Business Facilitation Advisory Committee
Wholesale and Retail Task Force

Medical Device Administrative Control System (MDACS)

Purpose

This paper aims to brief members on the voluntary Medical Device Administrative Control System ("MDACS") under the Medical Device Division ("MDD") of the Department of Health ("DH").

Background

2. Currently, there is no specific legislation to regulate the manufacture, import, distribution, supply and use of medical devices ("MD") in Hong Kong. Depending on the nature and characteristics of the products concerned, some products may be regulated by existing pieces of legislation including the Pharmacy and Poisons Ordinance (Cap. 138), the Radiation Ordinance (Cap. 303), the Trade Description Ordinance (Cap. 362), the Consumer Goods Safety Ordinance (Cap. 456), and the Electrical Product (Safety) Regulation (Cap. 406G), etc.

3. To raise public awareness of the importance of MD safety and pave way for future statutory control, the DH has been administering a voluntary MDACS under the MDD since 2004. The framework of MDACS is largely in line with that recommended by the Global Harmonization Task Force ("GHTF") and International Medical Device Regulators Forum ("IMDRF")[1]. It incorporates internationally accepted best practices relating to safety, quality and risk management, and at the same time provides for the flexibility and capability to regulate the rapidly advancing medical technology.

[1] GHTF was formed in 1992 by regulatory authorities and trade representatives of the United States of America, Canada, Australia, Japan and the European Union to harmonize the standards and principles of regulating MDs. In 2011, GHTF was disbanded, and a new regulator-led group known as IMDRF was formed to build on the foundational work of GHTF and aims to accelerate international MD regulatory harmonization and convergence.

Medical Device Administrative Control System ("MDACS")

4. Under the MDACS, a risk-based approach is adopted whereby the level of control will be proportional to the degree of risk associated with the MD according to separate sets of classification rules for general MD and in vitro diagnostic MDs ("IVDMD") (see **Annex I** for the definition and the classification of MD).

5. The MDACS provides a two-pronged protection to the users of MD which include –

(a) Pre-marketing

6. Following the risk-based approach, Class II to IV general MD and Class B to D IVDMD can be applied for listing under MDACS. To be eligible for listing under MDACS, a MD must meet specified requirements on safety, quality and performance ("SQP") which are assimilated by a set of Essential Principles of Safety and Performance of Medical Devices ("Essential Principles") adopted from GHTF's recommendations.

7. The MDACS adopts a hybrid approach in the evaluation in MD. The manufacturers of a MD or their representative (i.e. the Local Responsible Person ("LRP")) can apply the listing through entrusting a Conformity Assessment Body ("CAB") recognized by the DH to conduct conformity assessment on the MD to demonstrate that their MD are in compliance with the Essential Principles. Alternatively, they can submit the marketing approval from one of the referencing jurisdictions[2] as a supporting evidence that the device conforms with the requirements. This hybrid approach could enhance effectiveness and to overcome unnecessary regulatory barriers.

8. It is the responsibility of the trader in ensuring the safety of a MD supplied in the market. The MDACS also provides a listing system

[2] Referencing jurisdictions include five GHTF founding members: Australia, Canada, EU, Japan and the USA, and jurisdictions introduced in the trial schemes: Mainland China and South Korea.

for the traders, including the LRP, local manufacturer, the importer and the distributor. They will be subject to respective listing requirements, which include holding a valid business registration certificate; maintaining a recognised quality management system for the supply of MDs (for local manufacturers, they will be required to conform to Quality Management System ("QMS") certification requirements); and fulfilling any criteria as specified by the DH. They are also required to maintain a list of MDs supplied by them in the local market and provide to DH upon request, as well as comply with the post-market requirements.

9. Under the MDACS, there is also a recognition system for CABs. Recognised CABs may perform conformity assessment on MDs, as well as to provide third party conformity assessment services to traders.

10. The listing certificates for both MDs and traders are valid for 5 years. The information of the listed MDs, traders and recognised CABs are uploaded to the MDD's website for users' reference.

(b) Post-marketing

11. In order to protect public health by ensuring the SQP of listed MD placed on the market, a post-market monitoring system, consists of Adverse Event Reporting System and the MD Safety Alert Surveillance System, has been in place. The Adverse Event Reporting System receives and investigates Adverse Events reported by LRPs or users. It enables swift control measures against MD-related adverse events, or alleviate consequences of such adverse events through a reporting and information dissemination system.

12. DH also conducts surveillance of safety alerts of MD, especially those listed MD, issued by overseas regulatory authorities and follow up with the LRP of the concerned MD for remedial measures. Where appropriate, safety alert message would be posted to MDD's website and timely disseminated to the public and professional users.

Development of MDACS

13. While the preparation of MD legislation is in progress, DH

continues strengthening the promotion and education to raise public awareness of the usefulness of MDACS-listed MD database. DH also conducts pilot to include MDACS-listing as a preferable requirement in the procurement of certain MDs[3] in DH, and encourages other major buyers of MD, including HA, private hospitals, and healthcare professionals, to accord preference to MDACS-listed MDs in their procurement exercises in view of enhanced customer protection.

14. As a facilitation measure for Hong Kong residents working and living in the Guangdong-Hong Kong-Macao Greater Bay Area ("GBA") to seek healthcare services, designated healthcare institutions operating in the GBA are allowed to use Hong Kong-registered drugs with urgent clinical use, and MD used in Hong Kong public hospitals with urgent clinical use, subject to the approval of Guangdong Province ("the Measure" 港澳藥械通). To enhance the protection of public health and to increase the choice of MDs in the GBA, we will explore the opportunities of allowing the MDs listed under MDACS to be used in the designated health institutions in the GBA under the Measure.

15. Members are invited to note and provide views on the MDACS and encourage traders of MDs to participate in the MDACS for better protection of the public health.

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[3] As of 31 October 2022, the pilot includes glucose meter, glucose strips, condom and lubricating gel. Subject to the experience gained from the pilot, DH will include more MDs into the scheme.

Annex I

Definition and Classification of medical devices (MD)

Definition of MD

According to GHTF's (now IMDRF) recommendation, MD means –

"any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of –

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of MD;
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means"; and

2. Accessory to a MD means –

"an article intended specifically by its manufacturer to be used together with a particular MD to enable or assist that device to be used in accordance with its intended use".

Classification of MD

3. According to the rules of the GHTF, general MD are classified into four classes based on their risks (e.g. invasiveness, length of retention in body, location of implant, etc.). Examples of respective classes of MD are shown as follows –

Class	Risk Level	Examples
I	Low	Tongue depressor, bandage, dressing, walking aid
II	Medium-Low	Hypodermic needle, suction pump, gastroscope, transdermal stimulator, acupuncture needle, corrective contact lenses
III	Medium-High	External defibrillator, lung ventilator, contact lens disinfectant, orthopaedic implant, laser
IV	High	Heart valve, implantable cardiac pacemaker, heparin-coated catheter

4. For IVDMD, they are also classified into four classes according to another set of classification rules with respect to their risks to individual user and the public health as follows –

Class	Risk Level	Examples
A	Low individual risk Low public health risk	Clinical chemistry analyser, prepared selective culture media
B	Medium individual risk Low public health risk	pregnancy self-testing kit, Tests to detect infection by helicobacter pylori, urine test strips
C	High individual risk Medium public health risk	Blood glucose self-testing kit, Screening test for rubella
D	High individual risk High public health risk	Test for human immunodeficiency virus (HIV) blood donor screening, Test for diagnosis hepatitis C virus (HCV)