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HSA UPDATES

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HSA UPDATES NO 3/2023

HSA CONCLUDES ITS INVESTIGATION INTO AESTHEFILL

The Health Sciences Authority (HSA) has completed its investigation into AestheFill and found no evidence of any product-related safety and quality issues. HSA initiated the investigation after receiving an adverse event report on 29 July 2023 from Parvus (S) Pte Ltd, the product registrant, about an incident of blood vessel occlusion leading to blindness after AestheFill was administered. This was the first reported case of blindness resulting from the use of dermal fillers in Singapore.

2 In its investigation, HSA conducted a thorough review of the Device History Records (DHR) for the specific lot of AestheFill that was injected into the patient in the local incident of blood vessel occlusion. The DHR contains detailed information about the manufacturing process, including quality checks and the results of these tests in the form of a Certificate of Analysis (CoA). The CoA includes the results of chemical and microbiological tests, all of which were within the specifications. This indicates that the product was manufactured according to the required standards and is safe for use.

3 AestheFill is a brand of dermal filler used to temporarily improve facial wrinkles and folds by injection into the subcutaneous layer of facial skin. All dermal fillers are classified by HSA as Class D medical devices, the highest risk class. AestheFill has been registered in Singapore since 1 October 2021.

4 Blood vessel occlusion resulting in blindness is a known risk for all dermal fillers and is listed as a known potential adverse event in the Instructions For Use (IFU) which are provided to clinicians. The IFU for AestheFill states that injection into blood vessels should be avoided as it may cause blood vessel occlusion. HSA notes that to mitigate this risk, Parvus will strengthen the training of healthcare professionals (HCPs) and provide retraining for its existing providers, as well as develop a patient information leaflet for HCPs to explain the risks of the procedure to their patients.

Consumer Advisory

5 Consumers should be aware that dermal fillers carry certain risks, including blood vessel occlusion which can lead to blindness. Other common complications reported for dermal fillers include swelling, redness, raised bumps in or under the skin (nodules or granulomas), skin blanching (associated with injection into blood vessel) and temporary blurring of vision. To minimise the risks associated with dermal fillers, consumers are advised to discuss the procedure with their trusted HCPs before undergoing treatment.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
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▪ About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

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