Understanding Data Protection C.08.004.1, *Food and Drug Regulations*

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This presentation is for information only
and does not constitute advice respecting any individual drug submission.

Data protection will be considered on a case-by-case basis in accordance with the provisions of the *Food and Drug Regulations*.

Overview

- Basis for Data Protection
- Data Protection in Canada
  - How to Apply for Data Protection, Decision Points, Test
  - Pediatric Extension
- Register of Innovative Drugs
- When is Data Protection Triggered?
  - Decision Points, Comparisons
- Impacts
- Questions

Basis for Data Protection

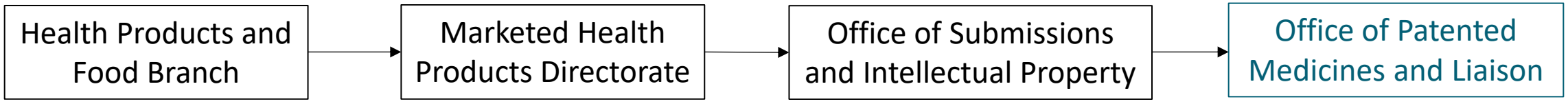
- Arises from international obligation (CUSMA, CETA and WTO/TRIPS) to protect research data submitted to regulatory authorities by innovative companies for the purpose of proving that a new drug (i.e. containing a new chemical entity) is safe, effective and of high quality
- Incentive for innovators to **invest in research**, and to **develop and market their products in Canada**

❖Distinct from patent protection

Data Protection in Canada

- **Up to 8 ½ years of market exclusivity for "innovative drugs"**
- Pharmaceuticals & biologics that receive NOCs may be eligible

- Administered by Health Canada under authority of the *Food and Drugs Act*
  - s. C.08.004.1 of the *Food and Drug Regulations* since 2006



How to Apply for Data Protection

- No application forms!

- All NDSs are considered
- All SNDS with pediatric data are considered

- Supporting information is welcome but not required in cover letter or module 1.2.4.2 – Data Protection Information

Decision Points – Innovative (S)NDS

Written preliminary decision on 8-Year Term

- *Eligible* → *Final decision on 8-Year Term*
- *Ineligible with opportunity for representations* → *Final decision in response to representations*

Decision on Pediatric Extension

Submissions flagged

Eligible: RID updated
Ineligible: Written preliminary decision with opportunity for representations

8-Year Term: Two-Part Test

1. New chemical entity

A drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph

2. New and significant data

(i.e. the product of considerable effort)

Not found in:

- Submission relying on third party data or literature
- Comparative submission (e.g. biosimilar)

Innovative Drug Scenarios

Not Previously Approved ✓

Not Previously Approved + Previously Approved ✓

Previously Approved + Previously Approved ✗

❖Human and veterinary drugs are assessed separately.

6-Month Pediatric Extension

- Encourage filing of data pertaining to use in pediatric populations
- Improve drug information regarding pediatric use that will assist health professionals, parents, caregivers, and patients in making informed choices about drug therapy

A manufacturer must file a submission containing

- clinical trials designed and conducted for the purpose of increasing knowledge of the use of the innovative drug in pediatric populations

  AND

- this knowledge provides health benefits to members of those populations

“…clinical trials…”

Timing Requirement

- Studies can be included with the NDS
- If studies are included in an SNDS, the SNDS must be filed within 5 years after the first NOC was issued

“pediatric populations”: Premature babies born before the 37th week of gestation up to people 18 years of age

"…clinical trials…"

- The study hypothesis, objectives, design and conduct can be used to understand if the clinical trial was developed and conducted for the purpose of increasing knowledge of the use of the drug in pediatric populations.

- Examples, not eligible
  - *In vitro* studies
  - Ongoing studies

“…health benefit…”

- Case-by-case analysis
- Knowledge must be available to the public through the approved labelling or Product Monograph
- Information that can support the extension:
  - Pediatric indication
  - Contraindications and/or other warning statements
  - Pharmacokinetic/safety-tolerability studies
  - Drug interaction studies

Example 1

ELOCTATE™ (Antihemophilic Factor (Recombinant BDD), Fc Fusion Protein) is an anti-hemophilic factor (recombinant) indicated in adults and children (≥12 years) with hemophilia A (congenital factor VIII deficiency) for:

- Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes.
- Control and prevention of bleeding episodes.

Example 2

ACTION AND CLINICAL PHARMACOLOGY

(…)

Special Populations and Conditions

Pediatrics (<18 years of age): In a pharmacokinetic study in 99 subjects aged 1 month to <16 years receiving BRIVLERA oral solution, plasma concentrations were shown to be dose-proportional in all age groups. BRIVLERA is not indicated in pediatric population (see **INDICATIONS AND CLINICAL USE, Pediatrics**).

There are limited safety data for children from 1 month to <17 years of age. A total of 152 children (1 month to <17 years of age) have been treated with brivaracetam in the adjunctive therapy epilepsy clinical programme. From the limited available data, the most frequently reported treatment emergent adverse events (TEAEs) were pyrexia (20%), nasopharyngitis (20%), convulsion (15%), headache (14%), and upper respiratory tract infection (13%). The most frequent TEAEs leading to discontinuation were aggression (3%, n=5 subjects), somnolence, weight decreased and suicidal ideation (1.3%, n=2 subjects each). No data are available on neurodevelopment or in neonates.

Timing and Transparency

- Health Canada is required to make its determination before the end of the 6-year no-file period when subsequent entry submissions are permitted

Register of Innovative Drugs

- Guidance Document: Data Protection under C.08.004.1 of the Food and Drug Regulations [2010-03-08]

Register Of Innovative Drugs [Updated: 2026-04-20]
(PDF, 299 Kb)

Contact: Office of Patented Medicines and Liaison

- Products for Human Use - Active Data Protection Period
- Products for Human Use - Expired Data Protection Period
- Products for Veterinary Use - Active Data Protection Period
- Products for Veterinary Use - Expired Data Protection Period

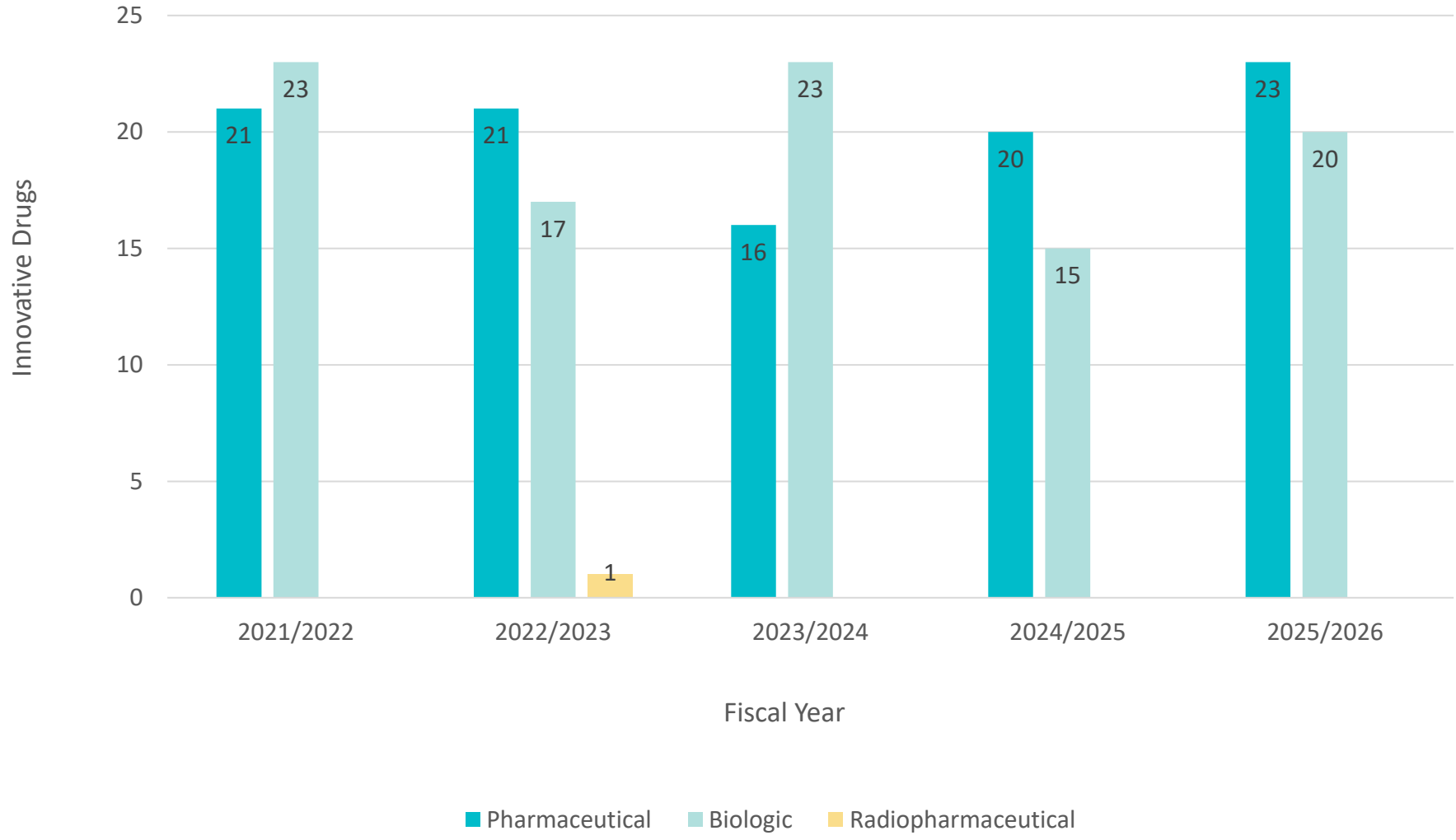
Filter items Showing 251 to 275 of 308 entries | **Show** 25 **entries**

Products for Human Use - Active Data Protection Period

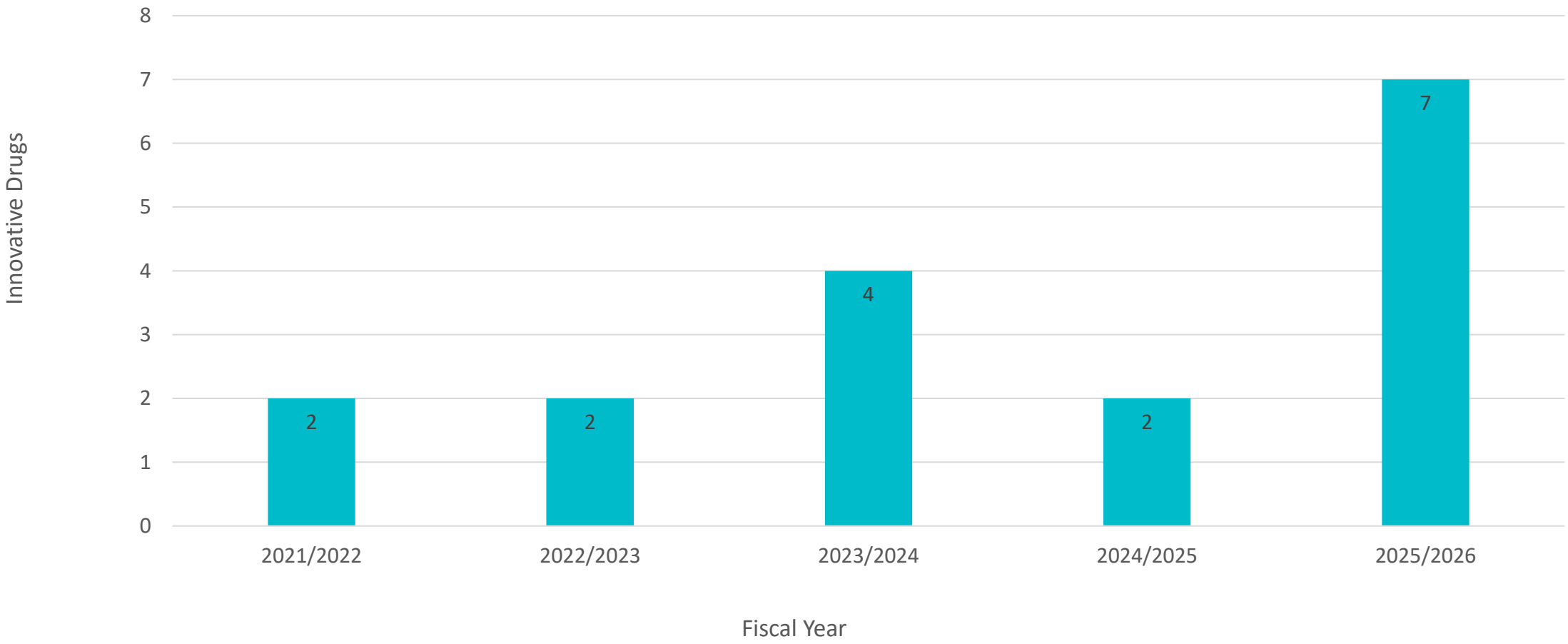
Medicinal Ingredient(s)	Submission Number	Innovative Drug	Manufacturer	Drug(s) Containing the Medicinal Ingredient / Variations	Notice of Compliance Date yyyy-mm-dd	6 Year "No File" Date	Pediatric Extension Yes/No	Data Protection Ends
teprotumumab	285296	Tepezza	Amgen Canada Inc.	N/A	2025-04-17	2031-04-17	N/A	2033-04-17
tezacaftor	211292	Symdeko	Vertex Pharmaceuticals (Canada) Incorporated	Trikafta Alyftrek	2018-06-27	2024-06-27	Yes	2026-12-27
tezepelumab	256188	Tezspire	AstraZeneca Canada Inc.	N/A	2022-07-28	2028-07-28	Yes	2031-01-28
tildrakizumab	224036	Ilumya	Sun Pharmaceutical Industries Ltd.	N/A	2021-05-19	2027-05-19	N/A	2029-05-19

https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/register-innovative-drugs.html

Human Innovative Drugs



Veterinary Innovative Drugs

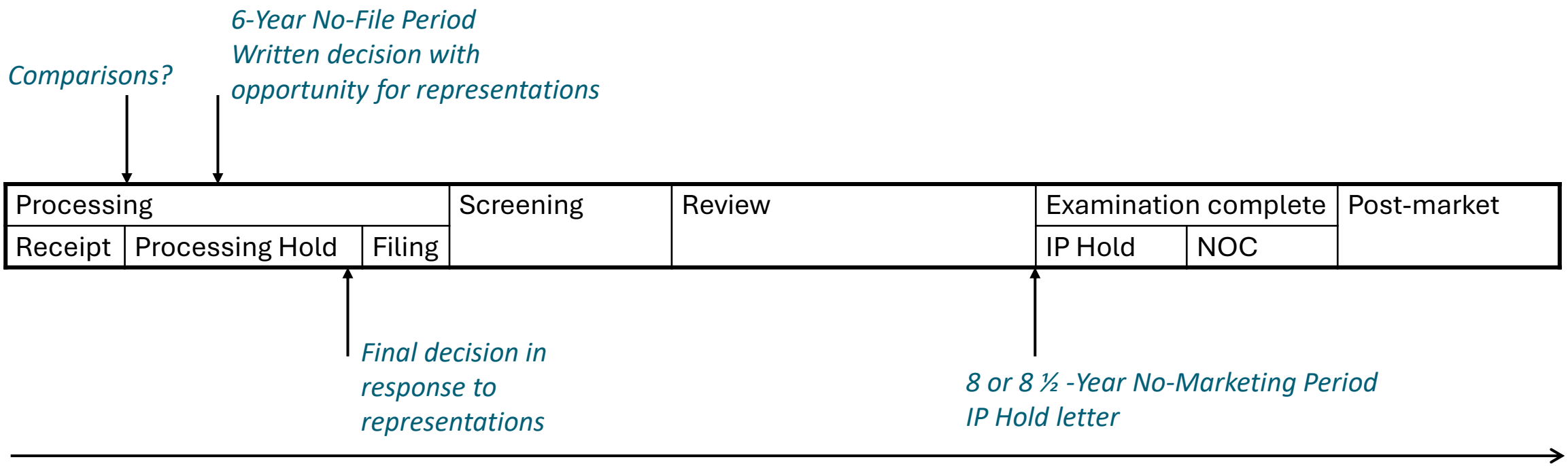


Impacts: When is data protection triggered?

If a manufacturer seeks a notice of compliance for a new drug **on the basis of a direct or indirect comparison** between the new drug and an innovative drug:

- No filing for 6 years
- No NOC for up to 8 ½ years
- Innovator can consent
- All (S)NDSs and (S)ANDSs are assessed

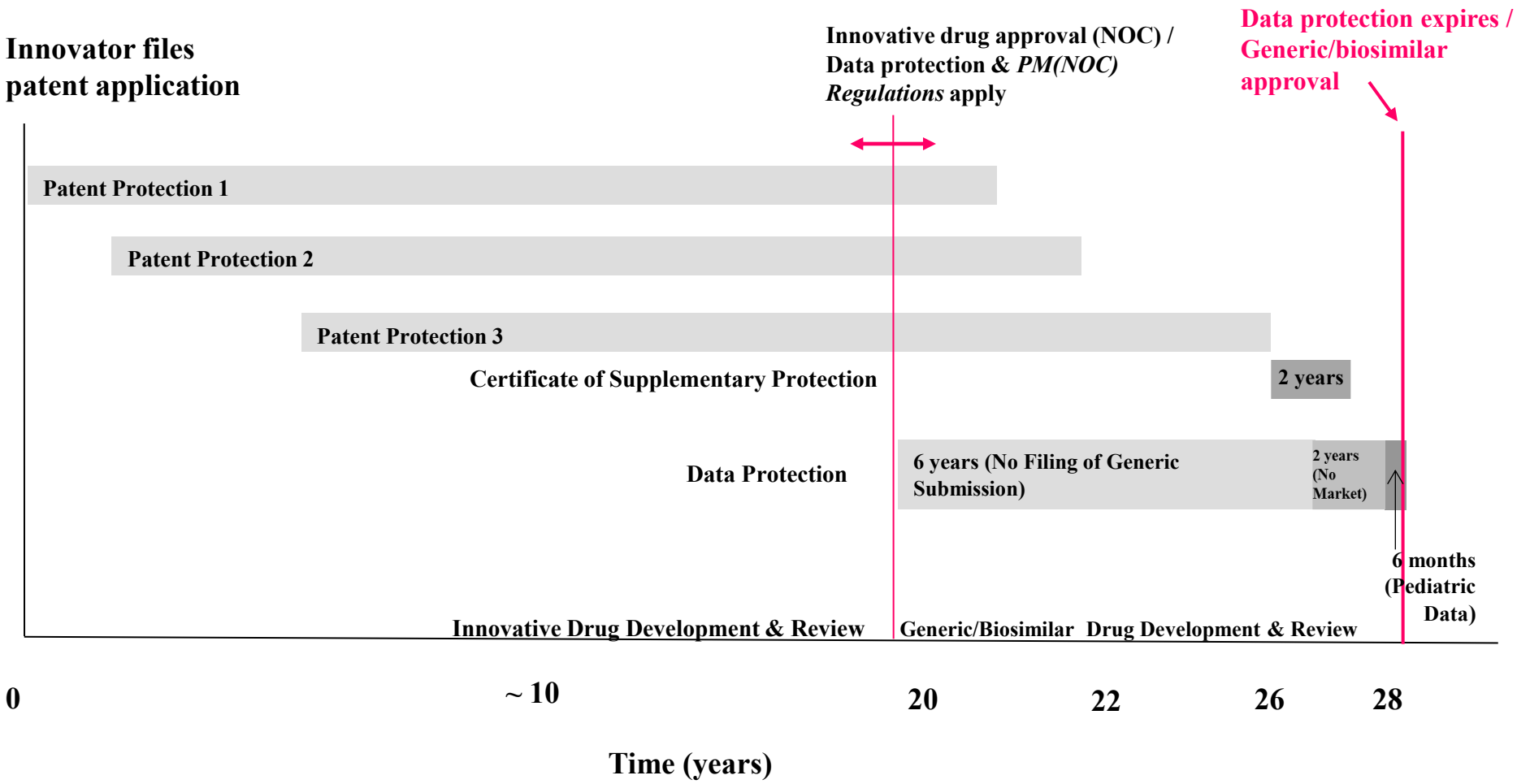
Decision Points – Comparative Submission



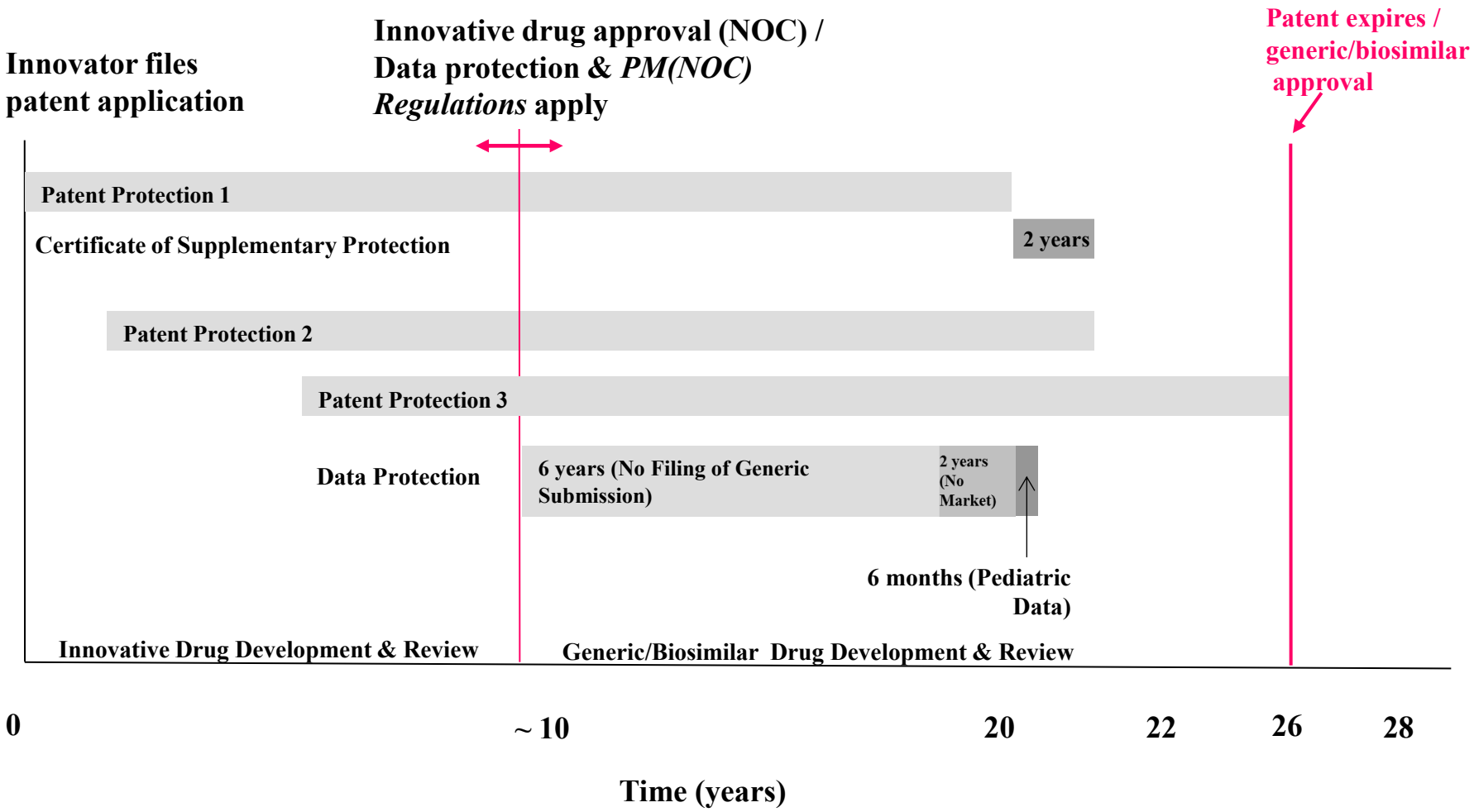
Not Comparisons - Examples

- Independent data and no reference product
- Indication for use in combination with an innovative drug
- Innovative drug as an active control in a clinical trial
- Product monograph language that is publicly available safety information on an innovative drug that may be relevant to the optimal, safe and effective use of the proposed drug for awareness for prescribers and patients

When Data Protection Impacts Exclusivity



When Data Protection Does Not Impact Exclusivity



Guidance Document: Data Protection under C.08.004.1 of the *Food and Drug Regulations*

https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/guidance-document-data-protection-under-08-004-1-food-drug-regulations

Contact

Office of Patented Medicines and Liaison

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Questions?