British Association of Dermatologists

MHRA consultation: revision of European legislation on medical devices

Dear Madam/Sir,

The British Association of Dermatologists would like to thank the MHRA for the opportunity to comment on this consultation on the revision of European legislation on medical devices. Please find below our comments, prepared by the Therapy & Guidelines sub-committee of the association.

Cosmetics

With regards to dermal fillers, we agree with the suggested changes in 1.3 – substances which are absorbed or dispersed in the human body should be excluded as medical devices. Absorbable dermal fillers fit into this category and should therefore be considered prescription-only medications (POMs). Substances such as hyaluronic acid, the most popular type of absorbable dermal filler, are not "inert." They can be used for medical purposes (linear morphoea, HIV-associated lipoatrophy) or for cosmetic, anti-ageing procedures. The indication (medical vs. cosmetic) does not alter the inherent risks of the procedure. It is well established in the medical literature that absorbable and non-absorbable (permanent) dermal fillers can result in complications which require medical and surgical intervention. These complications can be chronic and severely debilitating. Absorbable and permanent/non-absorbable fillers can result in skin necrosis, ulceration and permanent scarring, permanent nerve damage and permanent blindness.

Dermal fillers are injected freely into the tissue, and are not encapsulated like a breast implant. Therefore the tissue reactions which can potentially occur are similar to those of a ruptured breast implant.

We also agree with the need for an implant card (section 12, p18) or clear medical records with the ability to trace dermal fillers products. Dermatologists have noted patients who believe or were told they had hyaluronic acid injections (temporary filler) only to present 5-10 years later with granuloma formation (a tissue reaction similar to that seen in tuberculosis or sarcoidosis) to a permanent filler, proven with skin biopsy. This indicates at best the patient was confused about the injected product, and at worst that the practitioner was injecting fraudulent product. These cases have been presented at scientific meetings.

The concern regarding de-regulation of those allowed to inject dermal filler combined with its classification as a medical device causes grave concern amongst dermatologists, who favour reclassification of dermal fillers as POMs.

Lasers

(Questions 3-5)

We are not sure what the definition of 'without medical purpose' is. Again, these devices can be used for medical or cosmetic application. In fact, most were initially developed for the treatment of disease. The indication for treatment (medical vs. non-medical) does not alter or

mitigate the inherent risks of the procedure. Adverse events as a consequence of inappropriate laser treatment such as burns, dyspigmentation and permanent scarring is a very common occurrence; dermatologists who engage in medico-legal work report they are frequently asked to comment as expert witnesses on such cases.

We feel that any lasers or intense pulsed light devices whether or not they have a medical purpose should be included in legislation.

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On behalf of the British Association of Dermatologists' Therapy & Guidelines sub-committee