

Changing the Path for Drug Funding Recommendations

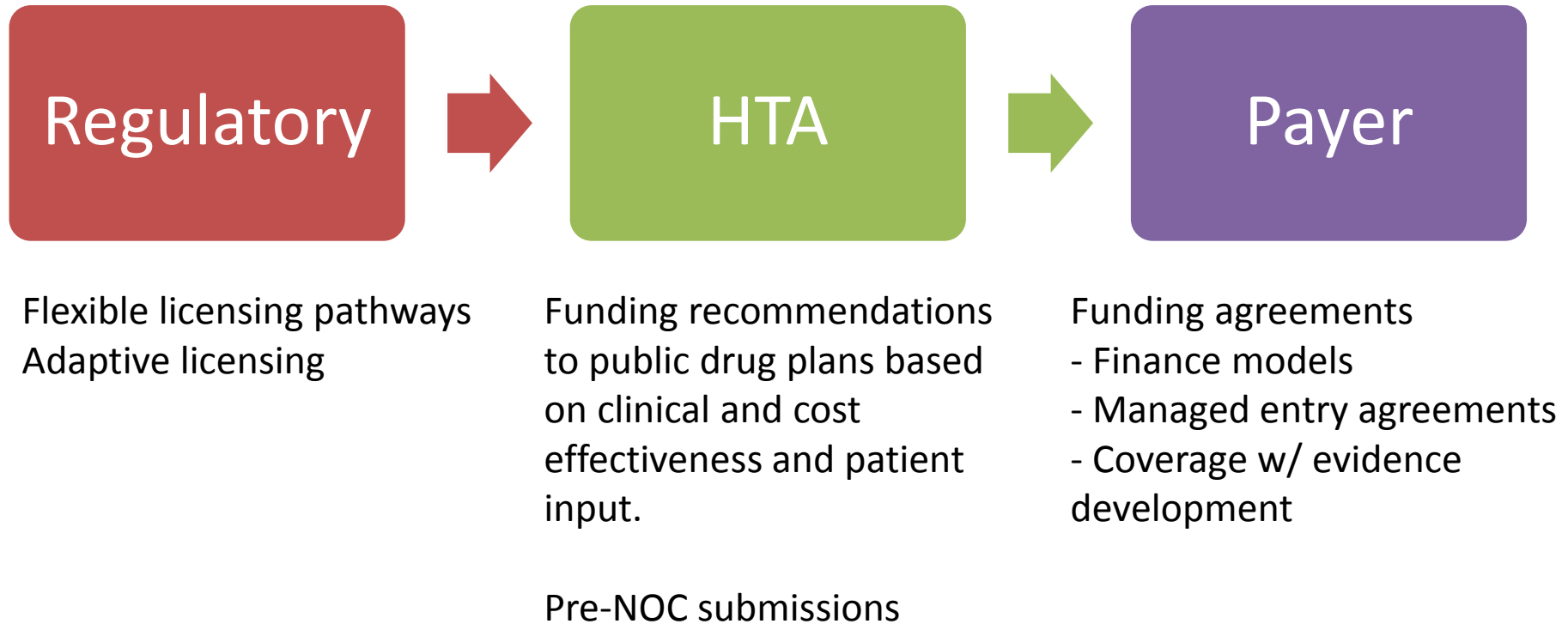
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CADTH

Current State



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>

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.

ACMETS Preuves
à l'appui.