

# Update on the Data Protection Program

CPDA-Canada Meeting  
December 15, 2016



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# Data Protection Program – Update on the changes implemented on December 18, 2014

- The objectives of the process changes were to:
  - Make the submission review process more transparent and predictable
  - Streamline the data compensation assessment
  - Resolve some operational challenges identified in processing these applications
  - Allow more accurate tracking and reporting on performance
- The process changes are achieving its objectives
  - Assessments being completed within the performance standards
  - Review of assessment prior to its finalization

# Generic Registrations

- 118 TGAI registrations
  - 99 of the registrations were based upon a generic data base
  - Compensable data was identified with 18 of TGAI registrations:
    - 11 registrations were based upon a LOA
    - 7 registrations were based upon the selective approach
- 83 EP registrations
  - 45 of the registrations were been based upon a generic data base
  - Compensable data was identified with 38 of the registrations
    - 21 registrations were based upon a LOA
    - 17 registrations were based upon the selective approach

# Generic Applications

## 1. Submission Workload

- Currently there are 98 applications at Phase I (i.e., equivalency and data compensation assessment) and 6 applications at Phase III (i.e. registration decision)
  - 60 applications received in 2015
  - 93 applications received from January to June 2016
  - 50 application received from July to November 2016

## 2. Phase I – Completed

- 125 applications where the Phase I has been completed

# Availability of Compensable Data Lists

- The PMRA makes previously finalized data compensation lists available upon request
  - Send requests directly to me and they will be sent by e-mail

# Data Compensation under Re-evaluation Program

- PMRA is planning regulatory changes to clarify data protection during re-evaluation and special reviews, for example by:
  - Creating a separate section of the regulations on data protection during re-evaluation and special reviews
  - Allowing both the registrant (data owner) as well as the registrant (who is relying on the data) during re-evaluations and special reviews to initiate formal negotiations by sending the Ministerial Agreement, and if necessary, to initiate binding arbitration, once a list of compensable data is established
- Aim to consult on possible amendments in the Summer 2017

# Status of a PMRA-developed searchable data base

- Investments are being made to the PMRA data base and include data protection applications
  - Ability to assign protection periods for data used in PMRA reviews
- Lead to the ability to generate a list of data supporting a registered product and the corresponding protection periods

## Next Steps

- Undertake a review of the current processes to determine if changes are necessary based upon comments received and experiences to date.
  - Plan to update the guidance found in Regulatory Directive 2010-04 and the Memorandum to Registrants and Applicants - Data Protection Submission Review Process



Questions?

