IADSA CONNECT

#14 JULY 2024

SAVE OUR SOS SUPPLEMENTS

SWEEPING REGULATORY CHANGES THREATEN THE VIABILITY OF THE CANADIAN DIETARY SUPPLEMENT INDUSTRY

AUSTRALIA'S REGULATOR PROPOSING STRICTER REGULATIONS FOR LARGE ORAL DOSAGE FORMS

U.S. DIETARY SUPPLEMENT TRENDS: KEY ISSUES AND REGULATORY UPDATE

IADSA
International Alliance of Dietary/ Food Supplement Associations

iadsa.org

#14

CONTENTS

3 SWEEPING REGULATORY CHANGES THREATEN THE VIABILITY OF THE CANADIAN DIETARY SUPPLEMENT INDUSTRY

5 AUSTRALIA'S REGULATOR PROPOSING STRICTER REGULATIONS FOR LARGE ORAL DOSAGE FORMS

7 U.S. DIETARY SUPPLEMENT TRENDS: KEY ISSUES AND REGULATORY UPDATE

CANADA

SWEEPING REGULATORY CHANGES THREATEN THE VIABILITY OF THE CANADIAN DIETARY SUPPLEMENT INDUSTRY

Canadian Health Food Association (CHFA) is Canada's largest trade association dedicated to all things natural, organic and wellness. Since 1964, the association has grown from a grassroots community of health food pioneers to an organization representing over 1,000 member businesses across Canada.

In spring 2023, Health Canada announced The Proposed Fees for Natural Health Products (cost recovery), which will be rolled out to Canadian-regulated natural health products (dietary supplements) in 2025 alongside mass scale labelling changes and a new legislation that introduces massive fines for non-compliance.

The proposed costs are not just excessive; they are potentially devastating, and response from both consumers and industry fierce and widespread. Many companies detailed the ramifications of this program on their business' viability in the Canadian market, with tens of thousands of responses submitted to the public consultation.

Overall, this proposal has been a solution in search of a problem. From its conception, there has been a lack of analysis, as part of proper regulatory process, on the impacts a program like this would have on Canadians, businesses, women, or those in marginalized groups or remote communities. This lack of consideration is deeply concerning and should not be overlooked.

Unfortunately, lack of analysis remains a running theme. The original Cost Recovery proposal (published in Canada Gazette I, May 2023) aimed to recoup $100M annually from the sector. The lack of cost-benefit analysis left businesses to do the math on whether they could afford to stay afloat - which many small to medium-sized companies realized would be near impossible. A gender-based analysis was also sorely missing, failing to recognize the disproportionate effects that these changes would have on women and women-led businesses in the sector.

The updated proposal (March 2023) attempts to reduce industry rates but still poses a significant financial burden, requiring hundreds to thousands of dollars for compliance. As the head of Health Canada, the Minister of Health has not justified this proposal adequately. Initially presented as a response to a failed Auditor General Report, most program modernizations and efficiencies have since been cancelled. In fall 2023, during a committee testimony, the Natural and Non-prescription Health Products Directorate (the branch of Health Canada that oversees natural health products) cited the need for increased regulation to ensure health and safety. However, a 2023 Deloitte study confirmed the safety of natural health products, which Canadians have trusted for decades.

Aaron Skelton,
President and Chief Executive Officer,
Canadian Health Food Association (CHFA)

The Save Our Supplements campaign, spearheaded by the Canadian Health Food Association, is now well into its second year. The response has been tremendous, with many Members of Parliament citing the campaign as the largest they have seen on Parliament Hill in recent memory. Despite this overwhelming response from the public and industry on the implications these changes will have on access to healthcare and the economy, Health Canada remains silent.

This silence will not only impact Canadian businesses, but it has potential to create trade barriers for foreign countries exporting legally into Canada. This issue has already been raised in the United States through official trade complaints given the disproportionate and significant amounts foreign manufacturers will be impacted by.

Health Canada's changes do not reflect the reality of the industry or the values of over 80% of Canadians who prefer natural health products. It is crucial for Health Canada to reset and address the damaging effects it has created through their piecemeal, unstudied, and poorly consulted regulations. The Minister of Health must collaborate with the industry to establish priorities based on proper consultations with key stakeholders, ensuring a well-informed, balanced natural health product framework that meets the needs of Canadians and businesses in this sector.

chfa®

John O'Doherty,
Chief Executive Officer,
Complementary Medicines
Australia (CMA)

AUSTRALIA'S REGULATOR PROPOSING STRICTER REGULATIONS FOR LARGE ORAL DOSAGE FORMS

Complementary Medicines Australia (CMA) is the industry body for the complementary medicines industry, representing members across the supply chain, including manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality. CMA aims to improve public health and wellbeing through education and information on the use of complementary medicines, to support and enhance a robust complementary healthcare products industry, and to support the ethical and responsible promotion of complementary medicines.

The Therapeutic Goods Administration (TGA), Australia's regulatory body for medicines, has ignited debate with its proposed labelling changes for large oral dosage forms such as tablets and capsules that are complementary medicines (dietary supplements) intended to be swallowed whole.

This move stems from growing concerns about the choking hazard these large dosage forms may pose, particularly products such as fish, krill or omega 3 oil capsules, glucosamine/chondroitin, calcium/magnesium, and multivitamin/mineral tablets.

The proposed regulatory changes are driven by adverse events, with the TGA highlighting the choking hazard posed, particularly by vulnerable populations like the elderly. Australia has a strict pharmacovigilance system for complementary medicines, requiring businesses to report any serious reactions to products. Businesses can be subject to pharmacovigilance audits to ensure they are complying.

To date, the TGA has addressed choking risks on a product-by-product basis where reactions have been recorded, but is now advocating for broader regulatory action to mitigate risks for all large complementary medicines.

The mandate would apply to all dosage forms that are wider than 9mm, or longer than 22mm, and intended to be swallowed whole. CMA's preliminary industry survey suggests this affects approximately one third of all complementary medicines in Australia. Controversially, equivalent changes are not being proposed for Over-the-Counter medicines such as paracetamol (acetaminophen) or prescription-only medicines, which CMA believes is labelling policy that will be confusing for consumers.

Labels would be required to show a photo or line drawing of the actual tablet or capsule size – unless they can be seen through transparent product packaging – as well as the words 'actual size', 'swallow with water' and 'Warning: Large tablet' (or capsule). It is proposed the changes are introduced in the short space of just two years.

The proposed regulations have sparked concerns within the complementary medicines industry, with some questioning whether the proposed tablet (capsule) dimensions actually reflect the evidence of choking risk.

Complementary Medicines Australia (CMA), the peak industry body representing stakeholders across the full complementary medicines supply chain in Australia, is concerned the TGA's proposed changes have not been fully assessed, risking regulatory overreach that could negatively impact the industry without significantly enhancing consumer safety.

Updating labels to meet the new requirements to a huge range of products will incur additional and significant costs for businesses, and may not even be able to be completed by some within such a short timeframe.

The increased compliance costs will also drive up the prices of some products, making them less affordable for consumers who are already facing a cost-of-living crisis in Australia.

This proposed approach by the TGA is unique, setting Australia apart from its international counterparts. For example, the US Food and Drug Administration (US FDA) offers only guidance recommendations to businesses on size and shape of pharmaceutical products, leaving the onus on manufacturers to minimise choking hazards. In New Zealand, advice is provided to consumers of pharmaceutical medicines, but there are no specific industry mandates.

While industry had offered to work cooperatively with the TGA on this safety measure, the proposals affect far too many products in far too short a timeframe, and that it is important that the TGA move to a more a balanced response.

While the safety concerns raised by the TGA are important to some consumers, particularly for the largest tablets and capsules, these concerns are the same regardless of whether the medicine is complementary, over the counter or prescription. It is crucial to implement balanced solutions that do not inadvertently harm consumers by reducing access to or increasing costs of complementary medicines that benefit their health and wellbeing.

CMA are currently surveying our members to determine the extent of the impact and alternative regulatory options for a balanced outcome.

cma Complementary Medicines Australia

Loren Israelsen,
President & Founder,
United Natural Products
Alliance, U.S.A.

U.S. DIETARY SUPPLEMENT TRENDS: KEY ISSUES AND REGULATORY UPDATE

United Natural Products Alliance (UNPA), is a leading US trade association that collaborates closely with industry leaders, government agencies, and stakeholders to champion responsible business practices. It advocates for standards that ensure consumer safety, access to reliable health information, and well-trained health practitioners.

30 YEARS OF DSHEA

The U.S. dietary supplement industry has grown from $4.5 to $65 billion in 30 years. This is largely due to the Dietary Supplement Health and Education Act of 1994 (DSHEA), now 30 years old in 2024. DSHEA was written to afford consumers maximum access to dietary supplements while setting requirements for GMPs, safety of new ingredients, and acceptable claims.

DSHEA is widely seen as one of the most liberal of dietary supplement legislation around the world. This is so because of a very active consumer base that lobbied hard for DSHEA and to protect its status. We feel that active consumer engagement with government leaders and regulators is central to a regulatory system for supplements that is not overly burdensome and yet establishes necessary rules. We realize this may be a unique aspect of American culture, but so far it has served us well.

THE FUTURE OF DSHEA

We do not see any credible efforts to amend this law. FDA has advocated for mandatory product listing (MPL). Given the partisan atmosphere in Congress and November elections, we do not see MPL as viable legislation.

FDA

The food side of FDA (Center for Food Safety and Applied Nutrition) has a new leader, Mr. Jim Jones. Formerly a longtime EPA official, Mr. Jones is making changes to the organization, its structure, priorities, and even its name, which is now the Center for Human Foods. His focus is on food chemical safety. Greater attention will be given to food additives, colors, flavors, and excipients. In addition, heavy metals, herbicides, pesticides, PFAS, microplastics and naturally-occurring toxins will be of interest.

Previously, FDA's focus was on the Food Safety Modernization Act (FSMA), which is a process. Now the focus is on food chemical safety – the products. We believe this will affect the U.S. botanical sector, in particular.

E-COMMERCE

Amazon continues to dominate the e-commerce channel. Dietary supplements have been a challenge, with concerns over quality, counterfeiting, fake brands, and fake certificates of analysis. Amazon-only brands are now common. These companies are unknown to us and do not participate in the supplement community. This reduces industry cohesion and discipline. The U.S. trade associations and leading companies continue to work toward improvements in the e-commerce channel.

INFLATION

Since COVID-19, inflation is a growing concern. Supplement prices have risen 10-20% in many cases. Consumers are now making hard choices including changing brands or retailers, reducing usage, or going without. Pressure on suppliers and contract manufacturers to reduce prices is high. We must be vigilant to assure product quality during this inflationary period.

ARTIFICIAL INTELLIGENCE

AI is now a daily topic of discussion viewed with either indifference, enthusiasm, or great suspicion. Areas most affected are intellectual property, whether AI can be an inventor, and who owns AI-generated IP. The rules have changed. There is great interest in AI as a research tool for R&D and innovation, market and consumer research, and reducing the work force, particularly in human resources, legal, regulatory, and accounting job functions.

U.S. SUPREME COURT "CHEVRON" DECISION

On June 28, 2024, the U.S. Supreme Court handed down a historic decision on the Loper Bright Enterprises v. Raimondo case. This case rejected a 40-year-old Supreme Court precedent known as "The Chevron Standard" that required courts to defer to government agency interpretations of federal law. This meant agencies like FDA, FTC, and EPA had a major advantage if industry disagreed with or disputed the agency's regulations as not reflecting the intent or language in statutes. Now the courts will no longer give deference to government agencies' interpretations of laws. All industries are carefully studying how this case will affect future litigation and perhaps a more cautious approach by agencies, who now fear they will lose in court when industries challenge their regulations. This certainly will apply to the dietary supplement industry.

CHANGES IN CULTURE AND CONSUMER ATTITUDES

Post-COVID public trust in government generally, and FDA specifically, has sharply fallen. There are various reasons, but the key factor is the fragmentation of trusted sources away from government experts and institutions and in favor of influencers and social media. This has created the misinformation wars. Our U.S. supplement industry sees the powerful role of influencers on consumer attitudes and brand and product preferences. This creates new challenges for companies on how to develop and promote their brands, challenges for FDA to regain public trust, and challenges for our industry as a whole when inappropriate information creates negative impressions or critical media news.

CONCLUSION

Our report is one of continued growth, shifting consumer preferences, disruptive technologies, and economic pressures on product pricing. FDA has new challenges with public trust as well as the Chevron case. Congress is largely seen as preoccupied with partisan politics and not DSHEA, which has proved to be a solid framework for the past 30 years. Today, adapting to rapid change will be our principal challenge, as we expect it will be for many of you.

UNPA™
UNITED NATURAL PRODUCTS ALLIANCE®

Gridiron Building
One Pancras Square
London, N1C 4AG
United Kingdom

iadsa.org

IADSA

International Alliance of Dietary/
Food Supplement Associations