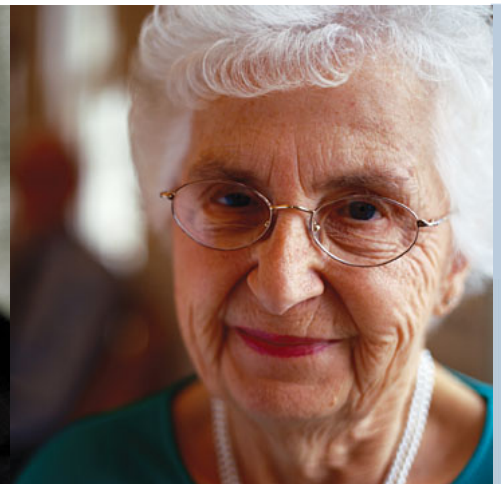
Regulatory Modernization Workshop –Pre-submission meetings and market authorizations including Drugs for Rare Diseases

For the Canadian Association of Professional Regulatory Affairs

Presented by Health Canada



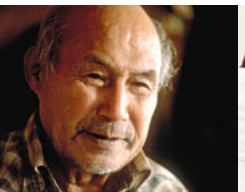


Canada

Overview

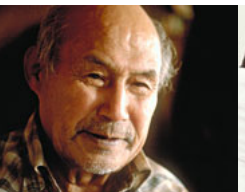
Initial Steps in the Regulatory Process

- Pre-Filing
- Applications for Market Authorization




Elements of Pre-Filing

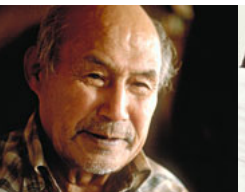
- Notice of Intent to File
- Pre-Filing Meeting
- Designation (Rare Diseases)
- Binding advice




Notice of Intent to File

Objective: To enable efficient workload management

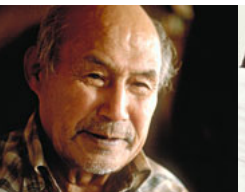
- Drug
- Brand name
- Intended use and route of administration
- Regulatory status in other countries
- Projected filing date
- Request for pre-filing meeting




Notice of Intent to File

Feedback :

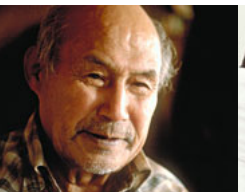
- 6 month pre-filing notification burdensome
- May not appropriate for all product lines;
- Timelines/filing requirements should remain flexible
- Information available at pre-filing stage limited/ subject to change as product is developed




Pre-Filing Meeting

Objective: To identify and resolve issues early

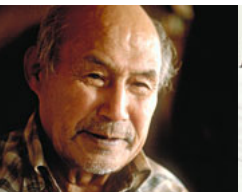
- Advice on complex technical matters
- Advice on acceptability of Brand Name (LASA)
- Advice on when information should be filed
- Health Canada may provide binding advice




Binding Advice

Objective: To stabilize the regulatory process

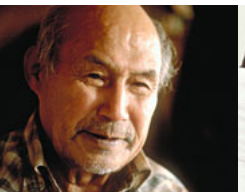
- Possible outcome of Pre-Filing meeting
- Detailed in writing
- Binding but allows for consideration of new evidence




Designation (Drugs for Rare Diseases)

Objective: to support a model for authorization and monitoring of drugs for rare conditions

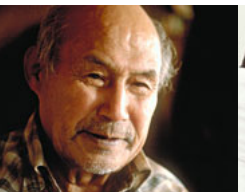
- A Rare Disease affects less than 5 in 10,000 persons
- Evidence of prevalence rate in Canada
- No existing therapy or substantial gain in benefit
- May be referred to designation committee
- May be reconsidered
- Designation will be publically available




Designation (Drugs for Rare Diseases)

Designation results in:

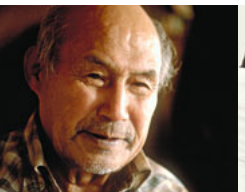
- Ability to gain clinical trial protocol advice
- Priority review of a market authorization application
- Extended market exclusivity




Designation (Drugs for Rare Diseases)

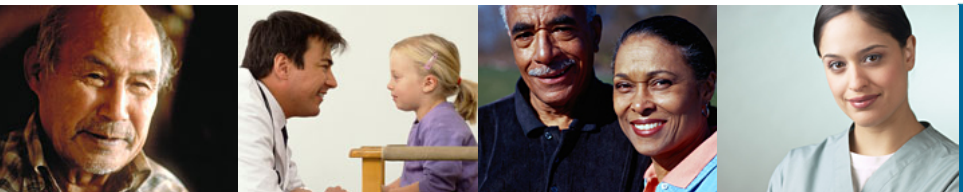
Feedback :

- Further clarify or define ‘rare disease’
- Flexibility for information requirements to support application
- Separate office to handle applications may be needed, including representation from patient groups
- Possibility of a committee with external experts
- Need for flexibility to gather safety and efficacy information beyond formal clinical trials
- Possibility of regulatory incentives




Elements of an application (General)

- *Basic Information*
- *Quality Information (Chemistry and Manufacturing)*
- *Use Information*
- *Labelling Information*
- *Benefit-Risk Information*



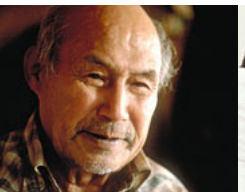
Elements of an application (General)

- The majority of the information required for most types of applications should not change much from that of today

However,

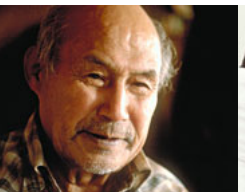
A modernized regulatory system will emphasize:

- Life-cycle approach towards gathering and utilizing information about a drug in a more efficient and sustainable manner




Application (Drugs for Rare Diseases)

- Early opportunity for input from interested parties; patients, health care providers, payers and others
- Common filing with other agencies
- Joint review opportunities
- Registration and disclosure of clinical trial results
- Ongoing commitments




Are we on the right track?

Help us design the world’s best regulatory system

Bring your experiences to the workshop sessions

Thank You