GALDERMA

30 September 2016

Dear Healthcare Professional,

Notice on Singapore-specific instructions supplied with Restylane Lidocaine 1mL

Galderma Singapore Pte Ltd is issuing this letter to inform that some units of **Restylane Lidocaine 1mL** were found to be attached with the Singapore-specific instructions for Restylane *Perlane* Lidocaine. The potentially affected batches of **Restylane Lidocaine 1mL** are: **13918-1, 13702-2, and 13763-2.**

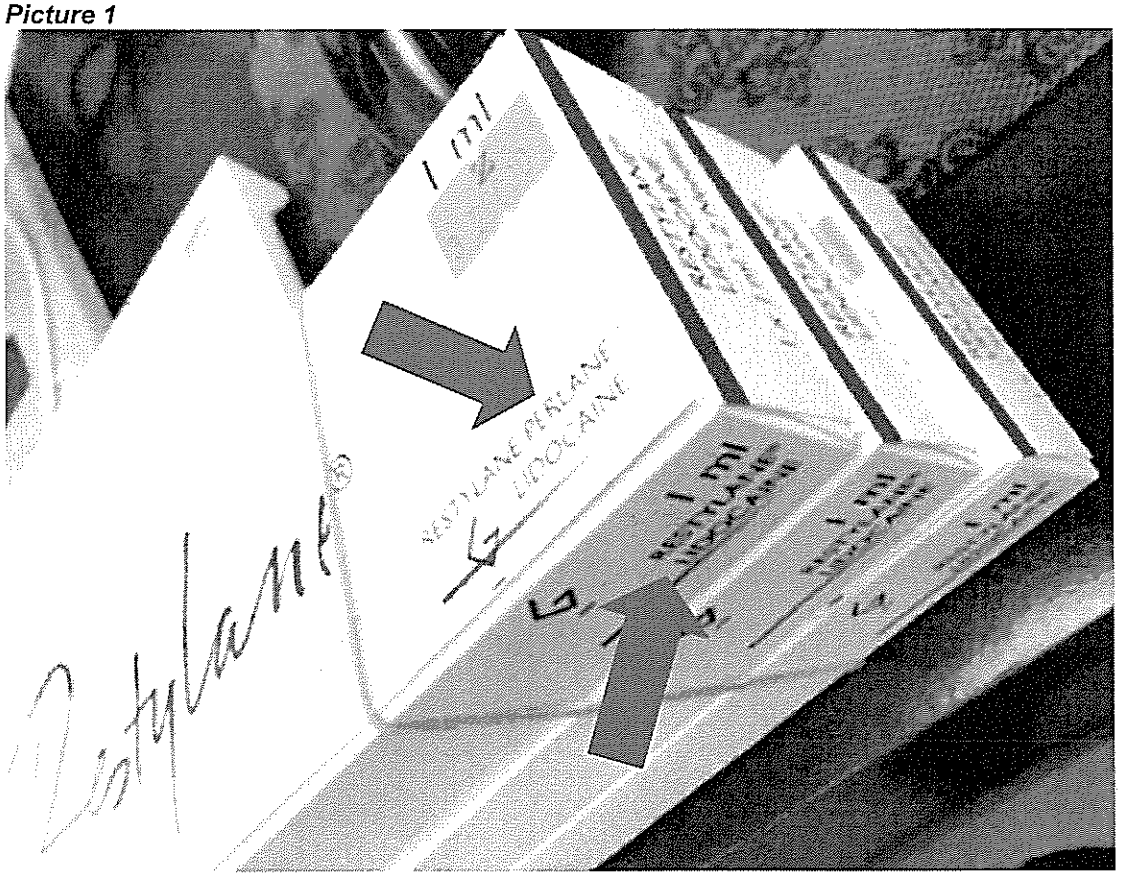
Background/Description of Problem

For the product **Restylane Lidocaine 1mL**, a sleeve containing HSA-approved, Singapore-specific instructions is usually pasted on the face of the product carton.

Some units were discovered to have the sleeve of Restylane *Perlane* Lidocaine pasted onto **Restylane Lidocaine** (refer to Picture 1). This error could hypothetically result in **Restylane Lidocaine** mistakenly being used instead of intended Restylane *Perlane* Lidocaine. However, the possibility is low, as the remaining 5 sides of the outer carton, the inner blister label and the syringe label are unaffected i.e. still reflecting the correct product name **Restylane Lidocaine**.

Based on our assessment, the risk to patients is low, as the Singapore-specific instructions for **Restylane Lidocaine** and Restylane *Perlane* Lidocaine are very similar in terms of Intended Use, and identical in terms of Mode of Action, Warning, Precautions, Adverse Events, and Treatment Procedure. There is minimal risk of injury to patients.

Picture 1



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Advisory to Healthcare Professionals

Healthcare professionals are advised to do the following:

1. *Check existing stocks of* ***Restylane Lidocaine 1mL*** *in clinic for correct sleeve attached.*
2. *If product with incorrect sleeve is found as per Picture 1, cross out the incorrect sleeve and set aside for exchange or modification (attachment of correct sleeve).*
3. *Fill in the attached Acknowledgment Form with batch number and corresponding affected quantity, and inform your area's Galderma sales representative of the affected quantity found.*
4. *If no such product is found, provide a nil reply.*

Reporting of Adverse Event

Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to Christina HSU or Angie TAN at *Tel: 6838 9383 or 68389359, Email: christina.hsu@galderma.com or angie.tan@galderma.com, Fax: 6836 3312.* Alternatively, healthcare professionals may report the adverse events to the Vigilance and Compliance Branch, Health Products Regulation Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online. Events that are reported to *Galderma Singapore Pte Ltd* will be investigated and subsequently reported to HSA.

Yours sincerely,

[redacted]

Tan Angie
Regulatory Affairs Associate
Galderma Singapore Pte Ltd

Attachments:

1. Acknowledgment Form - Restylane Lidocaine 1mL

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Acknowledgment Form - Restylane Lidocaine 1mL

Clinic Name		
Address		
Tel		
Fax / Email		
Affected Restylane Lidocaine 1mL found (sleeve of Restylane *Perlane* Lidocaine attached to product **Restylane Lidocaine)**	**Batch number**	**Quantity**
Preferred action for affected units, if any (please tick one)	☐ No affected units found ☐ Exchange of affected units ☐ Modification of affected units Attachment of correct sleeve completed on: _____ (dd/mm/yyyy) by Galderma sales rep:_____(name)	
Statement of acknowledgement	I have received the letter *"Notice on Singapore-specific instructions supplied with Restylane Lidocaine 1mL"* dated *30 Sep 2016* and have read and understood the contents.	

Clinic stamp	**Signature of doctor**	**Name of doctor**
Date		