Changing the Path for Drug Funding Recommendations

Brent Fraser
VP, Pharmaceutical Reviews
November 15, 2016

CADTH

Current State

Flexible licensing pathways
Adaptive licensing

Funding recommendations to public drug plans based on clinical and cost effectiveness and patient input.

Pre-NOC submissions

Funding agreements
- Finance models
- Managed entry agreements
- Coverage w/ evidence development

CADTH

Adaptive Licensing*

- Prospectively planned, flexible approach to regulation of drugs and biologics
- Iterative phases of evidence gathering to reduce uncertainties followed by regulatory evaluation and license adaptation

- Attempts to balance access with need to assess information
- Assumes early approval **and** coverage

* Eichler, H.G. *et al*. Adaptive licensing: taking the next step in the evolution of drug approval. *Clin. Pharmacol. Ther.* ***91:****426-37 (2012)*

Challenges – moving forward

Need for:

- Greater transparency
- Longer-term planning; integration of horizon scanning to coordinate activities
- Coordinated approach to evidence generation – need to ensure the “right” studies are done
- Prioritization

Adaptive Pathways

Helps to address a number of different factors:

- Unmet need – consider other inputs into the decision framework
  - Timeline of diagnosis should not be a driver of unmet need
  - Consider other factors such as burden of illness / loss of health

http://onlinelibrary.wiley.com/enhanced/doi/10.1002/cpt.59

CADTH

Adaptive Pathways

- HTA: moving from a one-off decision to an ongoing process

- Collectively: need to reduce uncertainty through evidence generation plans and specific timelines
  - E.g., post authorization studies for safety and efficacy studies should include evidence generation
  - Use of real world data

- Ability to implement across the health care sector

- Recognition of pharma industry investment

CADTH Evidence Driven.

ACMTS Preuves à l'appui.