Non-prescription drug modernization

Session – *Industry associations & Advertising pre-clearance agencies*

Fall 2025

Health Canada Santé Canada

Canada

Red Tape Review

Canada’s current government was elected on a mandate to spend less and invest more.

Treasury Board of Canada Secretariat launched a Red Tape Review of regulations in July 2025 across federal departments.

They identified a need to eliminate inefficient red tape – outdated and overly complicated regulations that raise costs, reduce productivity, and stifle economic growth.

On September 8, Health Canada (HC) and the Public Health Agency of Canada (PHAC) published a joint report on red tape reduction.

Report on red tape reduction – Simplifying the *Food and Drug Regulations*

Key Aspects	One set of application requirements	Modern, flexible language focused on outcomes	Authorization based on benefits outweighing risks	Improved post-authorization tools
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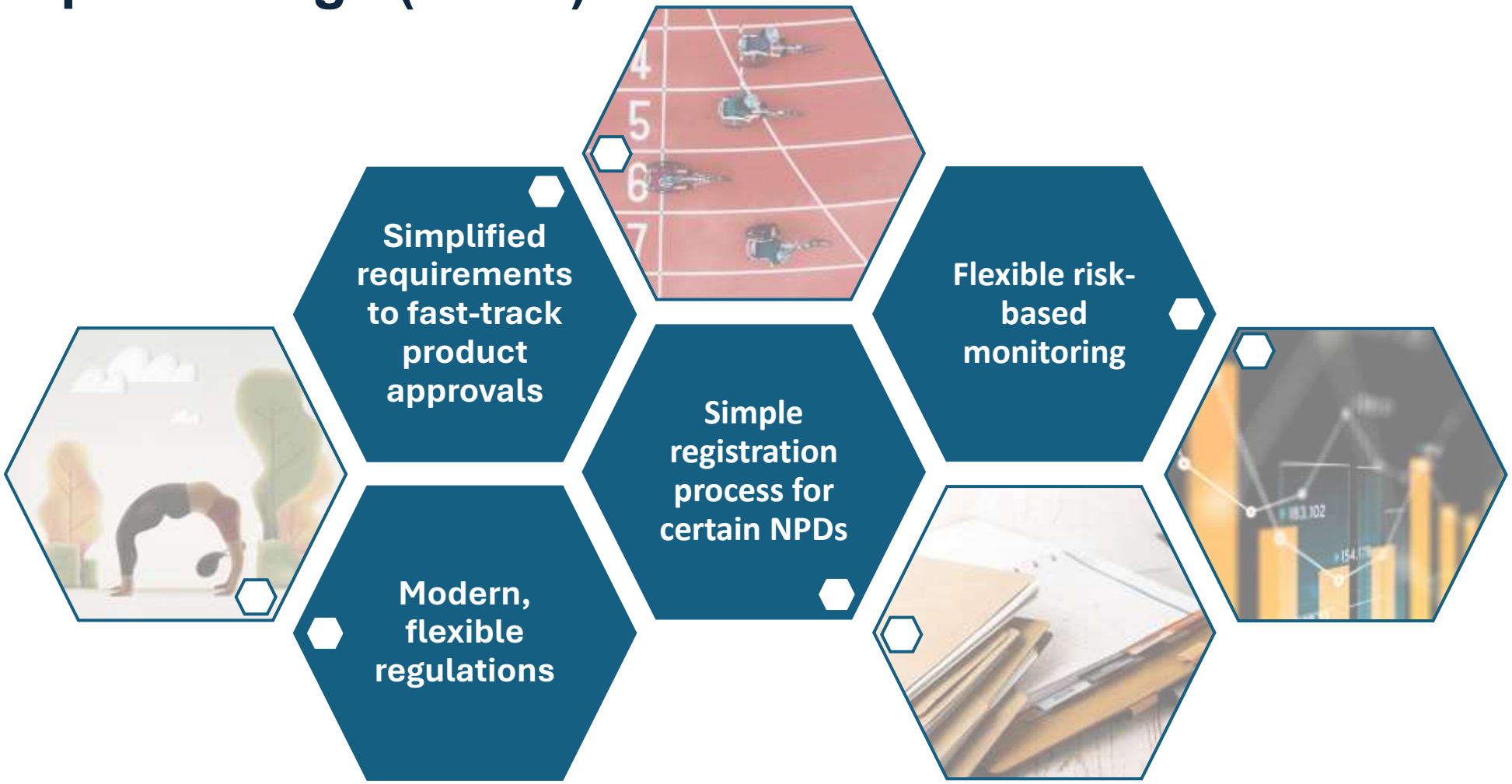
Future State	Tailored for specific drugs and pathways	Guidance will outline how to meet outcome-based requirements	Request information only if needed	Flexible stop sale, suspensions and revocation

Report on red tape reduction – Reducing red tape for Non-prescription drugs (NPDs)



Reducing red tape for NPDs

Expedited pathways – Pre-cleared information (PCI)

Current approach

Applicants only able to reference Health Canada PCI

Possible approach

Applicants can reference foreign PCI recognized by Health Canada

How this could look:

- Health Canada would determine and set out which foreign PCI can be referenced
- Changes to recognized foreign PCI would be consulted on except to address serious health risks
- Applications would need to reflect Canadian context, including naming conventions, units of measure, and labelling requirements

For discussion

1. Do you support the proposal? Why or why not?
2. Would this incentivize companies to bring more non-prescription drugs to market in Canada?
3. Are there any specific foreign monographs or labelling standards for non-prescription drugs that you would want to be included?

Package insert & Patient Medication Information (PMI)

Current approach

PMI section & package insert (same contents) required for Division 8 drugs, optional for Division 1

Possible approach

Package insert optional, PMI not required for any NPDs

How this could look:

Package insert used if all required information can't fit on labels

Package insert can be published online instead of printed, if it includes all label information

Health Canada reviews all label and package insert contents

For discussion

1. Do you support the proposal? Why or why not?
2. Are Product Monographs for non-prescription drugs used by companies as part of their business operations? If so, how?
3. Are companies likely to continue to use package inserts if optional? If so, when and why?

Mock-up labels

Current approach

Mock-up labels/packages required in all NPD applications

Possible approach

Mock-up labels only required for a small number of NPDs

How this could look:

- Current labelling requirements and guidance will continue to apply, such as the Drug Facts Table, plain language labelling, etc.
- For NPDs with high certainty, Health Canada will only review required label content, not label formatting
- To determine if benefits outweigh risks for NPDs with low certainty, Health Canada may request a mock-up label be provided

Note: Until application form updates are possible, applicants would need to include a document with all and label and package insert information

For discussion

1. Do you support the proposal? Why or why not?
2. Do you foresee any challenges with Health Canada no longer reviewing mock-up labels for most non-prescription drugs?

Brand name & company name

Current approach	Possible approach
One brand name per application	Multiple brand names per application
Brand name & company name changes require new DIN application	Companies notify Health Canada of these changes

How this could look:

Continued screening for acceptability

Notify before **X** days of the change

NPD must be identical other than brand name

Brand names may be listed in one data field in databases and extracts

Note: Health Canada would only require look-alike sound-alike assessments to be done for certain NPDs. Applicants would maintain them on file and only provide to Health Canada upon request.

For discussion

1. Do you support the proposal? Why or why not?
2. Are companies likely to use the flexibility to file one application for multiple brand names for the same product, if introduced?
3. Would a change to how brand names are represented in the Drug Product Database for non-prescription drugs (e.g., if multiple brand names appear for one DIN) impact your operations? If so, how?

Quality (chemistry & manufacturing) information

Current approach

Full drug substance & drug product quality required for all Division 8 drugs, requested for some Division 1

Possible approach

Tailored quality information for NPDs

How this could look:

- Tailored approach to when and what quality (i.e., chemistry and manufacturing) information would need to be included in an application to demonstrate benefits outweigh risks
- Good Manufacturing Practice and Drug Establishment Licensing requirements would still apply

Examples:

No quality information for PCI-based applications

Sterilization validation information for sterile ophthalmic NPDs

Drug substance and/or drug product quality information for other NPDs

For discussion

1. Do you support the proposal? Why or why not?
2. Would a tailored quality pre-market review approach impact a company's ability to export non-prescription drugs for sale in other jurisdictions?

Safety Monitoring

Current state	Possible approach
Required preparation of annual summary reports	Flexible safety monitoring

How this could look:

- Annual summary report to be removed as one-size-fits-all vigilance requirement and replaced with safety monitoring requirement to detect significant safety issues
  - Outcome-based requirements provide flexibility to market authorization holders in the design of risk-based systems and procedures to detect issues
  - Considers comprehensive real-world safety information in real-time, reducing potential delays to signal identification while reducing gaps and duplication
- Health Canada would still have authority to require a periodic summary report, when warranted (proportionate layered approach based on level of risk and uncertainty)

Note: Safety monitoring would be similar to the safety monitoring model for biocides

For discussion

1. Do you support the proposal? Why or why not?

Record Retention

Current approach

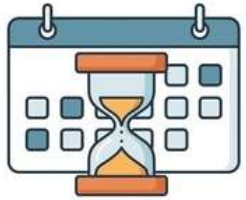
Retention of 25 years from creation of the record

Possible approach

Retention based on lifecycle of the product

How this could look:

Retain vigilance data



Duration of product's authorization in Canada, plus 10 years

Supports safety monitoring model

Increased alignment with international norms

For discussion

1. Do you support the proposal? Why or why not?

Engagement opportunities