



Canada Self-Care Products: new regulatory framework proposal

IADSA Issue Highlights Session

16 MAY | SEOUL

Self-care products

Health Canada considers 3 types of products used by consumers to improve appearance, maintain health and treat minor ailments



Cosmetics

for cleaning, improving or altering the complexion, skin, hair or teeth, such as moisturizing creams, deodorants, and shampoos



Natural Health Products (NHP)

includes vitamin and mineral supplements, probiotics, herbal preparations, homeopathic remedies, and traditional medicines, (including some personal care products with health related claims)



Non-prescription drugs

"over-the-counter drugs" including products for pain relief, cold and flu symptoms, and allergy relief.



Why a new framework proposed?

Cosmetics, Natural Health Products (NHP), non-prescription drug products are intermingled on store shelves based on “condition for intended use”



Same or similar claims – Health Canada concerned that consumers will be misled that the products are equally effective with same rules and oversight (i.e. toothpaste)



Cosmetic



NHP



non-prescription drug

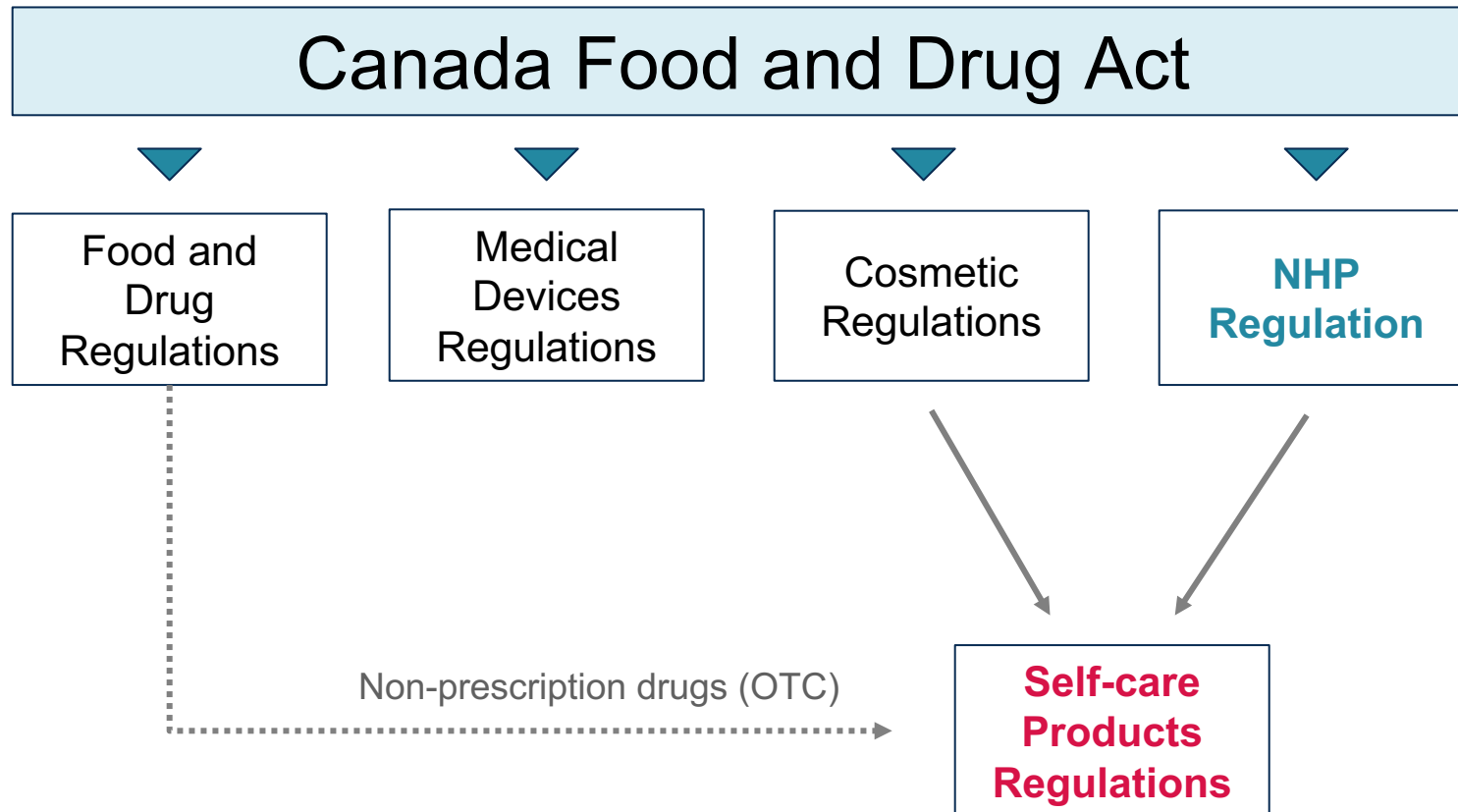


Current Framework

	Cosmetics	NHP	Non-Rx drug
# of Products	43,974 (notified in 1 year)	>100,000 approvals	5,000
Market Access	Notification (of product ingredients) within 10 days	Product License (review safety & efficacy) Class I, II, III (risk based) 10, 30, 180 days	Registration Similar to Rx-Drug
Label indication	--	NPN or DIN-HM (homeopathic)	DIN
Efficacy standard	No claims about health	Modern claim: - Scientific evidence Traditional/homeopathic claim: - history of use, encyclopedias of health & wellness philosophies	Standard similar to Rx drug - Scientific evidence
Quality standard	Sanitary Conditions	Site License - Submit documents to demonstrate meet GMP standard	Licensed facility - Requires Health Canada inspection of GMP standard
User Fees	no	no	yes



Regulation Proposal



Consultation Report

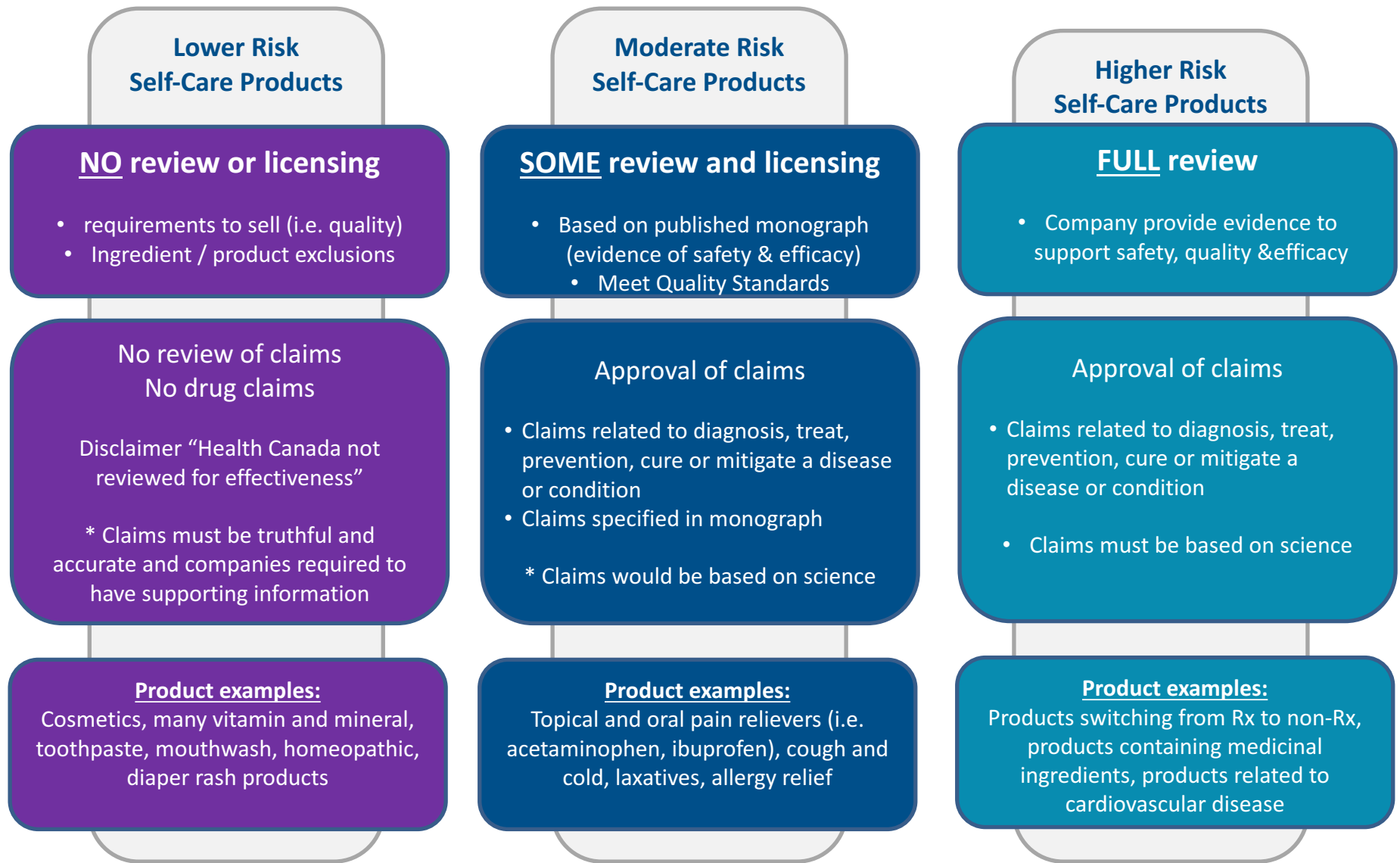
<https://www.canada.ca/en/health-canada/programs/consultation-regulation-self-care-products/full-report.html>

Risk-based approach

- Level of oversight corresponds to the risks posed by particular health products so that products of similar risk profiles treated in a similar manner.
- Ensure that the **benefits** of a product outweigh any known **risks** (based on safety and concern if efficacy fails).
- The identified level of risk determines:
 - ✓ amount and type of information Health Canada needs to review
 - ✓ degree of scrutiny necessary before the product can be made available
 - ✓ level of monitoring for safety and compliance with the law



Proposed Risk Classification System



Next Steps

Health Canada to revise proposal based on comments and undergo further stakeholder consultation