Progressive Licensing Framework (PLF)

An Innovative Industry Perspective

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Rx&D Regulatory Affairs Committee
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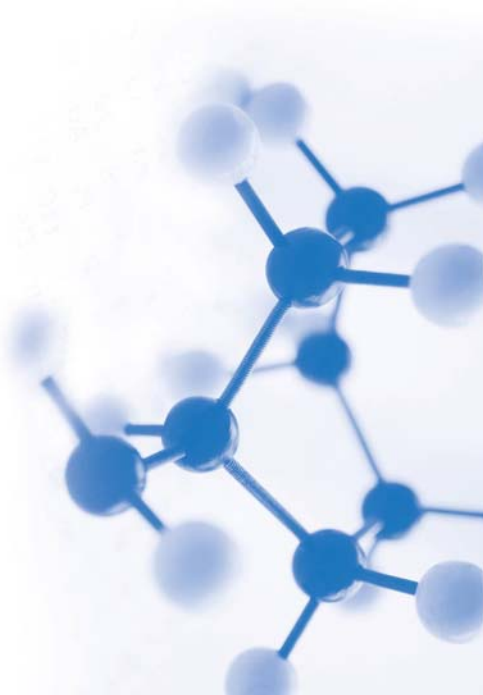

Rx&D PLF subcommittee

PLF Lead

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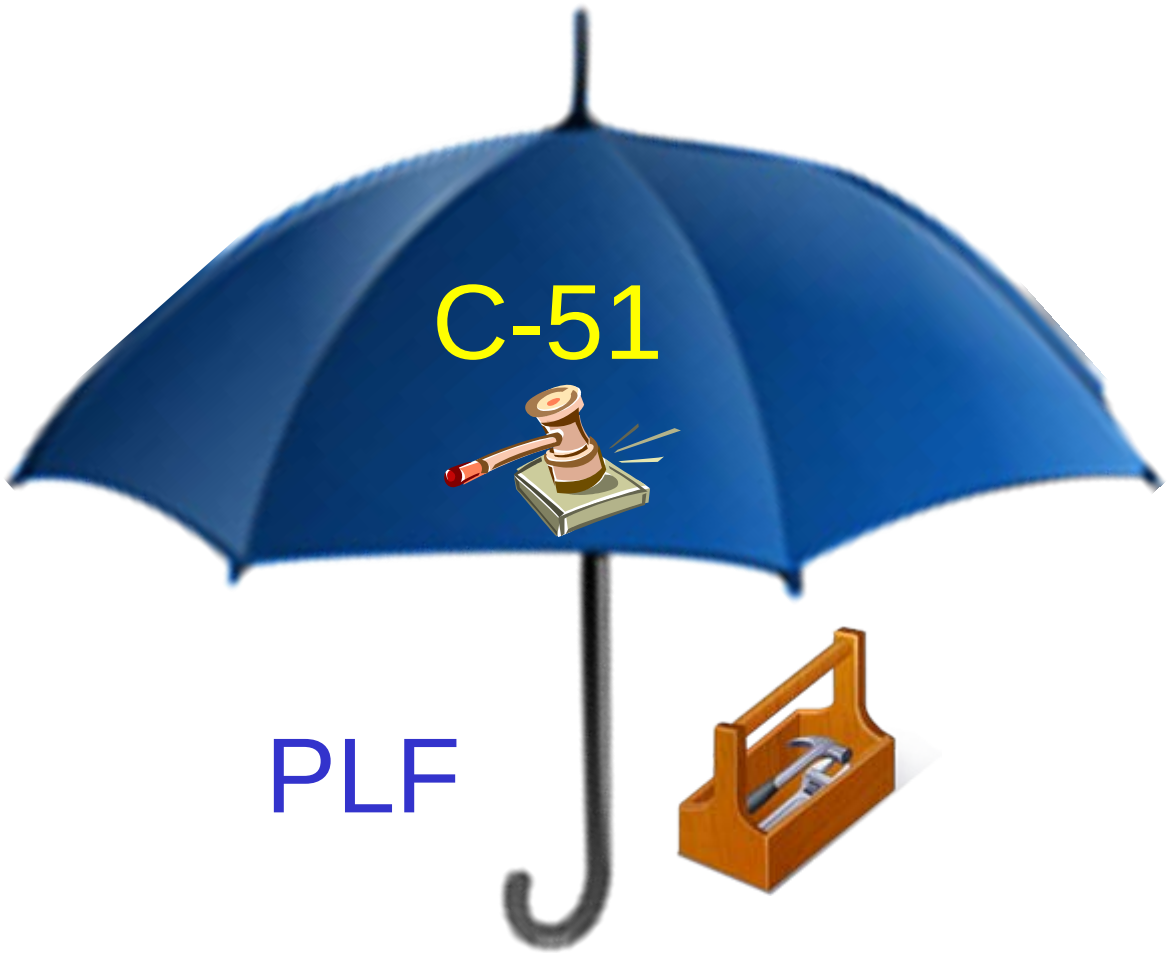
Rx&D C-51 subcommittee

- Regulatory Affairs
- Federal Affairs
- Communications
- Legal


C-51
PLF

Consultations

Consultations

PLF

- 3 Consultative workshops (July 06, Nov 06, May-June-07)
- Face to face meetings
- To date, the framework has focused on concepts and themes
- The release of the framework document will be industry's first opportunity to assess the full impact on the way drugs will be approved and regulated in Canada

Consultations

C-51

- December 17, 2007: Canada's Food and Consumer Product Safety Action Plan
- January, 2008, consultation launched by Health Canada
  - Overview provided, but not draft language.
- April 8, 2008: Bill C-51 introduced.
  - Comprehensive amendments (59 pages)
  - Much broader than PLF

C-51

C-51

- Rx&D is supportive of the modernization of Canada's regulatory regime to better meet the current and future needs of Canadians and of our health care system.
- Rx&D members are already fully compliant with many of the proposed legislative authorities. As a result, we support the inclusion of these regulatory elements into legislation.
- C-51 is an "enabling legislation" that brings into the *Food and Drugs Act* a number of principles needed to modernize the regulatory regime in Canada.
- C-51 is subject to broad interpretation and its true impact will only be apparent once the accompanying regulations are issued for consultation.

C-51 – Positive aspects

- Movement to a lifecycle management of drugs based on risk/benefit assessment
- Ability to harmonize with other Regulatory Agencies
- Formalize the striking of committees
- Formalize the provision of early scientific advice
- Efforts to curb counterfeiting (S.3.1&S3.2)
- Ability to accept electronic submissions
- Flexibility to consider housing environmental assessment regulations under the *Food and Drugs Act*

C-51 – Points for discussion

- Confidential Business Information (s21.1 & S21.2)
- Unlimited liability of offences (31.3a)
- Expanded power of inspectors
- Powers to mandate a wide range of post-marketing studies (s19.9)
- Threshold for recall

PLF

Vision for PLF

- To help shape a regulatory framework that supports ready access to promising new therapies while continuously monitoring and re-evaluating risk/benefit throughout their life-cycle.
- Establish a new Paradigm for Health Canada
  - That will easily accommodate the scientific and technical advances in medicine thus avoiding delays in access to new medicines
  - By committing resources to develop flexible and proactive processes and infrastructure that will support increased number of earlier scientific interactions.

How do we make it happen?

- Harmonize regulatory requirements by taking best practices from leading international regulatory agencies and avoiding “Canadian only” solutions.
  - Bring Canada even closer in collaboration with other international regulatory bodies
- Regulatory intervention proportional to risk by linking pre-market risk/benefit assessment with post-market management strategies.
- Enable regulatory science to be concurrent with scientific and technical innovations used in global drug development science.

PLF Proposal

- Innovative approach by the PLF team to structure the consultative workshops to stimulate real discussions between Industry and Reviewers
- Central Themes of the PLF
  - Good Planning
  - Life-cycle Management
  - Risk/Benefit Evaluation
  - Accountability

Good Planning

- Earlier dialogue with Health Canada on the drug development plans
- Greater predictability of decision making throughout the drug review and approval process
  - Tracking
  - Milestones
- Greater guidance/advice provided in pre-filing meetings with the inclusion of pre-filing agreements.

Lifecycle management

- Issuance of licences with terms and conditions
  - Risk management plans
- Ability to amend licenses
- Authority and process to request label changes
- Authority and process to request additional post-market studies

Risk/Benefit evaluation

- Flexibility of requirements, commitments and post-market activities based on a scientific evaluation of Risk/Benefit
- Concept of two types of licenses
  - Standard License
  - Provisional License

Accountability

- Ongoing requirement to justify decisions made by both Health Canada and Industry
- Decisions need to be justified and consistently applied
  - Guidance Documents

Conclusion

- It is recognized that a modern legislative and regulatory framework is needed to enhance Performance and Predictability.
- The framework should be internationally harmonized and capable of addressing emerging challenges in drug development and yield rigorous assessments yet facilitating timely access to new therapies.
- The framework should provide for regulatory intervention proportional to risk by linking pre-market risk/benefit assessment with post-market management strategies