Personal Care Products Council
Committed to Safety, Quality & Innovation

Thursday, January 25, 2018

Chairman of the Labor, Welfare and Health Committee
Mr. Elie Elalouf
Via email: elalouf@knesset.gov.il

Personal Care Products Council Continued Concerns with the "Pharmacists' Regulations (Cosmetics) 5773-2013"

On behalf of the U.S Personal Care Products Council, I am writing to express our industry's continued concerns with the newly re-drafted proposed Addendum to the "Pharmacists' Regulations (Cosmetics) 5773-2013" ("proposed Addendum"). We understand this will be deliberated in your Committee in the coming days, and therefore request that you review the issues raised in this letter with the utmost urgency. We remain at your disposal to discuss U.S. industry's concerns in greater detail.

As stated in our letter of August 4, 2017 (attached), Israel is an important market for U.S. cosmetics manufacturers, and therefore the outcome of this legislative process will significantly impact our members' ability to offer the most safe and innovative products to Israeli consumers.

We appreciate your interest in assuring that the proposed regulation will be aligned with international cosmetics regulatory best practices, and will be consistent with the EU Cosmetics Regulation, which is also closely aligned with the U.S. regulatory approach.

Our industry was pleased to welcome authorities from the Israeli Ministry of Health (MoH) and Ministry of Economy (MoE) to Europe this past November in order to clarify EU cosmetics regulatory policies and to observe how these policies are implemented by authorities in day-to-day practice. While we believe these meetings were informative, we are concerned that the most recent draft of the proposed Addendum remains inconsistent with the EU Cosmetics Regulation and other global practices in several important areas, and will result in barriers to trade and investment in Israel.

We have taken the liberty to outline below our most pressing concerns in the hope that these remaining issues will be addressed during the upcoming Committee and Knesset deliberations.

1. **Good Manufacturing Practices (GMP); *Chapter VI***

In the United States, European Union, and other countries around the world, compliance to cosmetic GMPs is self-certified by manufacturers and/or responsible persons. We remain concerned that the most recent draft Addendum does not adhere to this important principle,

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rather, it requires that GMP certificates be issued by a health authority or other authorized body. Such certification requirements add unnecessary time and costs to placing products on the market. The problem is compounded by the fact that certain regulatory authorities, including the U.S. FDA, do not grant GMP certificates as they rely on manufacturers' own compliance.

Request: We strongly recommend that relevant provisions be amended to allow compliance to GMPs to be self-certified via a declaration from the manufacturer or Responsible Person. We would also appreciate your support for our request to the Ministry of Health that certificates granted by our Association will continue to be allowed.

2. **Product Information File (PIF):** ***Chapter VI***

We are concerned that the recent draft continues to include the requirement that the PIF be made "immediately available" to the Ministry of Health upon request, which is highly impractical and would pose an undue burden on industry. The PIF is a dynamic, and extensive, technical document that is continuously updated. In the EU, if an enforcement authority has reason to question the product's safety, it can request relevant information in the PIF be provided within a reasonable period (usually 72 hours) to allow for the information to be assembled and translated into local language if necessary. This practice has worked well throughout the EU, allowing authorities and industry to work cooperatively to address any safety issues and to prepare for ordinary audits.

Request: We strongly recommend that MoH modify the proposed draft to require relevant sections of the PIF to be made "available within a 72 hour (or reasonable) period."

3. **Responsible Person (RP):** ***Chapter III***

Our industry has expressed serious concern that the draft regulation defines the "responsible person" as a physical person and not a legal entity, as would be the case in most countries. As envisioned in the draft regulation, the Responsible Person would have vast responsibilities, often for thousands of SKUs. These responsibilities need to leverage a corporation's expertise across a wide variety of disciplines. We believe this requirement will have a chilling effect on companies' willingness to do business in Israel, especially small and medium sized U.S. exporters, and should be reconsidered.

Request: We kindly request that the Committee allow time for further analysis of how the definition of "Responsible Person" could accommodate both the Israeli legal framework and the practical necessities of the role.

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4. Parallel Imports: *Chapter VII*

We appreciate that the recent draft places additional requirements on parallel importers in furtherance of consumer safety. However, we remain highly concerned that the proposed Addendum requires that the primary importer make the PIF available to the MoH for purposes of approving the parallel importer's permit, or in case of an adverse event related to products imported by parallel importer. These requirements would effectively skew competition by setting unfair obligations and additional costs for primary importers to support competitors and products over which they have no control. Moreover, we believe that these requirements would violate the commitments and spirit of the U.S.-Israel Free Trade Agreement, notably those contained in Article 14 on protection of intellectual property.

Request: We kindly request that the Committee amend the Proposed Addendum to address these issues and provide a level playing field for all economic actors on the Israeli market.

5. Product Notification: *Chapter IV*

We applaud the changes that have been made in the proposed Addendum, which streamline the notification process and will facilitate notification of products. We commend the MoH for their efforts to develop a user friendly electronic notification system, and we would be pleased to support future testing of the system.

We would like to point out two specific requirements in the legislation, namely for uploading of barcodes and product photos to the portal, that we believe would pose difficulties and limit companies' ability to launch innovative products in Israel at the same time as they are being offered in other countries. Barcodes and product photographs are normally available only at the last stage of production. The requirements to include these in notifications would delay placement on the market, and prevent companies from responding to consumer demands, especially for seasonal products.

Request: We kindly request that you remove product barcodes and product photographs from the notification requirements.

6. Nano Materials: *Chapter VIII*

We are highly concerned that the proposed addendum includes a special, and arduous, six month pre-submission process for products containing nanomaterials. Most regulatory authorities around the world, including the U.S. Food & Drug Administration, agree that nanomaterials are

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not inherently safe or unsafe.[1] The size of the ingredient, as well as all other ingredient properties, must be taken into consideration during the safety assessment process. In this way, nanomaterials do not differ from any other ingredient.

We are further concerned that the proposed approach does not take into account positive safety assessments of nano ingredients that have already been conducted by the European Scientific Committee for Consumer Safety (SCCS), the U.S. FDA and other authoritative bodies.

Request: We strongly urge that specific requirements related to nanomaterials be removed from the proposed Addendum, with the understanding that these ingredients will be assessed as part of the mandated safety assessment process. In any case, the proposed Addendum should not require pre-submissions for nanomaterials that have already been positively assessed by the EU and listed in relevant annexes of the EU Cosmetics Regulation.

7. Reasonable Implementation and Transition Periods

The proposed Addendum includes a one-year transition and implementation period, which we believe will be insufficient to assure a smooth implementation of the new framework. Experience in other countries has demonstrated that major changes to cosmetics regulations, such as are envisioned with the proposed Addendum, require both industry and authorities to make significant changes to policies and procedures. In most cases, authorities issue guidelines and conduct workshops on practical implementation of the upcoming framework in order to facilitate industry compliance with new requirements.

Request: For the above reasons, we strongly urge that the proposed Addendum allow for a phase-in period of at least two-four years, which would be consistent with the phase-in period given in the EU and other countries.

[1] 1 http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm301114.htm

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Conclusion

We greatly appreciate the opportunity to provide these comments regarding the proposed Addendum to the Pharmacists' Regulations. We hope that you will review and consider the points that we have raised in this submission.

Sincerely,

Lezlee Westine
President and CEO

cc: Ministry of Health
Ministry of Economy
Ministry of Justice

U.S. Trade Representative, Washington, DC
U.S. Department of Commerce, Washington, DC
U.S. Embassy, Tel Aviv

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