aid development of clinical practice guidelines**
 - **Support innovation by identifying & rewarding high-value products**
 - **Provide information to providers & patients to allow optimal treatment decisions**

Key Elements of HTA



- Scope
- Criteria
- Timelines

- Unmet medical need
- Relative clinical effectiveness
- Cost effectiveness
- Budget impact

- Decision rules
- Stakeholder involvement
- Appeals and arbitration process

- Communication of findings

Basic Characteristics

- HTA differs across countries, in terms of selection of technologies, responsible institution, scope, evidence requirements and methods
- Main elements
 - Mission: is the primary goal to improve cost-effectiveness of the overall health care system, or is a greater emphasis placed on evaluation of cost-savings
 - Mandate: are evaluations focused on technologies (medicines, devices, etc) or on a broader view that considers provision of care, prioritization of health care resources
 - Influence of access and pricing: are recommendations advisory, mandatory or “nice-to-have”
 - Effectiveness metrics: is the focus on relative clinical effectiveness or are some measures of cost-effectiveness are considered
 - Evidence requirements
 - Governance: independent or intertwined with payers and policy makers

Trends in HTA-1/2

- HTA is expanding in geography and scope with significant differences in expertise
- HTA methodologies and tools are evolving
- Harmonization of methodology and evidence requirements through formalized collaboration
- Evolving and increasing cooperation of HTA agencies with regulatory agencies and industries

Trends in HTA-2/2

- From single product evaluation towards the review of all new and existing products
- From advisory role towards ones of increasing influence
- From straight clinical comparisons towards the use of more comparative metrics
- From sole acceptance of regulatory data towards increasing demands for additional evidence and analysis

Potential Challenges with HTA

- Requirements of HTA process can result in deferred product reimbursement, restricting patient access to treatment needed
- Evidence requirements can be a significant burden, in particular for small companies, discourage pursuit of breakthrough technologies
- Limitations of current methodologies
- Lack of transparency and stakeholder involvement
- Limited talent pool in conducting HTA
- Separate process for evaluating economic evidence, pricing/reimbursement scope