Cosmetics Europe
the personal care association

Director-General

Mr. Elie Elalouf
Chairman of the Labor, Welfare and Health Committee
Israel

CC:
Prime Minister and Health Minister Mr. Benjamin Netanyahu,
Deputy Health Minister, Rabbi Ya'akov Litzman
Minister of Finance, Mr. Moshe Kahlon
Minister of Economy, Mr. Eli Cohen
Minister of Justice, Ms. Ayelet Shaked
Members of the Labor, Welfare and Health Committee

Brussels, January 26, 2018

Subject : Pharmacists' Regulations (Cosmetics) 5778-2018

Cosmetics Europe is the European trade association for the cosmetics and personal care industry. The association represents the interests of the European cosmetic, toiletry and perfumery industry. Our key priority is to ensure that consumers have access to safe, innovative and sustainable cosmetics and personal care products, while maximizing the potential of our industry for innovation and growth. As well as marketing products in Europe, many members of Cosmetics Europe also export to other parts of the world; and Israel is an extremely important and vibrant market for members.

We would like to follow up on the letter we sent you on 4 August 2017 (letter attached) which included our comments on the review of the Cosmetics rules under the Pharmacist Regulations. We have been informed that the Pharmacists' Regulations (Cosmetics) 5778-2018 has recently been submitted to the Knesset and notified to the WTO.

As you know, although we welcome the initiative from the Israeli Government to align with the EU Cosmetics Regulation 1223/2009, we have raised in the past the existence in the text of specific requirements that are not in line with the EU or International practices and if implemented as such will be very burdensome for companies and will result in product importation being blocked unnecessarily, delay to market access and potential product cost increase. We had the opportunity to meet and discussed with the Federation of the Israeli Chambers of Commerce and, the Ministry of Health (MoH) and the Ministry of Economy and Industry (MoE) when they visited Brussels in November last year, and had a very helpful discussion on several issues.

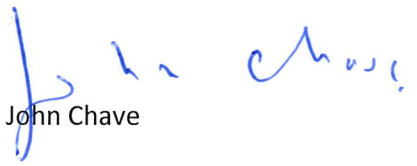
After assessing the new Pharmacists' Regulations (Cosmetics) 5778-2018, we are concerned that some of the requirements under the new proposal will not only be challenging for our members to implement but also could potentially cause legal challenges under the EU Israel Association Agreement and unnecessary barriers to trade.

We have also been made aware that Perfumes and Soaps will remain under the responsibility of the Ministry of Economy. We understand that the MoH and the MoE and Industry will have dedicated roles, and ask to get clarity on the scope of their remit and share comments on any legislative amendment that will be made by the MoH or MoE.

We welcome the ongoing collaboration we are having with Israeli authorities and we would like to propose a meeting at your earliest convenience to discuss the topics raised in this letter. We have been working as quickly as we can to translate and analyze the regulations since they were introduced last week, and we respectfully request an opportunity to seek clarification on some of the proposals found in the regulations before the Knesset moves forward. We share the Israeli government's objectives to protect both consumer safety and market access, and we would be happy to provide you with further information and to answer to any questions you may have. If you are happy with this proposal, we will send a CE delegation to Israel at a suitable date.

We hope you will find our detailed comment attached in Annex of this letter helpful.

Sincerely,



John Chave

Cosmetics Europe comments

---

1. Responsible Person

Under the EU Cosmetics Regulation, the Responsible Person (RP) can be either an individual or a company. However, the normal practice in Europe is for companies that manufacture or import the products - or for the companies that are specifically mandated by the manufacturer or the importer to serve as the RP - to take responsibility for ensuring compliance with the European Regulation. Therefore, the contact name and address to be labeled on the pack will be that of the company and not that of an individual working for the responsible company. We have noticed that the new Pharmacists' Regulations (Cosmetics) 5778-2018 refer to an actual person and not an entity. The Ministry of Health is aware of the EU position on this issue and that European companies expect to be able to designate a legal entity and not an individual as their RP in Israel. During our meeting in November, the MoH highlighted the fact that Israel's primary legislation defines a responsible person as an individual with full civil, administrative and criminal responsibility for a product. The MoH committed to raise this issue with the Israeli Ministry of Justice in order to assess whether it is possible to change the interpretation of the existing legislation and shift responsibility to a company as per in EU. Given that the cosmetics portfolio of an RP can cover thousands of products it is not feasible for a single natural person to have all the technical competences and time to personally carry out all duties for each and every product. Also we would like to stress that no one person needs to read the entire PIF before placing the product on the market. It is usually a work done by dozens of people within a company. The RP also have to ensure that a system to manage undesirable effects is in place. The management of customer complaints is normally fulfilled by several people inside a company not just one person. Having all RP obligations to be fulfilled by one person will be very challenging for the company and the individual. This is a

critical issue for our members and therefore we would like to really stress the fact that the new law should provide the option for the RP to be a legal entity.

- **Submission of quarterly reports for every product**

We understand that the new Pharmacists' Regulations (Cosmetics) 5778-2018 will require the RP to submit quarterly reports for every product. This is not in line with the EU Regulation and we are concerns that this requirement will be very challenging and time consuming for companies without providing added protection to the consumers. The PIF is a live document and the information need is **systematically updated,** every time there is a change in the data. Due to frequent updates and huge amount of data, the information is usually maintained on electronic format. Having to produce a quarterly report is therefore unnecessary and will impose additional administrative burdens on the RP. We would therefore recommend reconsidering this obligation.

2. Product Notification

The European industry welcome the move from a registration system to a notification system proposed under these new rules to guarantee immediate market access as is the case under the EU Cosmetics Regulation. At the same time, we would like to seek clarity on the content of the notification as well as the notification portal itself.

- **Bar code**

We understand from this list that the notification will include the barcode entry. This means that companies that do not have barcode on their products, due to the specificity of their supply chain, will not be allowed to notify their products under the new system and consequently will not be authorized to place their products on the Israel market anymore. We believe this presents a clear barrier to trade and will not bring any gain in term of consumer safety.

- **Notification Portal**

We understand that the Ministry of Health intends to organize a trial project to ensure that the future notification portal is user-friendly and sustainable. Company members of Cosmetics Europe would appreciate the opportunity to participate in such trial and share with the Israeli authorities the experience gained through the implementation of the CPNP in the European Union.

- **Ingredient names**

Ingredient names in the notification may be quoted following INCI (International Nomenclature of Cosmetic Ingredients) and CosIng EU database reference number; the EU legislation also allows chemical identification should INCI or CosIng not be available, this is the case for new ingredients not yet listed on INCI and CosIng.

3. Product Information File (PIF)

We noticed that under the new proposal, the Product Information File (PIF) shall be available at any time for examination by the Ministry of Health. We raised previously the challenge of having to provide the Product Information File immediately to the authority and the implication such request, which differs from the EU interpretation, will have on businesses. This has been discussed at our November meeting with the MoH, and we welcome the fact that the authorities were open to consider the EU approach. The MoH explained that routine inspections will be scheduled, but there should be an option to have an immediate inspection of the

PIF. The common practice in the EU is that PIFs must be made available to national competent authorities at the RP premises in order to address specific questions that arise during in market control, for example, in the event of an alleged reaction to a product or a quality issue. There may also be routine inspections. These are normally preceded by a notice period that is understood to be 72 hours or that is mutually agreed between authorities and the RP and can vary up to 7-10 days. In the context of the in-market control, when the EU control authorities request to have access to the PIF, they are not expecting to have an immediate access to the entire PIF. This is captured in the notion of "readily accessible" stated in the EU Cosmetics regulation. The EU Regulation does not require for the entire PIF to be located at all time at the PIF address (some of the information is located at company labs). The address on pack is the place where the information should be readily available for inspection. Requirements that go above and beyond the "readily available" approach would add additional burdens to companies seeking to operate in Israel's market without adding protection to consumer safety.

- **Content of the PIF**

We would like to get clarity on the content of the PIF under the new Pharmacists' Regulations (Cosmetics) 5778-2018, in particular with regard to the requirement for the RP to keep the information and documents, including copies of invoices, relating to the identity of the distributors and retailers of the product for a period of at least 5 years from the marketing date. Identification of the supply chain is taken into account under article 7 of the EU Regulation. The RP, at the request of a competent authority, shall identify the distributors to whom they supply the cosmetic product for a period of three years following the date on which the batch of the cosmetic product was made available to the distributor. There is no obligation regarding the format of such information, and therefore it could be an invoice but also any other information that could fulfil this obligation. We would recommend aligning with the EU approach as it could reduce administrative burden without compromising the objective.

4. Good Manufacturing Practices

Unlike the EU, the Israeli Ministry of Health indicated that GMP self-certification by manufacturers will not be accepted in Israel, the expectations being that GMP certificates are issued or validated by competent authorities in the country of origin. If no flexible approach is warranted for GMP compliance certification in Israel, exports to this country will be severely impacted given the impossibility for companies to obtain GMP certificates satisfying the Ministry of Heath's requirements in their respective countries.

In its dialogue with Cosmetics Europe, the Ministry of Health has shown openness to consider the European situation and to look at other possible options. We noticed in the new proposal that companies will have to provide a certificate from a health authority or any other authorized body in the State of production recognized by the Ministry of Health, certifying that the product is manufactured under proper production conditions or that the production site complies with ISO 22716; It is also stated that the Ministry of Health shall publish the list of authorities and bodies as stated on its website.

At the moment it is still unclear what the practical options envisaged by the Ministry of Health will be. Such requirement to have GMP certification form an authority is not in line with the the EU cosmetic regulation or any international practice across the world. The EU Regulation specifically mentions GMP self-certification and having to provide authority or other bodies documentation on this issue will be very challenging and will create barriers. It is therefore critical that we engage further with you on this issue in order to discuss potential solutions that can be actually met by cosmetics companies. Cosmetics Europe would like to propose that self-certification is reconsidered.

5. Parallel Imports

Cosmetics Europe considers that primary importers and parallel importers should be subject to identical requirements as is the case in the EU, and that parallel importers should take full responsibility for the products they place on the Israeli market.

We understand from the new proposal that the Ministry of Health may approach the official Importer's responsible person and ask to inspect the Product Information File of a certain product for the sake of approving the permit for a parallel imported product. It would be unfair to impose obligations on primary importers with regard to products imported by other economic operators, and over which they have no control. Even though the process established under the new proposal requires a permit for high risk products, the mere fact that the products are in circulation in other markets does not guarantee that the products are genuine or intended to be marketed in Israel by the manufacturer or the brand owner.

Cosmetics Europe also considers that such incentive for parallel imports in Israel may contradict the commitments taken under Article 39 of the EU-Israel Association Agreement, if it becomes impossible for brand owners, as a result of this policy, to protect effectively their trademark rights or their other intellectual property rights in Israel. In addition, the European industry seeks clarification on the enforcement of the rules for parallel importers and what options, if any, main importers will have to seek redress if the rules are not followed

6. Nano notification

The requirement to pre-submit a PIF to the MOH 6 months ahead of launch for any product containing a nano ingredient is very concerning. Cosmetics Europe understands these requirements is present both for new nano-materials and for established ones that are already listed in the Annexes of the EU legislation. For those materials in their nano form (e.g. carbon black, zinc oxide and titanium dioxide plus a few others) the EU industry asks that this requirement is reconsidered. The listing on EU annexes shows that these materials have gone through very extensive scrutiny and have a favourable opinion (in their nano form) of the EU Scientific Committee for Consumer Safety (SCCS). The EU industry believes the pre-market submission amounts to a pre-market authorization thus defeating the purpose of notification for this specific category of products using nano-ingredients. We would be willing to accept that for new nano-materials that are not listed in any EU annexes the pre-notification process remains. This would be a more aligned situation to the EU legislation.

7. Implementation period

Finally, we would like to stress the fact that sufficient period of time is needed to ensure the functioning of the new notification system prior to implementing the new regulation. We would recommend a transition period of at least one year to implement the new legislation and at least 6 months after the notification portal is fully functional, to ensure that companies comply with the new requirements and to avoid blockages at the borders. On top, industry will need time to adapt and potentially produce new artwork in line with the new regulatory requirements. It is important to note that when the notification system was introduced in Europe in 2013 it happened after a 4 years transition time (legislation published in 2009).