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INTRODUCTION & OBJECTIVE

- There is growing awareness of the challenges faced by introducing innovative medications in women's health in Canada.
- This study aimed to generate quantifiable and tangible evidence on the access to innovative women's health products in Canada.

METHODS

- A TLR was conducted to identify a list of women's health conditions, excluding rare diseases and oncology.
 - Database included Center Watch, Cochrane, and Google
- For the condition of interest, all associated drugs with a specific indication approved by FDA were identified.
 - Date of approval restricted between January 1, 2003, to December 31, 2023.
- The FDA-approved drugs were searched in Health Canada's database, Canadian HTA agencies (CDA-AMC, INESSS), the pCPA website, and public/private drug plans to assess regulatory and reimbursement status.

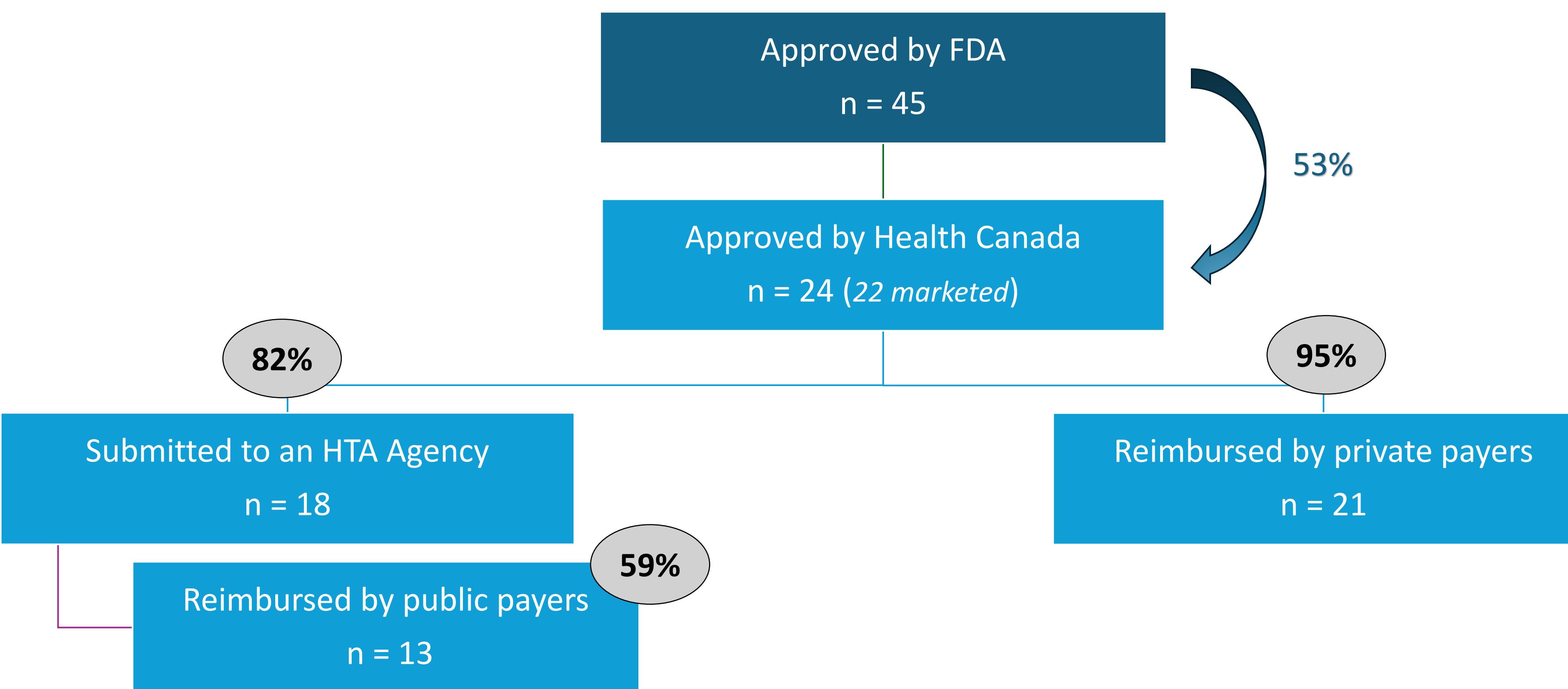
RESULTS

- Compared to about 67% of new active substances approved by FDA have been submitted to Health Canada in general (1), 53% of women's health medications approved by FDA sought approval in Canada.
- The most common indications seeking approval by Health Canada (and the FDA) in women's health conditions are menopause and associated symptoms, post-menopause and associated symptoms as well as contraception.
 - Health Canada still only approves around 60% of medications in these conditions compared to the FDA.
- Neither of the treatments for post-partum depression approved by the FDA have been also approved by Health Canada.
- None of novel treatments for vaginal infections approved by the FDA have been also approved by Health Canada.

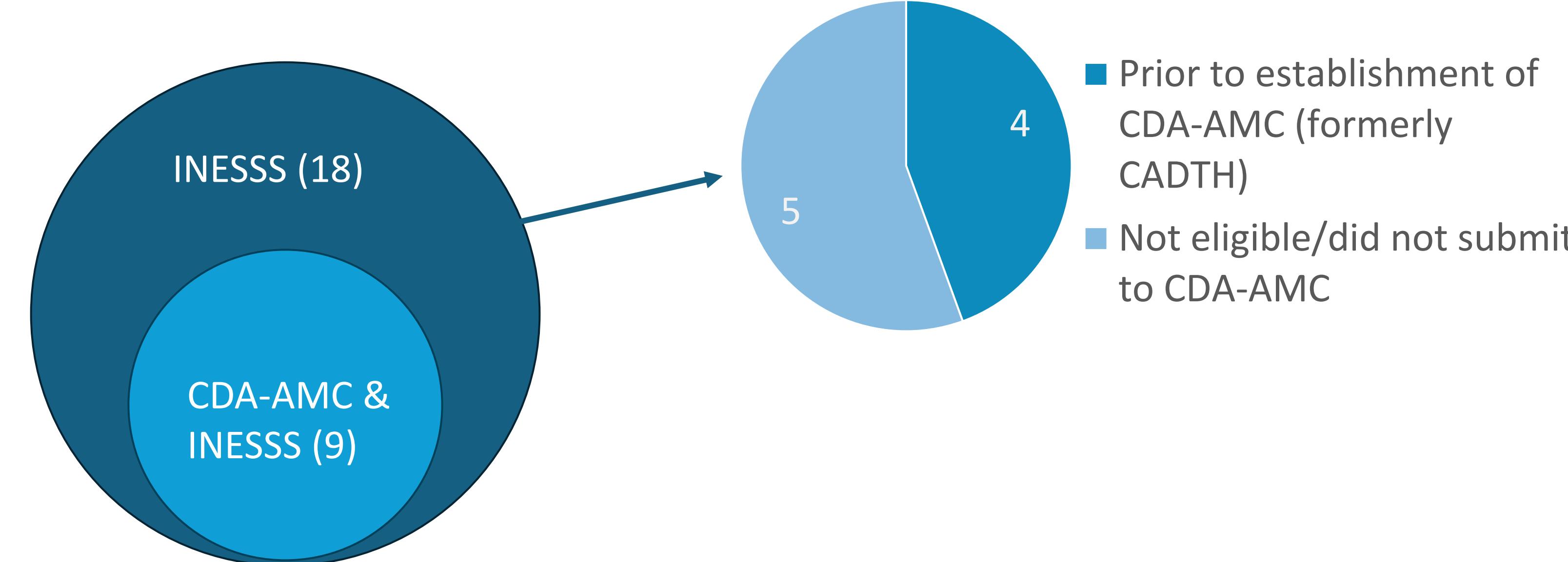
Table 1. Drugs approved by Health Canada / Drugs approved by FDA (%)

CONDITIONS	Drugs approved by HC (n=24) / Drugs approved by FDA (n=45)
Menopause and associated symptoms	5 / 9 (56%) 2 / 3 (66%)
Post-menopause and associated symptoms	3 / 5 (60%)
Contraception	7 / 13 (54%) 1 / 1 (100%)
Heavy menstrual bleeding	1 / 1 (100%)
Uterine fibroids	0 / 1 (0%) 1 / 1 (100%)
Endometriosis	1 / 1 (100%)
Premenstrual dysphoric disorder	1 / 1 (100%)
Hypoactive sexual desire disorder	1 / 2 (50%)
Vaginal infection	0 / 4 (0%)
Pregnancy (nausea/vomiting and post-partum depression)	1 / 3 (33%)

RESULTS

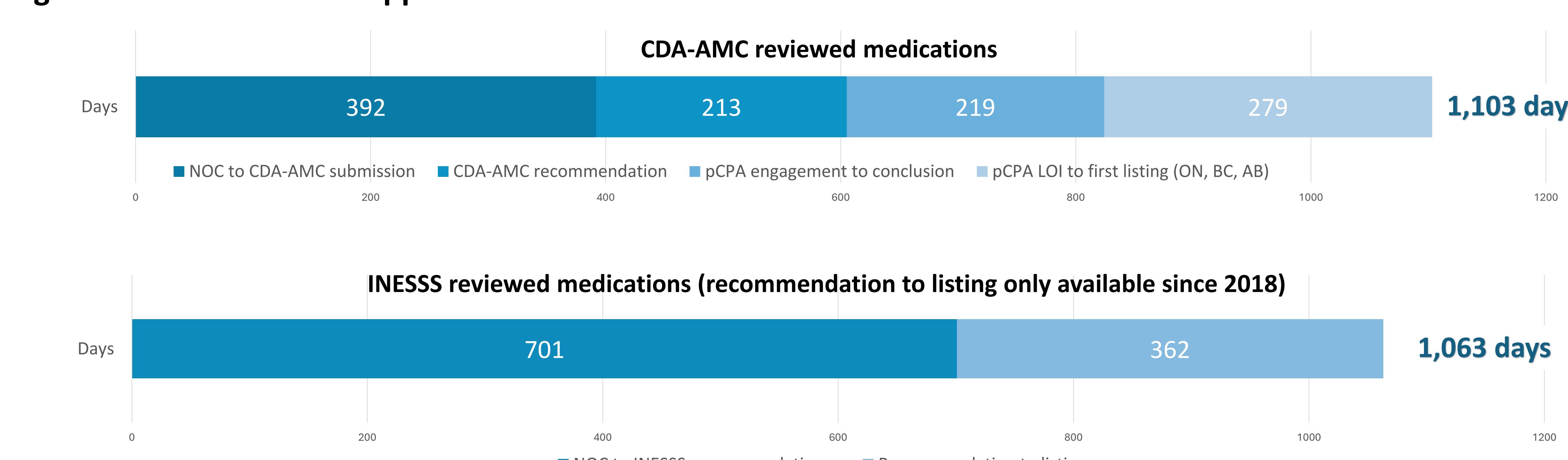
Figure 1. Gaps between regulatory approvals, HTA submissions, the reimbursement status

- 82% of drugs approved by Health Canada and available in Canada were submitted to an HTA agency, but less than 60% would eventually be reimbursed by public payers.

Figure 2. Submission to CDA-AMC and/or INESSS**Table 2. Alignment between CDA-AMC and INESSS recommendations**

CDA-AMC	INESSS	Reimburse	Reimburse with condition	Do not reimburse
Reimburse		0	0	0
Reimburse with condition		1	6	0
Do not reimburse		0	1	0

- Reimburse with conditions for new drugs are generally economical, especially with CDA-AMC where price reduction suggestions ranged from 21% - 93%, with high price reduction leading to a failure in pricing negotiation afterwards.
- In medications receiving reimbursement with clinical conditions, patient will require special authorization to access the drug, which may create an additional barrier.

Figure 3. Total time from approval to access for women's health medications in Canada

DISCUSSION

- Innovative medicines in women's health are less likely to be seeking regulatory approval in Canada as they are generally developed by small pharmaceutical companies.
- Most women's health medications targets hormonal pathways, which are occupied by old molecules available at a cheap price, further deterring innovative medicines to enter this market.
- Compared to access to medications in general in Canada, the approval to access process (public listing) takes one year longer for women's health medications, totalling over three years.
- Women need to have private insurance to receive the best care, but several new drugs that are not listed publicly are for conditions that mostly affect women covered under public health care.

Study Strengths

- This is the first study focused on market access for women's health medications in Canada.
- The TLR covered key databases along the pathway to access in Canada using a clear, defined methodology, allowing a comprehensive overview regarding women's health medications in Canada.

Study Limitations

- Although this study investigated FDA-approved medications that were also approved by Health Canada, the inverse is possible and was not captured in this analysis.

CONCLUSIONS

Canadian key stakeholders need to recognize the tangible gap in women's health, and to ensure that women's voices are prioritized in the discussion. Access to innovative drugs for Canadian women must be realigned significantly to impact the landscape in the next 20 years.

REFERENCES

- Gaudette É., et al. CMAJ 2023 June 12;195:E815-20.

ABBREVIATIONS

CADTH = Canadian Agency for Drugs and Technologies in Health; CDA-AMC = Canada's Drug Agency; FDA = Food and Drug Administration; HC = Health Canada; HTA = health technology assessment; INESSS = Institut national d'excellence en santé et en services sociaux; pCPA = pan-Canadian Pharmaceutical Alliance; TLR = targeted literature review

DISCLOSURES

- Maggie Dong and Avril Gouault Laliberté are employees of PeriPharm Inc.
- Dany Hallé is the VP, Market Access lead at Duchesnay Pharmaceutical Group.
- Carla Létourneau is an employee of Duchesnay Pharmaceutical Group.
- Catherine Beauchemin is a partner at PeriPharm Inc., a company that has served as a consultant to Duchesnay Pharmaceutical Group and has received funding from this same company to conduct the study.
- Duchesnay Pharmaceutical Group participated in the design and provided financial support for the study. No honoraria or payments were made for authorship.