SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for comments: The US FDA draft guidance "Over-the-Counter Sunscreens: Safety and Effectiveness Data."

1. BACKGROUND

The discussions under the Transatlantic Trade and Investment Partnership (TTIP) on cosmetics follow ideas put forward jointly by the EU and US cosmetics industry and the existing cooperation between the EU and US regulators under the International Cooperation on Cosmetics Regulation (ICCR).

There are certain differences in the way cosmetics are regulated in the EU and the US. The main US legislative instrument of most relevance is the Federal Food, Drug and Cosmetic Act (the FD&C Act), which is administered by the Food and Drug Administration (FDA). The FD&C Act does not require cosmetic products and ingredients to be approved by the FDA before placing them on the market, with the exception of colour additives (other than those intended for use as coal tar hair dyes). These products must nevertheless be safe for consumers under the labelled or customary conditions of use, and as such cosmetic firms are responsible for due diligence and safety evaluation for their ingredients and products before marketing. Sunscreen products are however regulated differently in the US - as over-the-counter (OTC) drugs - that are also subject to certain dosage and labelling restrictions. The UV filters used in sunscreens are regulated in terms of compliance against pre-set standards (i.e. already approved monographs) before being allowed for use in sunscreen products. The labelling requirements define whether a sunscreen product is 'broad spectrum' – i.e. with a sun protection factor (SPF) of ≥15 and can protect against both UVA and UVB, or not broad spectrum and with ≤14 SPF. Labelling is also limited to a maximum SPF value on a sunscreen label to 'SPF 50+'. Additional data are required on safety and effectiveness of certain sunscreen products formulations - such as in spray forms - to determine whether they present a safety concern if inhaled unintentionally.

In 2014 the US Congress passed the bill 'Sunscreen Innovation Act' with the objective of speeding up the approval of UV filters. The bill does not change the classification of UV filters as OTC drugs but sets deadlines to be respected during the assessment. A number of implementing guidelines in support of the 'Sunscreen Innovation Act' were published on 23 November 2015 for public comments until 22 January 2016.

In the context of the TTIP, an active interaction between the SCCS and FDA experts on various topics tackled in the negotiations plays an important role in achieving one of the objectives, namely regulatory convergence of cosmetics regulations between the EU and US. This entails participating in technical (video) conferences with FDA or providing written answers to US questions. Additional requests for the SCCS's assistance, such as providing written comment to US guidelines, can also be considered, subject to necessary mandates.

Against this background, it is of utmost importance that the EU provides comments on the published US draft guidance which will impact the authorisation of UV filters in the US for many years ahead. Given the scientific nature of the announced draft guidance, the comments of the SCCS experts would be very much appreciated as a major

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contribution to the general EU comments to be sent officially to the US, if possible within the commenting period.

2. TERMS OF REFERENCE

If the available information allows it, could the SCCS provide comments related to the scientific sections of the US draft guidance documents in the Annex?

3. DEADLINE:

March 2016

4. SUPPORTING DOCUMENTS

Annex

1. Over-the-Counter Sunscreens: Safety and Effectiveness Data

2. Nonprescription Sunscreen Drug Products Content and Format of Data Submissions To Support a GRASE Determination Under the Sunscreen Innovation Act