

*Canadian Agency for
Drugs and Technologies
in Health*



*Agence canadienne
des médicaments et des
technologies de la santé*

Common Drug Review

Mike Tierney

May 22, 2008

What is the Common Drug Review?

A single process for:

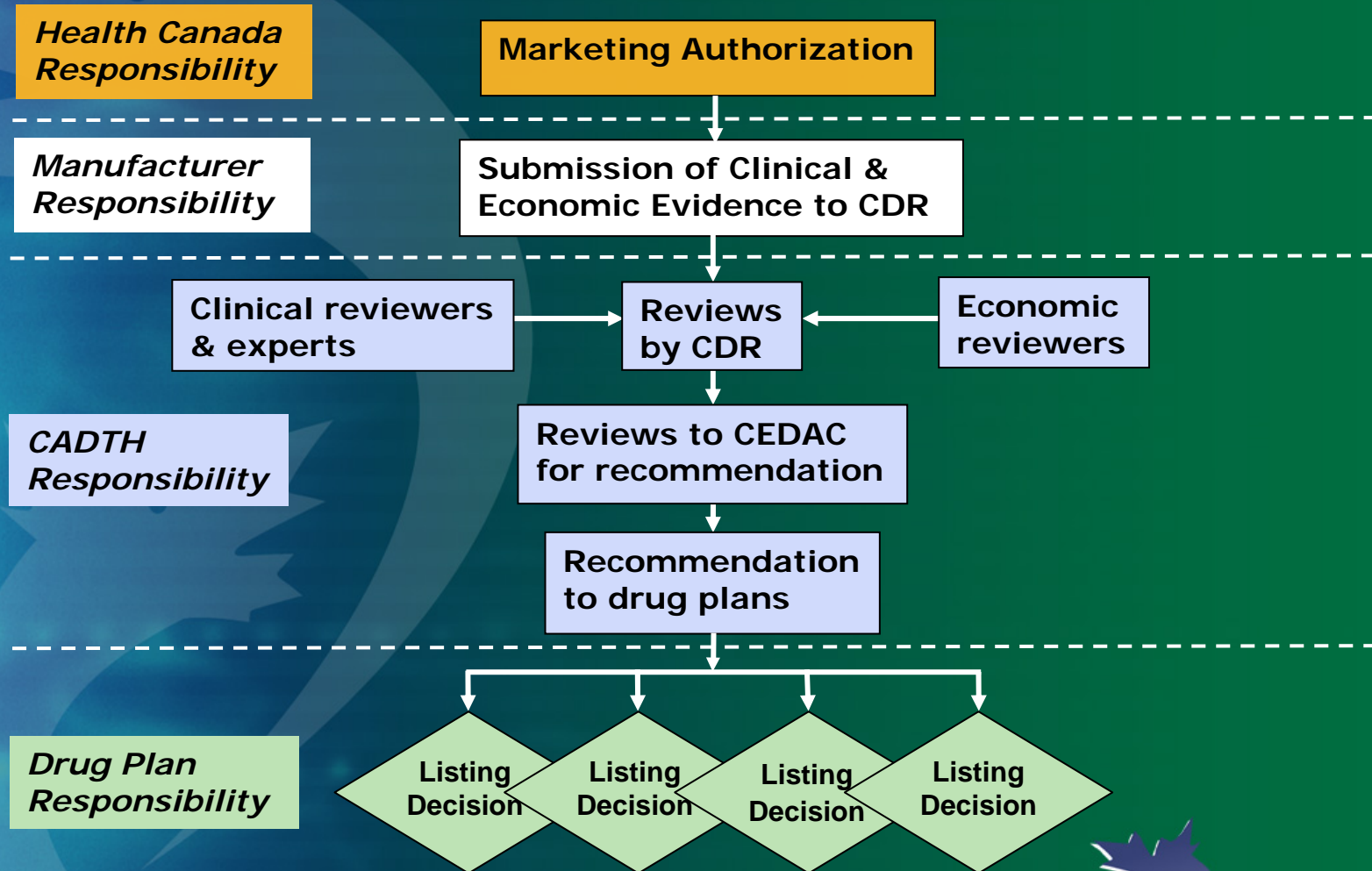
- conducting objective, rigorous reviews of the clinical and economic evidence for drugs, and
- providing formulary listing recommendations to the publicly funded drug plans in Canada (except Quebec)

Formulary decisions are made by the drug plans

- based on CDR recommendation, and plan mandates, priorities, resources



Common Drug Review (CDR) Process



CDR Reviews

Review team

- includes internal and external clinical reviewers, health economists, clinical experts, librarian, review manager

Clinical Review

- systematic review of published and unpublished trials
- also includes:
 - supplemental issues, background on condition

Pharmacoeconomic Review

- critique of manufacturer's economic evaluation



Canadian Expert Drug Advisory Committee (CEDAC)

Thirteen members

- eleven with expertise in drug therapy and evaluation
- two public members
 - full voting members
 - do not represent any particular region, interest group or organization

Follows strict Conflict of Interest Guidelines

Meets monthly to consider reviews, make listing recommendations



CEDAC Recommendations

Based on established criteria:

- safety, efficacy and effectiveness of the drug compared to alternatives
- therapeutic advantages and disadvantages relative to current accepted therapy
- cost-effectiveness relative to current accepted therapy

Detailed reasons for recommendations published



Current CDR Initiatives

Initiatives to Increase Transparency

Expansion to review of new indications

Meaningful public involvement

Health Canada Collaboration

- Pre-NOC review project
- Progressive licensing framework

Opportunities for international collaboration

Canadian Agency for
Drugs and Technologies
in Health



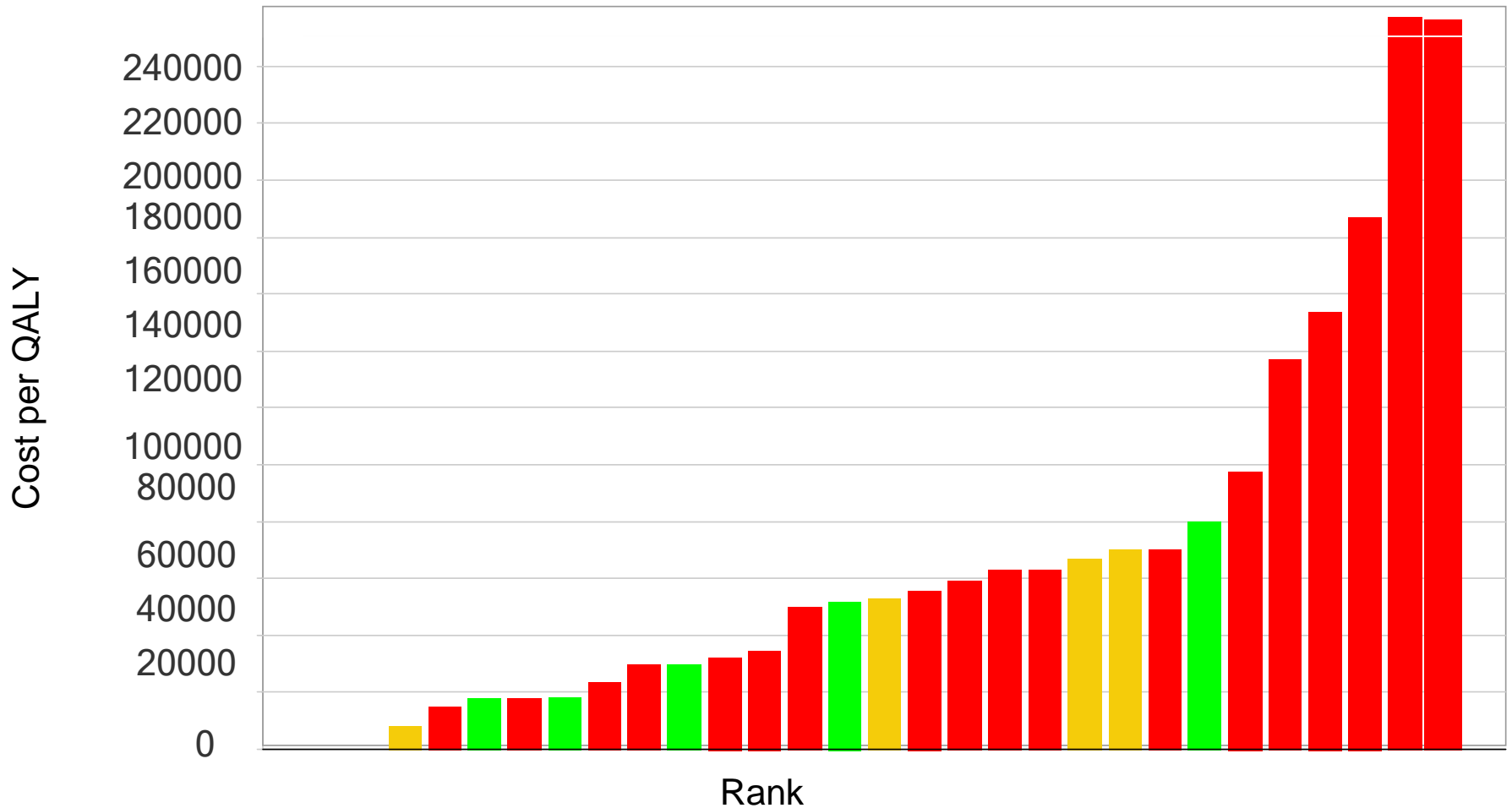
Agence canadienne
des médicaments et des
technologies de la santé

CDR Activity to May 15, 2008

Number of submissions	137
Number of priority reviews requested/granted	32/12
Number of final recommendations issued	101
Number of recommendations to "list"	50
Number of recommendations to "not list"	51



CDR submissions ranked cost per QALY (Manufacturer ICER)

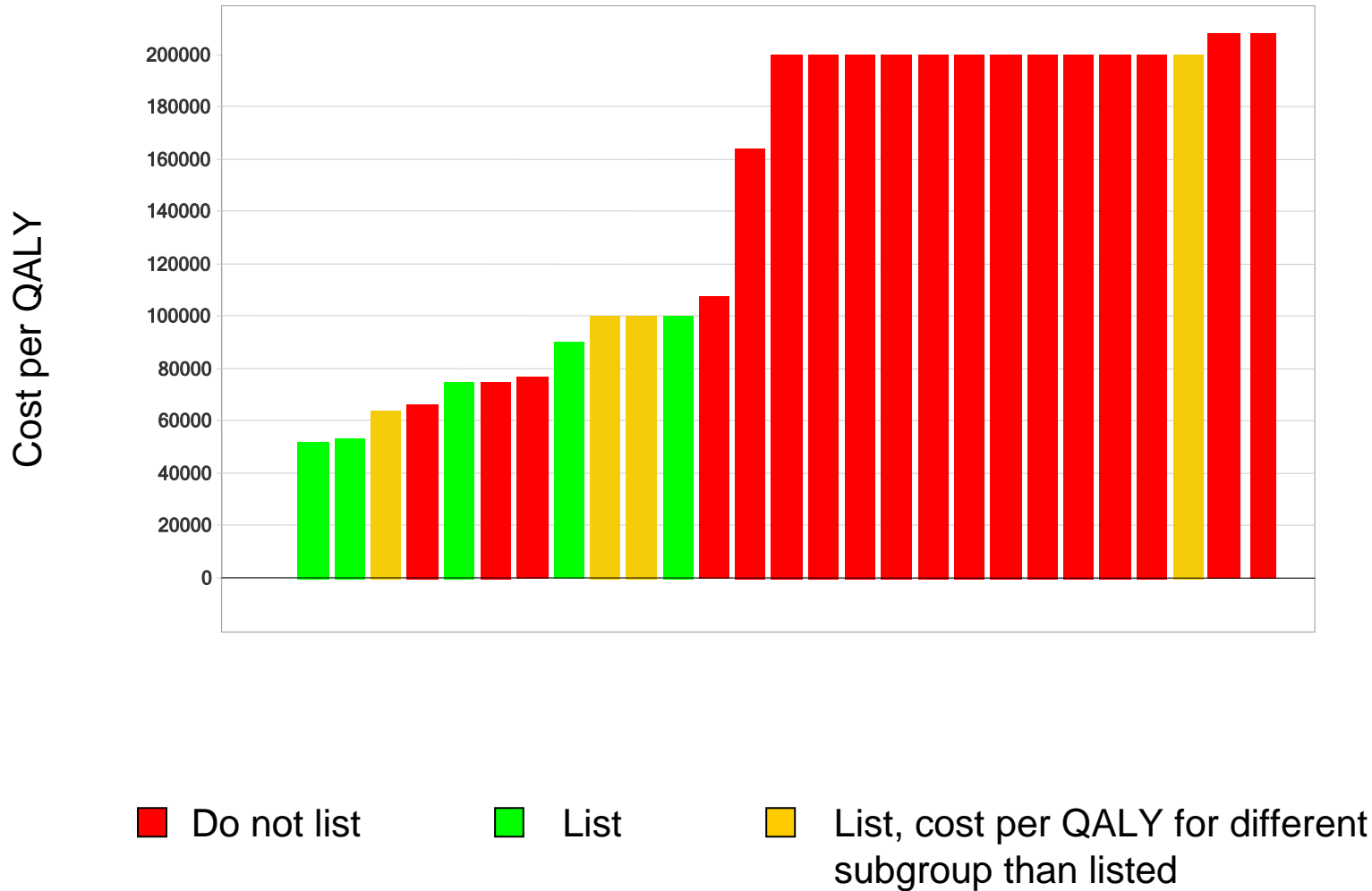


■ Do not list

■ List

■ List, cost per QALY for different subgroup than listed

CDR Submissions Ranked Cost per QALY (CEDAC best guess)



Evidence Requirements

- **Clinical trials with clinically meaningful outcomes**
- **Validation of surrogate markers**
- **Stronger link between clinical trials and economic evaluations**
- **Evaluation framework that accommodates evolving evidence**

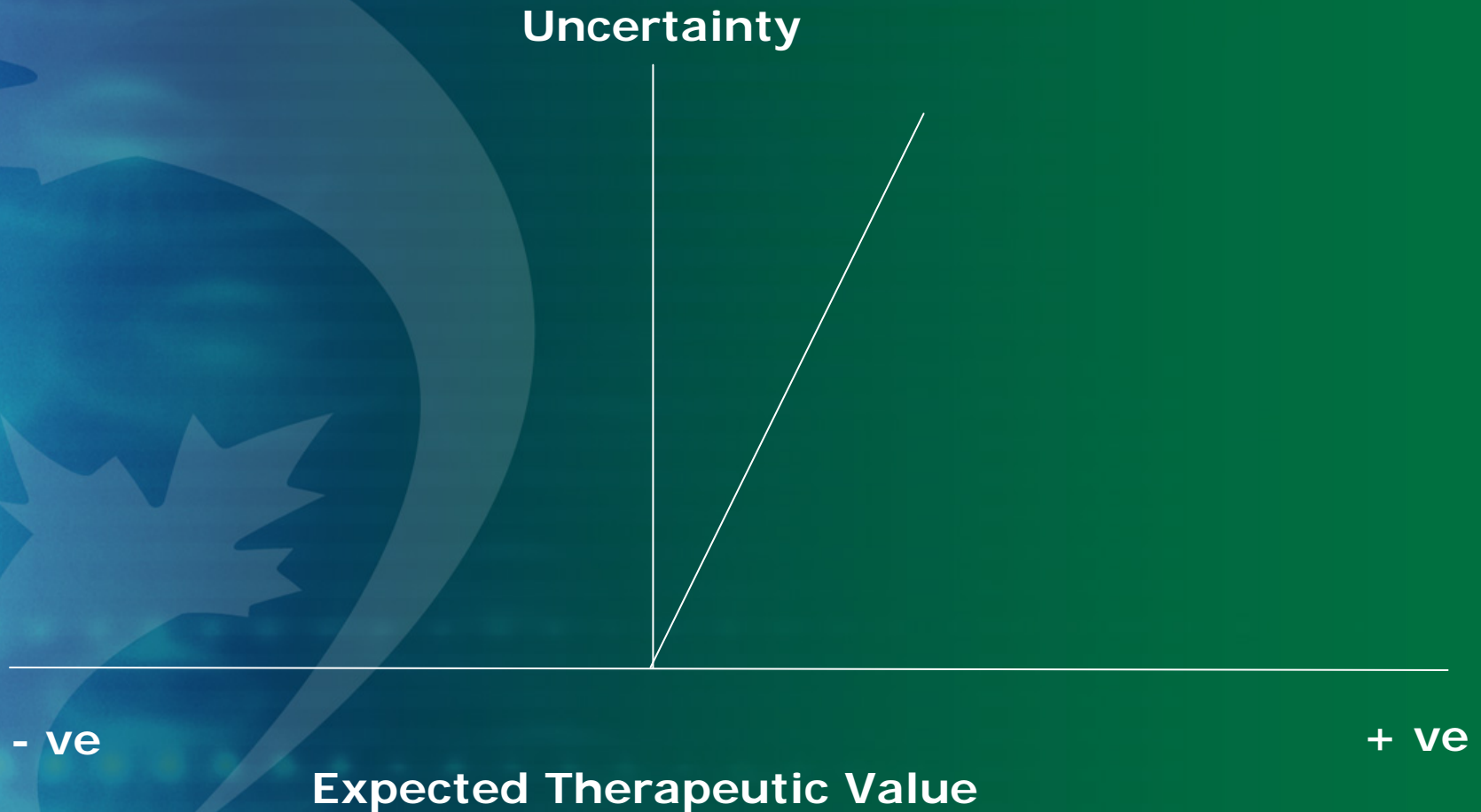


Coverage with Evidence Development

- CED refers to coverage of a healthcare technology while further evidence is generated to address uncertainty
- Limited experience with application to pharmaceuticals to date
- Potential advantages and disadvantages for decision makers, manufacturers and patients
- When and how to apply CED remains debatable



Potential Application of CED



Int J Tech Assess Health Care 2007;23:425-35.

Canadian Agency for
Drugs and Technologies
in Health



Agence canadienne
des médicaments et des
technologies de la santé

CED Checklist

- Does the drug offer a clinically important advance for a serious condition, but with important uncertainty?
- Will collection of additional information in a real world setting address the uncertainty?
- What is the best trial design to collect the required information e.g. RCT vs registry?
- Can CED provide the required information within a reasonable timeframe?
- Are the costs of CED worth the potential for better information (value of information analysis)?

Int J Tech Assess Health Care 2007;23:425-35.

Canadian Agency for
Drugs and Technologies
in Health



Agence canadienne
des médicaments et des
technologies de la santé

CEDAC Recommendation on Efalizumab

CEDAC recommends that all patients who meet clinical eligibility criteria be entered into a registry to collect outcome information on:

- Patients that are responders, partial responders and non-responders to efalizumab therapy;
- Patient follow-up must continue for a minimum of 12 weeks after efalizumab is discontinued;
- An annual summary of patient outcomes must be made available to drug plans (and preferably disclosed publicly);
- The oversight for such a registry must have sufficient independence to ensure impartiality.



Questions



Canadian Agency for
Drugs and Technologies
in Health



Agence canadienne
des médicaments et des
technologies de la santé