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Overview: Key Steps in How Governments Decide what Drugs to Pay For

Government programs for prescription drugs such as Kuvan for PKU rely for safety upon evidence reviews by the federal health department (Health Canada) and for clinical benefits and value for money on what are called health technology assessments. These assessments are conducted by a governments-funded agency which runs a process called the Common Drug Review. (There is a different process for cancer drugs and Quebec has its own process.)

The Common Drug Review (CDR) makes non-binding recommendations to federal, provincial and territorial government drug plans to:

- (a) pay for a new drug,*
- (b) pay for it if certain clinical criteria and/or other conditions (e.g. lower cost) are met, or*
- (c) not to pay for it.*

Final decisions rest with each government drug plan.

The CDR considers evidence submitted by the drug manufacturer and does its own review of scientific literature. In recent years, there has been an opportunity for patient groups to provide input in writing only on what matters to patients and caregivers (i.e. families).

When Kuvan was first considered by the CDR in 2010 following safety approval by Health Canada, CanPKU made the first ever patient group submission. Now that Kuvan is going back to the independent "Expert Advisory" committee for the fourth time, CanPKU made a fresh submission six years later, in March 2016, which is attached.

We are delighted that almost 300 people responded to an on-line survey. The survey results formed the basis of our submission. Thank you to everyone who participated.

Kuvan is scheduled to be considered, again, by the Canadian Expert Advisory Committee of CDR in July. If the schedule is met, we should learn what recommendation it makes by September. Then the most likely result will be a series of negotiations between the drug company and some government plans over price/value and clinical criteria. These processes can be as slow as molasses. Our submission becomes part of the public record on the CDR website at the end of this process.