

# Safety Notice

## Medical Devices

### DERMA C

#### Priority 2 – Warning



HPRA Safety Notice: SN2015(14)

Issue Date: 12 June 2015

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Falsified- unknown origin.	MS24223

#### ISSUE

'Derma C' is being marketed online in Ireland and in other European countries as a 'Whitening Vitamin C injection' claiming that it will moisturise skin, fade scars and dark spots, reduce wrinkles, improve skin complexion and elasticity.

The product labelling suggests that the product is a certified medical device manufactured by a company in France. It is not. The product is falsified and is not in compliance with the medical device legislation.

While the HPRA has not received any safety reports relating to this product, as a result of the above, the product's safety and performance is not known.

#### ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- 1 Do not buy or use DERMA C. If you supply DERMA C, please quarantine the product and contact the HPRA.

- 2 If you have used DERMA C or have had 'treatment' with DERMA C, stop using it immediately and consult your doctor.
- 3 Inform the HPRA if you have had any adverse incidents or reactions after having used DERMA C.

## TARGET GROUPS

General public

Beauticians

## BACKGROUND

'Derma C' is marketed as an injectable solution of hyaluronic acid for intramuscular or intravenous administration. This falsified product is intended by the manufacturer to "1) *Moisture skin*, 2) *Fade scar and dark spot*, 3) *Reduce wrinkles*, 4) *Improve skin complexion*, 5) *Increase skin elasticity*" and as a "Whitening Vitamin C injection".

The HPRA has recently been made aware that DERMA C is available to purchase on the Irish market. The product packaging claims that the product has been certified and CE-marked as a medical device by a notified body- it has not. The product packaging claims the product is manufactured by a company in France. This company has confirmed to us that they do not manufacture and have never manufactured this product, and that their company name is falsified on the DERMA C product.

The regulatory authorities in each European country are aware of this product and are following up as required.

## HPRA CONTACT INFORMATION

When notifying the HPRA of quarantined product, please contact [devices@hpra.ie](mailto:devices@hpra.ie)

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority  
Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
Dublin 2

Telephone: +353-1-6764971  
Fax: +353-1-6344033  
E-mail: [devicesafety@hpra.ie](mailto:devicesafety@hpra.ie)  
Website: [www.hpra.ie](http://www.hpra.ie)