

Workshop on Post Market Drug Safety and Effectiveness – Drug Coverage and Plan Management Perspective – Ontario

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Impact of Gap in Safety and Effectiveness Data

- Review of new benefit listings may have limited information
- New drug product submissions may be based on surrogate markers or limited clinical evidence
- Safety information is not complete:
 - limited numbers of patients in trials
 - exclusion of high risk patients from trials who may be more susceptible to adverse events
 - information not accurately/adequately collected post market
- Future impact of progressive licensing on review process

Response to Data Gaps

- Listing agreements:
 - requirement for additional data collection
 - concern regarding observational versus trial data
 - what to do with the data?
- Trial programs:
 - limited experience
 - reimbursement based on clinical effect

Drug Innovation Fund

- Mandate:
 - generate strong, high-quality, independent scientific evidence on the impact and value of new and existing drugs across the health care system
 - support linkages between researchers, clinicians and drug policy decision makers
 - support and develop research capacity in area of drugs and health outcomes
- Areas of Focus:
 - impact on drug access and utilization
 - optimal use of drugs
 - drug adherence
- 8 proposals funded – \$3.8 million