**IDEA**

**PRE-CLINICAL STUDIES**

**CLINICAL TRIALS** (in humans)

**SAP**

**NOC**

**DRUG AVAILABILITY**

**pCODR** (cancer drugs only)

**CDR**

**INESSS** (Quebec only)

**pCPA**

**GOVERNMENT FUNDING**

**REIMBURSEMENT** 6-36 months

**RESEARCH**

12 months

**REGULATORY REVIEW**

**HEALTH TECHNOLOGY ASSESSMENT**

**PATIENTCARE**

**Government Funding**

- Individual governments negotiate with the drug company to determine both the cost and criteria under which that government will pay for the drug, concluding with a Product Listing Agreement.

- A Product Listing Agreement is typically modeled on the Letter of Intent negotiated through pCPA, but not always.

- There is a formal mechanism for patient input only in Ontario and British Columbia.

**Common Drug Review**

- National review process for non-oncology drugs that focuses on the cost-effectiveness of a drug vs. current therapies.

- CDR issues a recommendation to the government drug plans (except Quebec - see INESSS) as to whether or not a drug should be publicly funded for patients who need access.

- There is a formal mechanism for input from organized patient groups.

**pan-Canadian Oncology Drug Review (pCODR)**

- National review process for oncology drugs that focuses on the cost-effectiveness of a drug vs. current therapies.

- pCODR issues a recommendation to the government drug plans (except Quebec - see INESSS) as to whether or not a drug should be publicly funded for patients who need access.

- There is a formal mechanism for input from organized patient groups and individual/groups of physicians.

**Institut national d’excellence en santé et en services sociaux (INESSS)**

- Quebec's review process to evaluate therapeutic value and cost-effectiveness of oncology and non-oncology drugs.

- INESSS issues a recommendation to Quebec's Minister of Health and Social Services as to whether or not a drug should be publically funded for patients who need access.

- There is a formal mechanism for input from individual patients and patient groups, caregivers and physicians.

**pan-Canadian Pharmaceutical Alliance (pCPA)**

- National mechanism designed to achieve greater value for government drug plans.

- pCPA negotiates with a drug company to determine both the cost and criteria under which governments will pay for a medication, concluding with a Letter of Intent to fund the drug.

- Drugs with a CDR/pCODR/INESSS recommendation are not necessarily invited into the pCPA process.

- There is no formal mechanism for patient input.

**Drug Approval and Funding Process in Canada**

- 12 months for regulatory review.

- 6-12 months for health technology assessment.

- 6-36 months for reimbursement.

©2017 Cohn & Wolfe and Advocacy Solutions’