

Know-X Rapid Alert

Administrative information**Type of reporting entity:** Health**Name of the reporting entity:****Reporting country:****Reporting date:****Main contact:****Phone:****Email:****Laboratory / Authority case number:** 21/27293**Other contact:****Phone:****Email:****Sample provider:** Other (Please specify)**Date of seizure:****Sample origin:** Internet No sample provided, not asked for. Manufactured in Italy, imported to Norway sold to clinics and via the internet**Product description****Product type:** Cosmetic products Declared as cosmetics for topical use, but is advertised as products for injection.**Medical device group:****Medical device class:****Notified Body name and address for MD:****MD registered with competent authority:****Product name labelled:** Desoface and Desobody**Dosage form:** Solution for injection Vial, sterile according to declaration**Active ingredient labelled:** Deoxycholate (no strength labeled)**Strength:****Unit of measurement:** Unknown**Therapeutic class labelled:** Not applicable**Packaging type:** Packs 10 ml x 5**Primary/Secondary:** secondary**Batch number:** All**Expiry date:****Unique identifier (A list can be attached at the end):****Quantity (seized or received) and/or pack size:****Language labelling:** English And Italian**Manufacturer/Marketing authorisation holder:** Manufacturer**Name:** Love Cosmedical S.r.l. Italy**Distribution path:** Internet (give URL adress) sale via https://fillershop.no and direct to clinics**Legal status in the reporting country (from a regulatory perspective):** Unlicensed

Product assessment**Active ingredient identified:****Strength:****Unit of measurement:****Analytical information:****Mass Information****Other analytical parameters:****Details for mass information:****Outcome****Analytical conclusion:****Criminal phenomenon:** Other (Please specify) Illegal import and sale, no MA, illegal advertisement.**Follow-up / Actions****Involved authorities:** Enforcement team**Public health risk assessment:** May cause side effects**Risk communication:** Letter So far warning letter is sent, and if they do not comply, we will issue a fine.**Withdrawal / Recall information:** Distribution stopped**Additional information / comments**

These products have been marketed on-line on <https://fillershop.no> as injectables even though they are labeled with "topical use only". When injected the substance has an effect on tissue, melting cell membranes, so when injected into fat cells, fat is removed. This is not happening with topical use. There is an approved medicine Belkyra which contain the same API. There is a lot of unlicensed alternatives to Belkyra online which claims to be cosmetics and are labeled with topical use, but according to the different websites their products should all be sold to practitioners and/or only be used by skilled health professionals. This is of course because every practitioner knows it needs to be injected to have any effect. When advertised as injectables or as available treatment for injection by clinics, NoMA classifies these products as medicines.

So far the company Scandinavian Aesthetics AS (behind/owner of fillershop.no) has received a letter from NoMA. If they do not comply with the regulation and stop import, sale, advertisement and notify their customers, we will issue a fine. So far they have changed their internetpage. The case is still ongoing.

We are thinking about publishing a general warning. This is not the only case with these types of products we have had. These kind of cases seem to pop up from time to time.

Photos



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