Comparative Study of Regulations of Devices for Aesthetic Purposes: US, European Union, China, and Taiwan

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Abstract

Purpose The aim of this study is to examine how aesthetic devices are defined and managed. Regulation discrepancies between clinical use and home use in four regions are also described.

Methods The official websites and databases of US, European, Chinese, and Taiwanese authorities were used to collect regulation information for aesthetic devices. Moreover, the regulations for eight aesthetic products, four used in clinics by experts and four used at home by lay people, were compared.

Results The results show that the principle of operation and intended use are key points for determining whether an aesthetic device is a medical device (MD). Although the term “aesthetic” is not included in the MD definition, most aesthetic devices are regulated as MDs by the four regional authorities based on the devices’ technical specifications and intended use, especially for high-risk devices and high-end products. For home-use aesthetic devices, the control measures also depend on function and intended use, but different authorities have different acceptance ranges. Manufacturers should pay more attention to regulation requirements in difference regions before putting devices on the market.

Conclusion With the fast growth of aesthetic devices, government authorities need to make regulations to keep up with new products. Determining whether an aesthetic product is an MD on the basis of its risk could be a practical option for administrators. This study evaluated the regulation of aesthetic devices as MDs in the US, European Union, China, and Taiwan, and provides important information for further policy and regulation development.

Keywords Aesthetic device · Medical device · Regulation

1 Introduction

The demand for aesthetic surgery has increased significantly in recent years. According to statistics provided by the International Society of Aesthetic Plastic Surgery (ISAPA), over 10 million surgical procedures were performed on average per year from 2013 to 2016, and nearly 12 million

nonsurgical procedures were performed in the same period [1–5]. The latest report by ISAPA showed that the total number of procedures grew by 9% from 2015 to 2016. A report by Grand View Research Inc. showed that the global aesthetic medicine market is expected to reach USD 11.9 billion by 2022 [6]. The global aesthetic medicine market is thus booming, and related industries have been developed, especially devices for aesthetic purposes. Various types of aesthetic products are available in the market, such as decorative contact lenses, intense pulsed light facial rejuvenation devices, laser hair removal devices, radio-frequency wrinkle reduction devices, and electrical facial devices, for both clinical and home use. How to manage and control such devices has become a challenge for regulatory authorities.

High-risk devices, such as dermal fills, breast implants, and laser equipment, are regulated as medical devices (MDs). However, there are no consistent global rules for managing aesthetic devices that can be followed by

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manufacturers. Furthermore, due to the growth of the beauty market, an increasing number of medical technologies is being applied to the development of home-use aesthetic products, which have a wide variety of functions and can be easily purchased by the general public. How to supervise and manage home-use aesthetic products while taking into consideration the safety of consumers and the development of the aesthetic industry is a serious issue for MD and cosmetic authorities. Therefore, it is necessary to examine existing aesthetic product management information in different regions for future aesthetic device policy and regulation development.

This study evaluated four important plastic surgery markets, namely the US, EU, China, and Taiwan, to examine their regulation policies regarding aesthetic devices to determine the regulatory framework for aesthetic devices. This study also attempts to discern regulation differences by examining eight different aesthetic products, four used in clinics by experts and four used at home by lay people. The aim of this study is to draw attention to aesthetic device management, especially for home-use products, by investigating current regulation mechanisms, to suggest reference points

that will be helpful for enhancing device use safety, and to provide valuable information for authorities and industry.

2 Methods

Regulations in the US, EU, China, and Taiwan on aesthetic devices were examined. The data collection and analysis step of this study is shown in Fig. 1.

2.1 Collection of Regulation Information on Aesthetic Devices for Four Regions

High-risk aesthetic devices are regulated as MDs. Information on how aesthetic devices are defined as MDs and complementary control measures was collected using the search terms “aesthetic” and “aesthetic purpose” in the medical regulation and product classification databases and lists for the four regions. Since the US, China, and Taiwan MD authorities have official websites and the EU has an official website for finding law information, these were the major sources for data collection in this study.

Fig. 1 Data collection and analysis step used in this study

2.2 Collection of Regulation Information for Clinical Use and Home-Use Aesthetic Products for Four Regions

Aesthetic devices are usually based on one of four principles of operation: heating/cooling, ultrasound, optics, and electricity. In this step, four clinical use devices and four home-use devices based on the principle of operation were respectively selected. For each principle of operation, one high-end product and one personal use product were selected. The regulations for these eight products (Table 1) were obtained for the four regions. The category and classification were the primarily information collected for later comparison and analysis.

2.3 Information Analysis and Comparison

In order to clarify the regulation differences among the four regions, information on aesthetic devices was analyzed and compiled based on region. Then, the regulation information for the eight selected products (product description, classification, code, and MD status) was analyzed. Finally, the analyzed regulation information for the four regions was compared.

2.4 Results and Discussion

The results of the aesthetic device definition analysis for the four regions and a comparison of regulations for high-end and home-use products are presented in this section. A discussion is also given.

The regulation information was obtained from the official websites and databases of the United States Food and Drug Administration (FDA, <https://www.fda.gov>), European Commission (EC, <https://ec.europa.eu>), China Food and Drug Administration (CFDA, <http://samr.cfda.gov.cn>),

and Taiwan Food and Drug Administration (TFDA, <https://www.fda.gov.tw>).

3 Results

3.1 Regulation Summaries of Aesthetic Devices for Four Regions

3.1.1 United States

In the US, the legal authority that regulates MDs is the FDA. Any product that is labeled, promoted, or used in a manner that meets the requirements in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act is regulated by the FDA. In section 201(h), the definition of an MD does not include the terms “aesthetic” or “aesthetic purpose”. However, at least 14 devices (material not included) classified in the Center for Devices and Radiological Health (CDRH) classification database have descriptions that include “aesthetic use” (Table 2), such as electrosurgical coagulation for aesthetic use (product code: ONQ) and laser for disruption of adipocyte cells for aesthetic use (product code: PKT) [7]. Aesthetic devices are not limited to the 14 product codes listed in Table 2. As long as a device’s working principle and intended use conform with the information listed in the CDRH product classification database, then the device is regulated as an MD. If a device is not covered by the scope of MDs, the intended use and label should not include anything medicine-related. Cosmetic use is also regulated by the FDA but under different regulations. Manufacturers should check product classification and regulation rules based on a product’s characteristics when launching a product. Table 3 summarizes the aesthetic device regulations for the US, EU, China, and Taiwan.

Table 1 Eight aesthetic devices selected in this study based on four principles of operation

Principle of operation	Clinic use product name and description	Home-use product name and description
Heating/cooling	Skin cooling system for lipolysis Description: <i>A non-invasive body contouring treatment used to reduce fat cell volume by freezing</i>	Hot/cool facial massager Description: <i>A device for facial skin care. It relaxes skin and accelerates blood circulation</i>
Ultrasound	Focused ultrasound system for lipolysis Description: <i>The system delivers high-intensity focused ultrasound energy to non-invasively disrupt subcutaneous adipose tissue</i>	Ultrasonic facial massager Description: <i>To deliver high-frequency waves to user skin</i>
Optics	Powered laser surgical instrument Description: <i>Removes unwanted brown spots, sun freckles, or tattoos from user’s skin</i>	Light-based hair removal Description: <i>Uses light or intense pulsed light to slow down hair growth by damaging hair follicles</i>
Electricity	Radio-frequency energy system Description: <i>Delivers radio-frequency energy deep into dermal tissues for skin tightening and wrinkle reduction</i>	Electric facial massager Description: <i>Uses micro-current to enhance results of skin-care products and improve metabolism</i>

Table 2 Product code of devices with aesthetic purpose listed in FDA medical device classification database

#	Product code	Device	Device class	Regulation description
1	GEX	Powered laser surgical instrument	2	Laser surgical instrument for use in general and plastic surgery and in dermatology
2	NFO	Stimulator, transcutaneous electrical, aesthetic purposes	2	Transcutaneous electrical nerve stimulator for pain relief
3	NYX	Stimulator, electrical, transcutaneous, with limited output, for aesthetic purposes	2	Transcutaneous electrical nerve stimulator for pain relief
4	NYZ	Stimulator, muscle, powered, with limited output, for muscle conditioning	2	Powered muscle stimulator. Not intended to be used for medical purposes (e.g., rehabilitation), for aesthetic purposes (e.g., changing the physical appearance of the muscle or body), or for the purpose of improving athletic performance
5	OHV	Focused ultrasound for tissue heat or mechanical cellular disruption	2	Focused ultrasound stimulator system for aesthetic use
6	OLI	Fat reducing low level laser	2	Low level laser system for aesthetic use
7	ONE	Powered light based non-laser surgical instrument	2	Laser surgical instrument for use in general and plastic surgery and in dermatology
8	ONF	Powered light based non-laser surgical instrument with thermal effect	2	Laser surgical instrument for use in general and plastic surgery and in dermatology
9	ONG	Powered laser surgical instrument with microbeam\ fractional output	2	Laser surgical instrument for use in general and plastic surgery and in dermatology
10	ONQ	Electrosurgical coagulation for aesthetic	2	Electrosurgical cutting and coagulation device and accessories
11	OOK	Dermal cooling pack/vacuum/massager	2	Contact cooling system for aesthetic use
12	PAY	Over-the-counter radiofrequency coagulation device for wrinkle reduction	2	Electrosurgical device for over-the-counter aesthetic use
13	PKT	Laser for disruption of adipocyte cells for aesthetic use	2	Low level laser system for aesthetic use
14	QAI	Powered microneedle device	2	A powered microneedle device is a device using one or more needles to mechanically puncture and injure skin tissue for aesthetic use

Table 3 Summary of aesthetic devices controlled by medical device regulations in the US, EU, China, and Taiwan

Region	Regulation
US	<ul style="list-style-type: none"> • FDA has specialized product codes for aesthetic devices in CDRH database • Devices are regulated by MD regulation if their function complies with the description in MD product classification • Products that are not MDs cannot make any medical claim on labels and intended use
Europe	<ul style="list-style-type: none"> • Certain product groups listed in Annex XVI are regulated by MDR, including aesthetic or other implantable or invasive products such as non-corrective contact lenses, equipment for liposuction, and hair removal lasers • For unclear products, manufacturers should refer to guidance documents such as the manual on borderline products and classification provided by the European Commission. Some borderline products need to be confirmed case by case depending on their characteristics • Cosmetic products should not make any explicit or implicit claims related to prevention or treatment
China	<ul style="list-style-type: none"> • The term “aesthetic purpose” is not included in the CFDA MD definition • CFDA does not have any specialized product codes for aesthetic devices in MD list • Any device that conforms to the product description in MD list is regulated as an MD • CFDA announces notices of product definitions as supplementary material for defining whether a product is regulated as an MD
Taiwan	<ul style="list-style-type: none"> • TFDA does not have any specialized product codes for aesthetic devices in the MD classification database • Devices are regulated by MD regulation if their function complies with the description in MD product classification • Aesthetic device that claims a medical intention or treatment effects, such as skin improvement, reducing wrinkles, or to stimulate collagen or cell production, needs to follow MD regulation (e.g. classification number I.0008-Transcutaneous skin stimulator)

3.1.2 European Union

The latest regulations on MDs in EU are the Medical Devices Regulation (MDR), Regulation 2017/745, published on 5 April, 2017, and entered into force on 25 May, 2017 [8]. The regulation, in an effort to reshape and improve essential health and safety practices and guidelines, has widened the scope not only of aesthetic products but also non-medical devices. Six groups of products listed in the MDR (Article 1, Annex XVI) without an intended medical purpose are listed below.

- (1) Contact lenses or other items intended to be introduced into or onto the eye.
- (2) Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
- (3) Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intra-dermal injection or other introduction, excluding those for tattooing.
- (4) Equipment intended to be used to reduce, remove, or destroy adipose tissue, such as equipment for liposuction, lipolysis, or lipoplasty.
- (5) High-intensity electromagnetic radiation (e.g., infrared, visible light, and ultraviolet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo, or hair removal or other skin treatment.
- (6) Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

Before the United Kingdom left the EU, the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care in the UK, provided guidance to clarify that devices without medical purposes are not considered as MDs [9–11]. This means that even high-risk products were not officially regulated as MDs; they were only listed in a proposal by the European Commission until the MDR entered into force in 2017. Now, high-risk aesthetic products are included in the MDR for user safety. Moreover, for borderline products, which are not clearly cosmetic or medical products, the European Commission evaluates them based on risk. For example, for products delivered via iontophoresis or similar principles, a case-by-case evaluation of all characteristics of

the product is necessary. If the use of a device only affects the skin epidermis, then the product is cosmetic; if the use of a device induces a deeper penetration of certain ingredients, then the product is not cosmetic [12].

3.1.3 China

The CFDA is the legal authority that regulates MDs in China. Their definition of an MD is [13]:

Any instrument, apparatus, appliance, material, in vitro diagnostic reagents and calibration substances and other similar substances and related articles, including the needed computer software. Its main effectiveness is achieved via physics ways and so on. It does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but which may be assisted in its function by such means; the use of which is to achieve the following intended objectives:

- *Diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap conditions;*
- *Investigation, replacement or modification for anatomy or a physiological process;*
- *Life support or maintenance;*
- *Control of conception;*
- *Offer information for medical or diagnosis purpose via inspecting the human samples.*

According to an announcement by the CFDA, a new medical device classification catalog (MD List) was implemented on August 1, 2018 [14]. For CFDA registration applications submitted on or after the August 2018 deadline, the new catalog will fully apply. Compared to the existing MD list (issued in 2002), the new catalogue provides a more clear and complete structure, and has the follow major modifications:

- (1) Reduces the number of device categories from 43 to 22 based on the MDs' functions and clinical uses.
- (2) Provides clearer guidance and product examples that enable companies to determine the level of regulatory control. For example, each catalogue of the new MD List contains a primary type, sub-type, device description, intended use, device examples, and classifications for Classes I, II, and III. It also includes 6609 devices in the device example column, while the existing MD list offers only 1008 example devices.
- (3) Downgrades the classification of 40 devices to Class II (e.g., infusion pumps for surgical instruments) or Class I (e.g., plate washers). It upgrades the classification of

certain types of devices to Class III (e.g., alcohol swabs and active breathing coordinators).

From the MD definition above, if a product does not have a medical purpose, it is not considered as an MD. Furthermore, for the new MD list, there were no results for the terms “aesthetic” and “aesthetic purpose”, even in device descriptions, intended use, and device examples. However, high-risk aesthetic devices are regulated based on the device’s working theory. For example, a facial skin care device or hair removal device that uses intense pulsed light (IPL) is regulated under the code 09-09-04-Intense pulsed light therapy equipment [14, 15].

3.1.4 Taiwan

The TFDA is the legal authority that regulates MDs in Taiwan. The Pharmaceutical Affairs Law (PAL) regulates the manufacturing, importation, and sale of MDs and pharmaceuticals in Taiwan. According to PAL Article 13 [16], an MD is:

The term “medical devices” as refer to instruments, machines, apparatus, and their accessories, fittings and parts which are used in diagnosing, curing, alleviating, or directly preventing the diseases of human beings, or which may affect the body structure or functions of human beings. The central competent health authority shall establish Regulations Governing the Management of Medical Devices in regards to its scope, classification, management, and other matters in accordance with practical needs.

Same as the other regions, the definition of an MD does not include the terms “aesthetic” or “aesthetic purpose”. However, for protecting customer safety and keeping up with the product development, TFDA updated MD classification database irregularly. According to the latest database update announced on July 25, 2017, new 27 device categories had been added on the database and 18 device categories had been amended. Which updates associated with aesthetic product included [17]:

- (1) Added new device category I.0008-Transcutaneous skin stimulator. The identification of this device is to apply energy (e.g., electrical current, optical energy or ultrasound energy) on a patient’s skin up to dermal or subdermal layers to modify skin appearance (e.g., skin tightening, toning, lifting or reducing wrinkles) or to stimulate collagen or cell production. Base on the identification of I.0008, many facial toning devices or skin care devices based on micro-current or ultrasound technology need to get approval before them be distributed on Taiwan’s market [18].
- (2) Amended the identification of device category I.0001-High density subcutaneous electrical wrinkle reduc-

tion device as a device applying an electrical current to electrodes on a patient’s skin up to subdermal or muscle layers for reducing body wrinkles and connective tissue swelling by physical action. This device applies high density electrical current to stimulate collagen and elastin production by heating tissues in the deep layers of the skin [19].

- (3) Adjusted the class of device category O.5525-Iontophoresis device from class III to class II. The iontophoresis device uses a current to introduce ions of drugs or non-drug solutions into the patient’s body for achieving specific medical purposes. According to the identification, an ionic facial device which claim with ionic treatment function need to follow the MD regulation as Class II in Taiwan [20].

3.2 Regulation Comparison for Clinical Use and Home-Use Aesthetic Products Based on the Four Principles of Operation and Four Regions

The control features under MD regulation of the eight selected products in different regions are highlighted in Table 4. The regulations are described below in detail.

3.2.1 Heating/Cooling

A skin cooling system for lipolysis is a non-invasive treatment for reducing fat cell volume by freezing. Lipolysis or the reduction of adipose tissue is an important market in plastic surgery. Different kinds of technology are applied in this market. A skin cooling lipolysis system uses high energy delivery to reduce adipose tissue. This system is regulated as an MD and is classified as Class II or III in all four regions.

A hot/cool facial massager is a device for personal facial skin care. It relaxes skin and accelerates blood circulation. Generally, the device’s maximum temperature should be not over 42 °C and not below 6 °C. This study did not find a corresponding product code for the hot/cool facial massager in the CDRH product classification database based on the temperature change and massage function. In EU, the hot/cool facial massager may be classified as a cosmetic product according to the borderline working manual [12]. For the CFDA, based on the working theory, this device is not regulated as an MD. Furthermore, if this product does not claim any medical purposes, the TFDA would not treat this device as an MD in Taiwan.

3.2.2 Ultrasound

A focused ultrasound system for lipolysis delivers high-intensity focused ultrasound energy to non-invasively disrupt subcutaneous adipose tissue. In China, this device

Table 4 Comparison of eight selected items regulated by medical device regulation in US, Europe, China, and Taiwan

Principle of operation	Product name	Product description	US	Europe	China	Taiwan
Thermal/cooling	Skin cooling system for lipolysis	A non-invasive body contouring treatment used to reduce fat cell volume by freezing	Product code: OOK, dermal cooling pack/vacuum/massager, Class II. Submission type: 510 K [7]	Complies with MDR Annex XVI Article 1 product groups, Class IIa (Rule 10) [8]	Product code: 01-01-05, cryosurgery equipment and accessories, Class III [14]	Classification Number: I.4340-Contact cooling system, Class II [17]
	Hot/cool facial massager	Device is used for facial skin care. It relaxes skin and accelerates blood circulation	No corresponding product item found in CDRH database	The product has no medical intention and no special technology, and is thus inferred to not be an MD	No corresponding product item found in MD list. It is thus inferred to not be an MD	No corresponding product item found in MD database, and no medical intention. It is thus inferred to not be an MD
Ultrasound	Focused ultrasound system for lipolysis	The system delivers high-intensity focused ultrasound energy to non-invasively disrupt subcutaneous adipose tissue.	Product code: OHV, focused ultrasound stimulator system for aesthetic use, Class II Submission type: 510 K [7]	Complies with MDR Annex XVI Article 1 product groups, Class IIb [8]	Product code: 01-01-02, high-intensity focused ultrasound (HIFU) therapy system for lipolysis, Class III [14]	Classification Number: I.4590-Focused ultrasound stimulator system, Class II [17]
	Ultrasonic facial massager	To deliver high-frequency waves to user skin	Two product codes in CDRH database related to this product 1. Product code: RAL, massager equipment using ultrasound to provide massages in a household application that has no medical claims Not classified 2. Product code: ISA, therapeutic massager, Class I [7]	If the device only affects the epidermis, then it is cosmetic. Generally, a sonic facial massager without medical claims only affects the epidermis, and is thus not regulated as an MD [12]	This device is not an MD [24]	Classification Number: I.0008-Transcutaneous skin stimulator, Class II [18]
Optics	Powered laser surgical instrument	Removes unwanted brown spots, sun freckles, or tattoos from user's skin	Product code: GEX, powered laser surgical instrument Class II Submission type: 510 K [25]	Complies with MDR Annex XVI Article 1 product groups, Class IIb, [8]	09-03-01 Laser treatment equipment Class III [14]	Classification Number: I.4810-Laser surgical instrument for use in general and plastic surgery and in dermatology, Class II [26]
	Light-based hair removal	Uses light or intense pulsed light to slow down hair growth by damaging hair follicles	Product code: OHT, light based over-the-counter hair removal. Class II Submission type: 510 K [27]	For IPL, hair removal products comply with MDR Annex XVI Article 1 [8]	For IPL device, product code: 09-03-04 intense pulsed light treatment equipment, Class II [14]	Classification Number: I.4810-Laser surgical instrument for use in general and plastic surgery and in dermatology, Class II [26]

Table 4 (continued)

Principle of operation	Product name	Product description	US	Europ	China	Taiwan
Electricity	Radio-frequency energy system	Delivers radio-frequency energy deep into dermal tissues. It is used for skin tightening and wrinkle reduction	Product code: GEI electrosurgical, cutting and coagulation and accessories Class II Submission type: 510 K	Complies with with MDR Annex XVI Article 1, Class IIb [8]	09-07-02 RF superficial/epidermal treatment equipment Class II, [14]	Classification Number: I.0001-High density subcutaneous electrical wrinkle reduction device, Class II [19]
	Electric facial massager	Uses micro-current to enhance results of skincare products and improve metabolism	Product code: PAY over-the-counter radiofrequency coagulation device for wrinkle reduction. Class II	If the device only affects the epidermis, then it is cosmetic. Generally, an electric facial massager without medical claims only affects the epidermis, and is thus not regulated as an MD [12]	The electric facial device for aesthetic purpose is not an MD [24]	Classification Number: I.0008-Transcutaneous skin stimulator, Class II [18]

is controlled by product code 01-01-05 (Cryosurgery equipment and accessories) in the new MD list, and its risk is classified as the highest (III) [14]. For the FDA, the focused ultrasound system is controlled under product code OHV, and 510(K) clearance is necessary before distribution [7]. In EU, this system is classified as IIb according to MEDDEV 2.4/1 rev.9 [21]. In Taiwan, this system is regulated as Class II in MD classification list Classification Number I.4590- Focused ultrasound stimulator system [17].

The personal use ultrasonic facial massager claims to pass high-frequency vibration to a user's skin. This study found when massager claims to use ultrasonic or ultratherapy technology to achieve therapeutic effects, it would be regulated as Class II in CDRH database, and the devices would need a valid 510(K) to be distributed in the US market [22, 23]. In EU, high-frequency vibration facial massagers are in general not MDs. For further confirmation, it needs to be evaluated case by case depending on the device's function, power, and frequency [12]. In China, according to an official document published in 2013, high-frequency vibration devices for skin improvement are not MDs [24]. In Taiwan, facial massagers using ultrasonic technology are controlled by classification number I.0008 (Transcutaneous skin stimulator) as Class II MDs [18].

3.2.3 Optics

A powered laser surgical instrument can be used to remove unwanted brown spots, sun freckles, or tattoos from skin. It is useful and common equipment in surgical and dermatology departments. This important medical device is classified as Class III in the China MD list. According to the classification rules of MDR (Chapter III rule 9) and a guidance document published in 2010, a laser surgical instrument is classified as Class IIb in EU [8, 21]. Both the US and Taiwan regulate laser surgical equipment as Class II [25, 26].

All light-based over-the-counter (OTC) hair removal devices need to have 510(k) clearance before they can be distributed in the US market [27]. In EU, intense pulsed light (IPL) hair removal equipment is controlled by MDR [8]. Devices that use other light sources, such as LEDs, need to be evaluated case-by-case to confirm whether they comply with EU MDR. In China, IPL hair removal equipment is regulated by product code 09-03-04 [15]. In Taiwan, according to the description of classification number I.4810-laser surgical instrument for use in general and plastic surgery and in dermatology on the MD classification database, light-based over-the-counter hair removal device is classified as Class II by I.4810 [26].

3.2.4 Electricity

A radio-frequency energy system is a non-invasive device that delivers radio-frequency energy deep into dermal tissues for skin tightening and wrinkle reduction. It is a popular device in plastic surgery clinics. This machine is controlled as a Class II MD in the US, EU, China, and Taiwan [14, 19, 21, 28].

An electric facial massager uses micro-current to enhance the results of skincare products and improve metabolism. It is a popular item in online stores. In the US and Taiwan, electric facial massagers with therapeutic effects need a valid 510 K and need approval to be distributed in the market [18, 29]. In EU, this device is generally classified as cosmetic but this depends on the characteristics of the device [12]. In China, electric facial massagers for aesthetic purpose are not MDs [24].

According to the information presented in Table 4, the four high-end products used in clinics were all regulated as MDs in the four regions, but the four home-use products were not all listed in the authorities' MD databases.

4 Discussion

This study collected information from the US, EU, Chinese, and Taiwanese authorities regarding the regulations of aesthetic devices as MDs. Moreover, this study examined four clinical use products and four home-use products based on four common aesthetic application principles.

For the US and Taiwanese governments, if the working principle and intended use of the product comply with the MD list, the device must meet MD requirements before it can be distributed in the market. In European Union, manufactures need to follow the MDR classification rules to determine whether their device is an MD. Six aesthetic product groups are described in Article 1, Annex XVI of MDR. If a product does not belong to the six groups, the manufacture can follow the manual provided by the European Commission to determine whether the product is an MD

[12]. Chinese authority also provides an MD classification database for the industry to check whether a product is controlled as an MD. Any device that conforms to the product description in MD list is regulated as an MD. Moreover, for the devices not included in the list, the authority will make announcement irregularly to explain whether an aesthetic device is an MD. Figure 2 shows the rule to determine whether an aesthetic device is an MD. Further descriptions are as the follows.

4.1 There is No Clearly Definition for the “Aesthetic Devices” in the Four Regions

Although most aesthetic devices are regulated as MDs based on their technical specifications and intended use, the term “aesthetic purpose” is not included in the MD definitions in the four regions. According to the medical device definition, the product would be regulated as a medical device when it has medical purpose. However, for aesthetic devices, sometimes it is hard to determine whether the “aesthetic purpose” pertains to medical purpose; for example, colored contact lenses for changing pupil colors, and electric facial products for skin tightening and wrinkle reduction. The definition of aesthetic devices has been discussed for long time and has not got a conclusion so far. Since it is difficult to define the relationship between “aesthetic purpose” and “medical purpose”, the authorities regulate the aesthetic devices based on the risk of each kind of product. In the latest MD regulation revisions of China, EU and Taiwan, several kinds of aesthetic devices have been added to the MD database and list. In particular, after discussions for long, the EU has made an amendment to list six groups of aesthetic products on the Annex XVI of MDR.

4.2 Aesthetic Products for Personal Use are Medical Devices or Cosmetics?

MDs and cosmetics are both regulated by food and drug administration, and each of them has clearly definition and regulation. Cosmetics are not MDs. However, different

Fig. 2 The rule to determine whether or not an aesthetic device is an MD

authorities have different definitions for cosmetic term. This study did not find consistent definitions for the term in the four regions. For example, electrical product for “wrinkle reduction” and “skin lifting” are generally identified as cosmetics in the EU and China, but as medical device in Taiwan. In the US, the principle of operation is also a major factor in determining whether an aesthetic device is a medical device. For example, the facial product using ionic mechanism may not be identified as an MD in the US, but it will be classified as Class II MD when the ultrathera technology is used in the product.

4.3 Challenges of Aesthetic Products for Personal Use

Aesthetic products for personal use can be easily purchased from pharmacies and online stores. It is not easy for lay people to distinguish the differences between cosmetic and medical use. Especially, some aesthetic devices on the market are only for cosmetic purposes, but they may overstate their performance to confuse consumers. On the other hand, some devices' specification may comply with medical device, but distributed on the market as cosmetic. The problems are particularly serious for cosmetic devices for personal use. Governments have made a lot of efforts to educate the public and have demanded manufacturers to state the intended use and apply proper labels. However, this mission has to be continued. Manufacturers should also promote and label products carefully to strike a balance between user safety and commercial profitability.

5 Conclusions

The information collected in this study suggests that determining whether an aesthetic product is an MD on the basis of its risk could be a practical option for administrators. Even though there are no clear rules for defining the differences between “aesthetic purpose” and “medical purpose”, the risk of a product could be objectively evaluated and estimated. The risk of a product is an important factor for medical device management, and thus this should be taken into consideration for making regulations.

With aesthetic medical and plastic surgery markets increasing rapidly, the demand for aesthetic devices has quickly grown. The government authorities need to make regulations keep up with new products. This study evaluated the regulation of aesthetic devices as MDs in the US, EU, China, and Taiwan. The regulation differences between high-end products and personal use products in these four markets were also examined. Although only four regions were covered in this study, the results are valuable information for improving aesthetic device management regulations.

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Compliance with Ethical Standards

Conflict of interest All contributing authors declare no conflict of interest.

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