Interest Holder Engagement Strategy

Aasha, Aaranie, Adina, Asghar

Schulich MEDICINE & DENTISTRY

Western Science

Proposed Solution

Our Health Canada team will work to revise the existing SGBA+ regulations and guidelines to make the submission of sex-disaggregated preclinical data a prerequisite for clinical trial approval and advocate for an international shift in gender norms in biomedical research.

Key Partnerships

- **Regulatory Boards**
  - Implement amendments to regulations to uphold Sex as a Biological Variable (SABV) standards in health product and biomedical research
- **Funding Agencies**
  - Help create a shift in sex and gender analysis requirements at the basic science and preclinical level
- **Pharmaceutical Industry**
  - Implementation of long-term gender bias shift in pharmaceutical research and application
- **Patient Advocacy Groups**
  - Advocacy for individualized medicine that moves away from the male normative model

Health Canada

Importance	Health Canada is important because it will be the **direct** regulatory body proposing amendments to current Food and Drug regulations and implementing updated guidance requiring consideration of sex differences in health-product development for international and research fields.
Responsible and Accountable	**Responsible** for developing new standards; **Accountable** for the explicit guidelines regardless of amendments to the regulation and the long-term impact of these changes.
Engagement Goals & Success Criteria	Creating standardized criteria for sex consideration, inclusion, analysis, and justification of exclusion to be proposed to the Governor in Council as an amendment to the Food and Drug Regulations and modifying current guidance to follow. Periodic review of research to increase compliance.
Likely Reaction	Health Canada already has an SGBA+ policy, so the proposed updates may seem redundant, but it will align with their current values. They may be worried about regulatory burden but should be supportive since the proposed updates aim to increase adherence.
Engagement Plan	Create partnerships and guidelines with funding agencies and other regulatory boards to implement stricter mandate for Sex as a Biological Variable (SABV) standard across domains of biomedical and pharmaceutical fields.

Direct Impact

Essential ★★★★★

Executive Branch of Government

Provides **internal** oversight and approval throughout the development and implementation of the proposed policy.

Priority and Power	The Governor General and cabinet members are the only individuals with the power to approve the amendment. Thus, they have **high priority and direct/significant influence** on the success of this solution. However, they do not affect the changes made to the Health Canada guidelines, making them not critical to the success.
RACI	Although Health Canada is predominantly accountable for the implementation of the entire strategy, representatives, especially the Governor General, are held **responsible and accountable** for approving the amendment. The proposed policies will become requirements rather than mere guidelines.
Engagement Goal & Success Criteria	The proposal to amend a standard in the Food and Drug Regulations, created by Health Canada, is to be passed on to the **Minister of Health** to bring forth to the **Governor in Council**. After review, the **proposal is hoped to be accepted** and signed off by the **Governor General**.
Concerns & Likely Reactions	The government has current efforts to prioritize SGBA+ research practices as seen through Health Canada's SGBA+ policies, yet has not translated these interests into a mandate. The cabinet may be hesitant to accept this proposal, as they may see it as **redundant to the guidance documents** Health Canada can publish itself; suggested standards of practice for industry research.
Engagement Strategy	Since Health Canada is still a part of this government structure, it can have **policy meetings** to address the key evidence and the gaps filled by, and the feasibility of, the new amendment **when needed**. Additionally, they can **brief the Health Minister on their findings before submitting** to the cabinet. However, there is limited engagement to be had directly with the cabinet.

Direct Impact

Essential ★★★★★

FDA & EMA

International regulatory bodies, such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) **externally** inform international alignment and evidence-based policy development.

Priority and Power	International regulatory boards do not directly inhibit the main goal of the solution to propose an amendment or revise the guidance surrounding SGBA+ in drug development. Yet, with the risk of limited drug proposals to Health Canada, the secondary task of developing international standards allows these boards to have **moderate priority and influence** over our solution as a whole.
RACI	These international drug regulatory boards will be **consulted** by Health Canada to potentially adapt their current policies to better align with those that Canada follows. They can also provide expertise and concerns to improve the amendment proposal submitted by Health Canada.
Engagement Goal & Success Criteria	Wish to partner with international drug regulatory boards to incorporate Health Canada's new mandates for sex-based collection, analysis, and reporting of findings during preclinical and clinical drug development trials into their regulations. This will ensure a standard of drug development followed worldwide, where industry partners will not be likely to submit their proposals internationally to avoid the extra requirements posed by Health Canada.
Concerns & Likely Reactions	The FDA already recognizes SBAV, focused on human trials, yet there is limited information on preclinical (animal) testing. On the other hand, the EMA does acknowledge that sex can be considered during animal testing, yet it has no requirement to analyze this data. With this, they are likely to be **frustrated or dismissive** when needing to update a policy that they barely address.
Engagement Strategy	During the initial stages of developing the new amendment, meetings can be held with regulatory heads to compare each board's approach to SGBA+. Additionally, as Health Canada periodically checks the impacts of the new policies, formal feedback can be provided by these international bodies to share information and further improve the solution.

Indirect Impact

Important but not Essential



ICH

International Council for Harmonization (ICH) **externally** provides international regulatory guidance and identifies opportunities for harmonized sex-based standards.

Priority & Power	The EMA and FDA are also regulatory members of ICH and hope to follow these guidelines. If ICH agrees to adopt Health Canada's guidelines sought in the amendment, other countries and their regulatory bodies would automatically follow to perform proper research. This makes ICH have **more influence on this project** than other regulatory boards themselves, yet **not as important** as proposing an amendment or revising the Health Canada guidance.
RACI	Just as the international regulatory boards, Health Canada will **consult** with ICH, where ICH guidelines and Health Canada's regulations will be compared to share information on gaps in both and understand how to better harmonize between nations.
Engagement Goal & Success Criteria	As Health Canada is an ICH regulatory member and uses ICH guidelines to practice good science, **a collaboration** should be had with ICH to address **gaps that Canada currently faces in implementing SGBA+** within preclinical and clinical drug trials to improve its proposal to the Canadian cabinet and its guidance document on SGBA+. Additionally, Health Canada should provide **recommendations to ICH** to improve their international guidelines, adopted by all regulatory members worldwide.
Concerns & Likely Reactions	ICH has committed to providing requirements for nonclinical testing, yet there are no broad guidelines that address their sex-based analysis. Thus, they may **be receptive** but might want evidence that shows that the mandatory approach is justified (actually improved outcomes). They might also question whether this issue **warrants changes** to the international guidelines.
Engagement Strategy	When working on the amendment proposal, **meetings with ICH** can be held before talking to the Minister of Health. Additionally, when suggesting changes to ICH's guidelines, initial meetings can address potential changes, and over time, Health Canada can aid in guideline development if needed.

Indirect Impact

Highly Important 

CIHR

Policy Alignment and Co-Development

- Health Canada establishes explicit, legally binding SABV definitions and data-stratification metrics
- CIHR partnership translates Health Canada's regulatory requirements into funding requirements

Pre-approval

- CIHR introduced mandatory, certified SABV experts to every grant review panels

Post-approval

- Continuous monitoring to enforce SABV analysis
- Timely progress reports detailing sex-disaggregated enrollment data

RACI	Responsible for upholding their commitment to SGBA+ guidelines. **Consulted** by Health Canada on the design of the standard, because of their expertise in basic research.
Engagement Goal	Align CIHR funding requirements with Health Canada's proposed regulatory requirements.
Success Criteria	CIHR agrees to participate in a joint working group with Health Canda. Common SABV criteria are developed.
Likely Reactions	Generally supportive, because the policy builds on CIHR's existing SGBA framework. CIHR may caution against unnecessarily strict requirements and emphasize scientific justification for single sex studies.

Indirect Impact

Essential ★★★★★

NIH

Policy Benchmarking and Implementation Learning

- NIH's SABV policy provides an establish model for integrating sex into federally funded biomedical research.
- Recent evidence shows that policy adoption does not necessarily translate into sex-based analysis, identifying implementation gaps that Canada can address

Policy Development

- NIH advises Health Canada on effective SABV definitions, reporting standards, reviewer guidance, and scientific justification for sing-sex studies.

Implementation and Monitoring

- Canada uses NIH evidence to establish measurable SABV compliance indicators throughout the research process.
- Ongoing Canada-US knowledge exchange identifies implementation barriers and effective strategies.

RACI	**Consulted** by Health Canada to provide expertise on implementation based on its established SABV policy and peer review framework. NIH stays **informed** of Canada's progress and any emerging evidence or challenges.
Engagement Goal	Learn from NIH's expertise and any existing gaps in implementation to develop an evidence-based standard in Canada.
Success Criteria	NIH participates in a policy consultation with Health Canada. Key implementation lessons are incorporated into Canada's SABV framework. Common metrics and best practices for SABV implementation are identified
Likely Reactions	NIH will probably be generally supportive, they may emphasize maintaining scientific flexibility and allowing researchers to

Indirect Impact

Important but not Essential



Apotex

Regulatory & Market Context

- Canada's largest generic/biosimilar manufacturer (~$5B revenue, ~8,000 employees, 550+ products)
- Abbreviated New Drug Submissions (ANDS) submissions rely on the originator's existing preclinical package, so exposure to a new dual-sex animal-model mandate is limited today

Compliance Expectations

- Sex-disaggregated adverse-event/pharmacovigilance reporting for generics and biosimilars post-market
- Confirmation, via CGPA-led consultation, that standard generic submissions won't require duplicative new preclinical studies

RACI	Consulted & Informed – provides feedback on regulatory feasibility for generics/biosimilars; not Accountable or Responsible for setting the standard (Health Canada's role).
Engagement Goal	Preserve an efficient, low-cost generic pathway while confirming Apotex can rely on the originator's sex-disaggregated data without duplicative testing.
Success Criteria	Apotex confirms no new preclinical studies are required for standard generics. Apotex/CGPA participate in the industry consultation on the revised standard.
Likely Reactions	Neutral to mildly cautious given low direct impact today. Could turn resistant if the mandate later extends to biosimilar comparability studies.
Engagement Plan	Represented through the Canadian Generic Pharmaceutical Association (CGPA) rather than direct bilateral meetings. Written comment period on draft guidance; semi-annual regulatory briefings.

Indirect Impact

Important but not essential



Sanofi Pasteur

Pharmaceutical Industry

Role in Canada's Vaccine R&D

- Operates Sanofi's North American vaccine R&D and manufacturing hub (Connaught Campus, Toronto; ~300 R&D staff), running its own preclinical research
- Sex differences in vaccine-induced immunity are well documented (stronger antibody response but more adverse events in females), making SABV directly relevant

Compliance Expectations

- Adoption of dual-sex animal models and sex-disaggregated immunogenicity/adverse-event analysis in preclinical vaccine development
- Public sharing of sex-disaggregated findings to help build the evidence base for Part II of the policy

RACI	Consulted & Informed – technical input on dual-sex animal protocol feasibility; not Accountable or Responsible for the regulation itself.
Engagement Goal	Align Canada's requirement with existing FDA/EMA SABV expectations so preclinical testing isn't duplicated across markets.
Success Criteria	Sanofi Pasteur joins a Health Canada pilot working group. A phased implementation timeline is agreed upon.
Likely Reactions	Cautiously supportive, drawing on existing sex-differences immunology expertise. Concerned about added R&D cost/timelines and competitive disadvantage if Canada's requirements exceed peer markets.
Engagement Plan	Invited into a Health Canada-industry technical working group/pilot program. Coordinated sector-wide through Innovative Medicines Canada, with advance briefings ahead of formal consultations.

Indirect Impact

Important but not essential ☆☆★★★

SWHR - Society for Women's Health & Research

Patient advocacy groups play an important role in supporting patients, educating communities, advancing research, influencing policy, and providing a voice for people whose experiences are often underrepresented.

RACI	**Consulted -** targeted consultation sessions with SWHR's Clinical Advisory Board on gaps in sex-disaggregated data and proposed regulatory requirements, with SWHR advocating for a shift away from the male-normative model beginning at the preclinical stage.
Goals/Success criteria	✓ Feedback provided on the proposed regulatory requirements ✓ Key concerns and recommendations communicated through consultation ✓ Awareness raised about gaps in sex-disaggregated preclinical data
Likely reactions	**Supportive -** aligns with SWHR's position statement to expand the exploration of SABV in preclinical and clinical research activities.
Potential concerns & issues	May bring up concerns to advocate for broader consideration of women's health beyond biological sex alone (race, SES, age, etc).

Engagement Plan

Type of Engagement Activity	Engagement Tool	When / How often
Targeted consultation session (virtual)	Virtual meeting with SWHR's Clinical Advisory Board to provide feedback on gaps in sex-disaggregated preclinical data and the proposed regulatory requirements.	Once during policy development, with additional written feedback as needed.
Advocacy & awareness	Engage SWHR to use its policy and educational platforms to raise awareness of the lack of sex-disaggregated preclinical data and advocate for moving beyond the male-normative research model.	At implementation, with ongoing advocacy through SWHR's existing platforms and initiatives.

Indirect Impact

Important but not Essential



CEWH - Centre of Excellence for Women's Health

CEWH is a research and knowledge-exchange centre that works to improve women's health and advance gender equity. Its strong connections across research, policy, and community settings make it a valuable stakeholder.

RACI	**Consulted** - engage CEWH for its experience implementing SGBA+ and knowledge exchange to raise awareness and advocating for sex-disaggregated preclinical evidence and its importance in moving research beyond the male-as-default model, strengthening the foundation for downstream SGBA+ application of drug development.
Goals/Success criteria	✓ Knowledge-translation resources developed/disseminated ✓ Awareness raised through CEWH's research and policy networks ✓ Importance of preclinical sex-disaggregated data communicated to relevant audiences
Likely reactions	**Supportive** - aligns with CEWH's focus on improving women's health through a SGBA+ lens.
Potential issues/concerns	May emphasize that preclinical sex-disaggregated data are only the starting point and should be carried into later stages of drug development, needing broader SGBA+ considerations.

Engagement Plan

Type of Engagement Activity	Engagement Tool	When / How often
Targeted consultation session (virtual)	Virtual meeting with CEWH representatives to discuss how its knowledge-exchange capacity can support awareness of gaps in sex-disaggregated preclinical data.	Once during policy development/implementation planning.
Posting & dissemination of information	Educational resources for researchers and policymakers and distribute them through CEWH's website, webinars, publications, and existing networks.	At implementation, with the resource remaining available for ongoing knowledge exchange.

Indirect Impact

Important but not Essential



References

Thank you!

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References

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