REGULATORY GUIDELINE FOR *DEVICES FOR MODIFICATION OF APPEARANCE OR ANATOMY

Medical Devices Branch

June 2018

* *For the purpose of this guideline, devices intended for modification of appearance or anatomy refers to devices intended for* ***aesthetic-related purposes***

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INTRODUCTION
Objective

The Health Sciences Authority (HSA) is issuing these guidelines to provide clarity on the types of *devices intended for modification of appearance or anatomy that are regulated as medical devices, as well as the regulatory approach and regulatory requirements for these medical devices.

The guidelines reflect HSA's current policy stance and practice, and should not be misconstrued as a new regulatory control on devices intended for modification of appearance or anatomy.

** For the purpose of this guideline, devices intended for modification of appearance or anatomy refers to devices intended for **aesthetic-related purposes***

INTRODUCTION
Background

- Devices intended for modification of appearance or anatomy include any instrument, apparatus, implement, machine or appliance intended for use on humans, for restoring, improving or modifying physical appearance. Some examples include:
  - treatment of wrinkles
  - improving skin texture
  - skin rejuvenation
  - body contouring
  - hair removal

- As a general rule, if the device is intended by the product owner for medical **and** for modification of appearance or anatomy, the device will be classified as a medical device and will be subjected to medical device regulatory controls by HSA.

- There are devices which are intended by the product owner **solely** for modification of appearance or anatomy. Based on surveillance data, there have not been serious adverse events associated with the majority of such products.

INTRODUCTION
Background

- There are also other existing regulatory oversight currently in place locally on some of these products and their use. For e.g.
  - Singapore Medical Council (SMC) published *Guidelines on Aesthetic Practices for Doctors*, which lists the allowed aesthetic procedures, premises and training requirements to conduct aesthetic procedures for doctors
  - National Environment Agency (NEA) imposes licensing requirements for individuals or facilities handling ionizing/non-ionizing radiation emitting equipment under the Radiation Protection Act

- A review of serious adverse events reported globally on similar devices was performed (refer to Table 1)

Table 1. Device types and reported serious adverse events

Device Types	Examples of Reported Serious Adverse Events
Gluteal implants, breast implants	Rupture, capsular contracture (scar tissues that forms around the implant and squeeze the implant), infection
Collagen/ hyaluronic dermal fillers, lip fillers	Injection site necrosis, nodules, allergic reaction
Lipoplasty/ liposuction equipment	Infection, pulmonary embolism, visceral perforation

This document applies to devices intended by the product owner solely for *modification of appearance or anatomy.

** For the purpose of this guideline, devices intended for modification of appearance or anatomy refer to devices intended for **aesthetic-related purposes***

PRODUCT OWNER (as stated in the Medical Device Regulations): in relation to a health product, is defined as a person who —

supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

DEVICES FOR MODIFICATION OF APPEARANCE OR ANATOMY (aesthetic-related purposes): any instrument, apparatus, implement, machine or appliance intended for use on humans, for restoring, improving or modifying physical appearance and/or anatomy.

CATEGORISATION OF DEVICES FOR MODIFICATION OF APPEARANCE OR ANATOMY AS MEDICAL DEVICES
Risk-based approach

- HSA will adopt a risk based approach and will subject only a positive list of high risk devices intended solely for modification of appearance or anatomy to the medical device regulatory controls

- The following positive list is drawn up based on the global post-market surveillance data and a comparison of risk presented by some of these products to that of other medical devices:

Annex A: Positive list of high risk devices intended for modification of appearance or anatomy to be regulated as medical devices:

i. any implant for the modification or fixation of any body part
ii. any injectable dermal filler or mucous membrane filler
iii. any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means

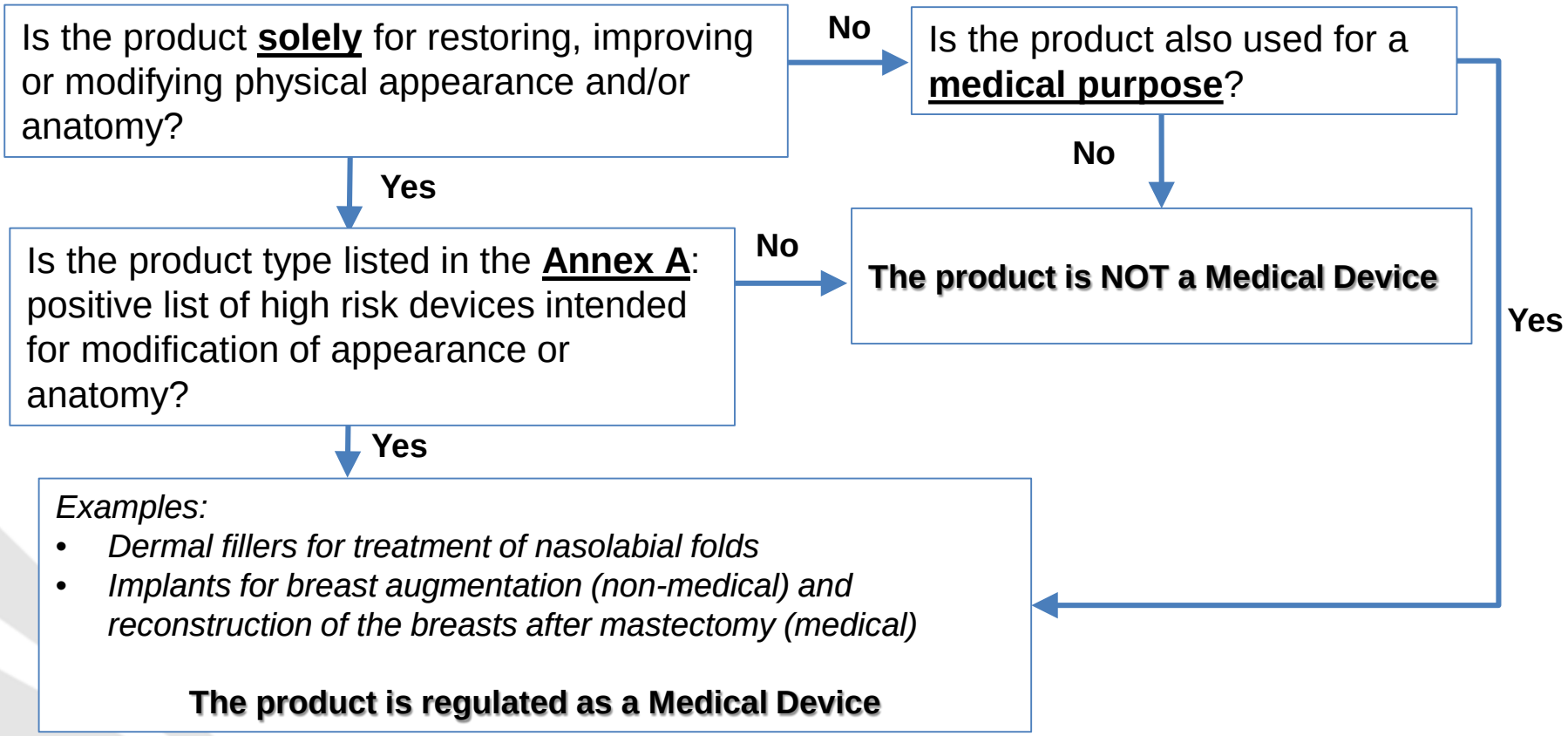
CATEGORISATION DEVICES FOR MODIFICATION OF APPEARANCE OR ANATOMY AS MEDICAL DEVICES
Risk-based approach

- The Annex A positive list may be expanded in the future as and when new risks are identified. New risks or hazards that are posed by the advent of new technology, new application or use of existing technology, and new risks surfacing from wide-spread use will be factors that will be considered when deciding to update the positive list in the future.

- The intended use of devices for modification of appearance or anatomy will determine whether it will be regulated as a medical device. The intended use is reflected on the specifications, instructions and information provided by the product owner of the product.

- In order to determine whether a product intended for modification of appearance or anatomy is a medical device, please refer to Flowchart 1.

Flowchart 1: Is the device intended for modification of appearance or anatomy regulated as a Medical Device?



REGULATORY CONTROLS

Medical devices for modification of appearance or anatomy (Annex A) are subjected to the following medical device regulatory controls:

- Product Registration;
- Dealer's licence requirements;
- Post-market obligations

REGULATORY CONTROLS
Product Registration

- In order to supply medical devices for modification of appearance or anatomy (Annex A) in Singapore, the company is required to obtain marketing clearance for the device from HSA via Product Registration before supply of the devices in Singapore.

- As with all other medical devices, medical devices for modification of appearance or anatomy (Annex A) are classified into different risk classification as per GN-13: Guidance on the Risk Classification of General Medical Devices, depending on the nature of the device and its intended functions.

- The submission requirements and process, depending on the risk class of the medical devices for modification of appearance or anatomy (Annex A), will follow as per GN-15: Guidance on Medical Device Product Registration.

REGULATORY CONTROLS
Product Registration

- Some key safety concerns specific to medical devices for modification of appearance or anatomy (Annex A) have been identified (refer to Table 2) that will have to be considered and addressed as part of the device validation. It should be noted that these safety concerns are largely similar to other regulated high risk medical devices and are **not** additional regulatory requirements.

- Like all other medical devices, medical devices for modification of appearance or anatomy (Annex A) undergo changes as part of their product life cycle. Please refer to GN-21: Guidance on Change Notification for Registered Medical Devices to determine whether a Change Notification submission to HSA is required for specific proposed changes to a medical device that is registered on the Singapore Medical Device Register (SMDR).

Table 2: Safety Concerns

Annex A: Positive list of high risk products intended for modification of appearance or anatomy	Specific risks to be addressed
Any implant for the modification or fixation of any body part *Examples:* ▪ breast implant ▪ gluteal implant	- Toxicity and long-term safety of the implant *Documentary requirements including but not limited to*: ▪ Biocompatibility studies ▪ Mechanical testing (e.g. elongation, rupture resistance test, fatigue test) ▪ Raw material certificate of analysis (COA) *Device labeling requirement (breast implants)* ▪ A statement indicating that breast implants are indicated for breast augmentation for patients of at least 18 years of age for saline-filled implants and of at least 22 years of age for silicone-filled implants or similar wording has to be presented in the product labelling.

Table 2: Safety Concerns (continued)

Annex A: Positive list of high risk products intended for modification of appearance or anatomy	Specific risks to be addressed
Any injectable dermal filler or mucous membrane filler *Examples:* ▪ soft tissue fillers ▪ wrinkle fillers	- Safety and toxicity of the implant and its degradation products *Documentary requirements including but not limited to*: ▪ Biocompatibility studies ▪ Degradation profile studies ▪ Safety of biological material (e.g. animal/microbial-derived material) ▪ Raw material COA *Device labeling requirement:* ▪ The **treatment dose limit per year*** has to be stated in the product labelling ***Justification for the ***treatment dose limit per year*** should take into account the volumes administered in clinical studies and/or results obtained from preclinical studies.*

Table 2: Safety Concerns (continued)

Annex A: Positive list of high risk products intended for modification of appearance or anatomy	Specific risks to be addressed
Any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means *Examples*: liposuction equipment Invasive lipolysis equipment	- Safety of the device *Documentary requirements including but not limited to*: ▪ Electrical safety ▪ Functional testing

REGULATORY CONTROLS
Dealers License Requirements

- To engage in the manufacture, import and/or wholesale of medical devices for modification of appearance or anatomy (Annex A) in Singapore, the appropriate dealer licences will need to be obtained from HSA.

- The submission requirements and process will follow as per GN-02: Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices.

- This licensing requirement is to ensure proper traceability and post-market monitoring of devices for modification of appearance or anatomy (Annex A) marketed in Singapore.

REGULATORY CONTROLS
Post-market Obligations

- Dealers of medical devices are obliged to perform post-market duties, including but not limited to reporting of adverse events, defects and recall to HSA and ensuring appropriate investigation, so as to ensure the continued safe use of the devices.

- Healthcare professionals and users of medical devices for modification of appearance or anatomy (Annex A) may also report any adverse events related to the use of a medical device or device failure related issues to HSA on a voluntary basis.

CONCLUSION

- This is the current position based on a risk-based regulatory approach and the current knowledge of foreseeable risks associated with devices for modification of appearance or anatomy (Annex A).

- Where deemed necessary, HSA may expand the positive list of high risk devices intended for modification of appearance or anatomy (Annex A) based on new scientific information to protect public health and safety

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