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GLOBAL PUBLIC AFFAIRS

FROM INSIGHT TO IMPACT

The "New" PMPRB -- *Impact on Access to New Drugs for Rare Diseases?*

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PMPRB: Positive or Negative for DRD Strategy?

Ensures price in Canada not "excessive" relative to other countries

Limits list price – leaves wide scope for payers to negotiate access, including OBAs

No special consideration for DRDs; no patient input

Ignores US – in identifying upper price limit in Canada

Potential risk for manufacturer - legal uncertainty for many

PMPRB Level Setting
(after tumultuous 2017-22)

New Board in Place

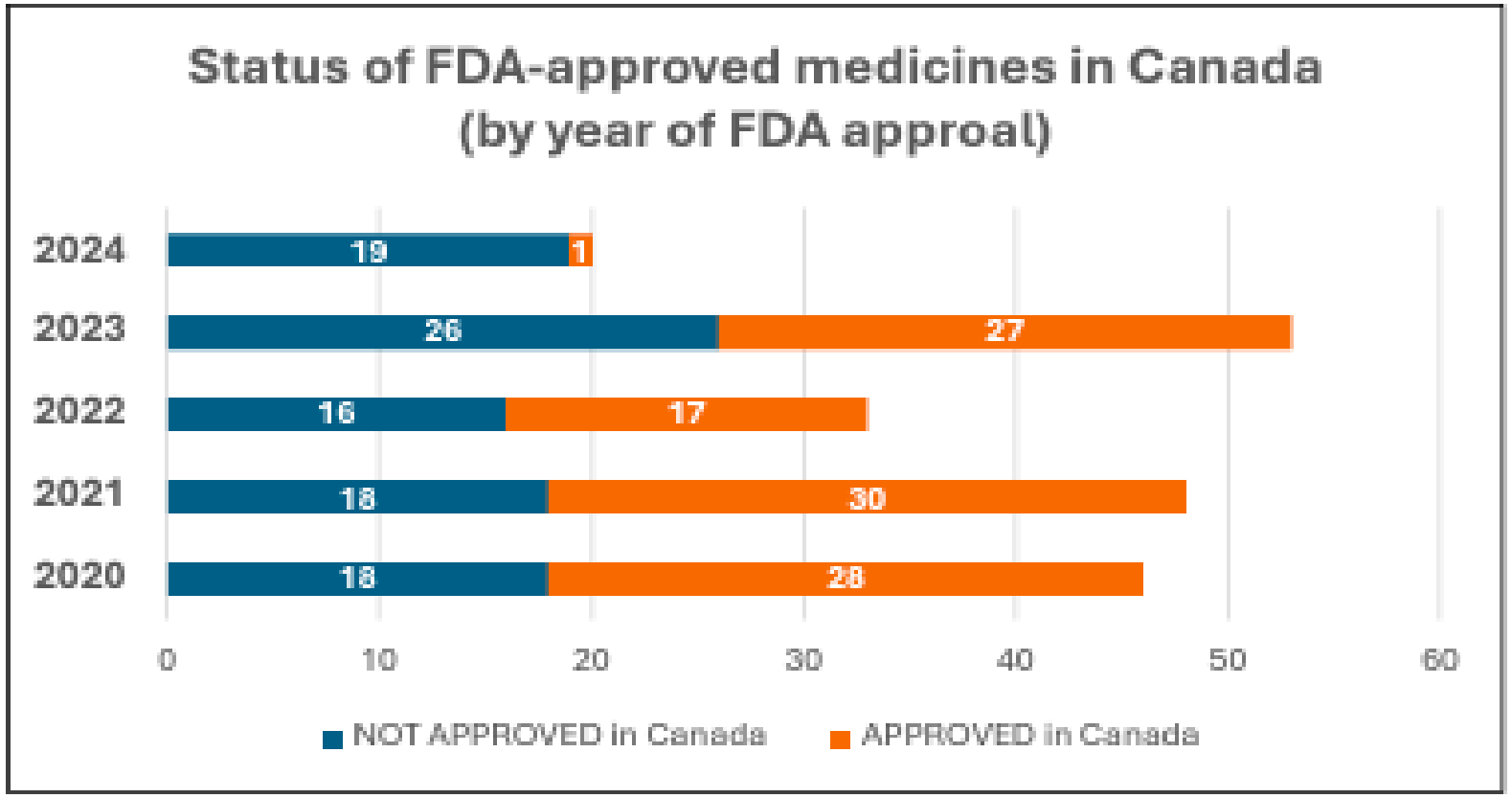
New list of comparator countries

New Price Guidelines under development

Enhanced consultations with patient organizations

Commitment to improved communications

Canada Lags US in new Drug Approvals



% approved in Canada Aug. 2024
5.0%
50.9%
51.5%
62.5%
60.9%
Total 2020-24 51.5%

Data from U.S. Food and Drug Administration and Health Canada Notice of Compliance database.

Factoring PMPRB in Decision to Launch in Canada

Market uncertainty as Guidelines still under development

Continued risk under likely Guidelines:

- Issues in international price comparisons
  - No US comparison
  - Uncertainty until drug sold in more countries
- "In-depth review" likely in many cases – ongoing post-launch

Greater uncertainty if Canada is an early-launch country

Next Steps

Consultations – continue into 2025

- Key Stakeholders

New draft Guidelines – December 2024?

New regime in place - July 2025?

CORD continues to be an important stakeholder for PMPRB