LCQ9: Regulation of medical devices

Following is a question by Dr the Hon David Lam and a written reply by the Secretary for Health, Professor Lo Chung-mau, in the Legislative Council today (December 6):

Question:

Earlier on, an insufflation device, which is mainly used for laparoscopic or endoscopic surgeries, was linked to a number of accidents in the United States causing 1 death and 10 serious injuries. After learning the incident, the Hospital Authority immediately suspended the use of 142 insufflation devices of the same model under its management. However, it is learnt that due to the absence of a specific legislation to regulate medical devices at present, the Government has no way to mandatorily require private hospitals to suspend the use of the relevant insufflation devices. In this connection, will the Government inform this Council:

(1) given that while the Medical Device Division (formerly known as the Medical Device Control Office) was established by the Department of Health in 2004 to be responsible for implementing the voluntary Medical Device Administrative Control System (MDACS) and developing a long-term statutory regulatory framework for medical devices, the voluntary MDACS has yet to achieve transition to a mandatory statutory control regime after almost 20 years of implementation, whether the Government has conducted a review in this regard; if so, of the details; if not, the reasons for that;

(2) given that while the Government indicated in January 2017 its plan to introduce a new bill setting up the regulatory framework on specific medical devices into this Council in the latter half of the 2016-2017 legislative session, it is learnt that no such action has been taken so far, whether the Government has set a specific timetable for the legislative amendment exercise; if not, of the reasons for that; if so, the details, and whether it will undertake to include the relevant bill in the 2024 Legislative Programme; and

(3) whether it will enact legislation to provide that medical devices (especially high-power or potentially hazardous devices) must only be operated by healthcare personnel?

Reply:

President,

The consolidated reply to the question raised by Dr the Hon David Lam is as follows:

While there is not yet specific legislation to regulate medical devices in Hong Kong, some products are already regulated by existing pieces of legislation, such as the Pharmacy and Poisons Ordinance (Cap. 138), the

Radiation Ordinance (Cap. 303), the Trade Descriptions Ordinance (Cap. 362), the Consumer Goods Safety Ordinance (Cap. 456) and the Electrical Products (Safety) Regulation (Cap. 406G), depending on the characteristics and features of the products concerned.

Making reference to the recommendation of the Global Harmonization Task Force (GHTF, now known as the International Medical Device Regulators Forum (IMDRF)) (Note), the Department of Health (DH) has introduced a voluntary Medical Device Administrative Control System (MDACS) since 2004, under which a listing system for medical devices and traders as well as a post-market monitoring system are in place to ensure that medical devices supplied in Hong Kong can meet the requirements on safety, quality and performance. The DH has fully implemented a strategy of priority procurement of listed medical devices since June 2023, and set up a working group with the Health Bureau (HHB) and the Hospital Authority (HA) to promote the early implementation of similar procurement arrangements by public healthcare facilities under the HA in phases, which will encourage and incentivise traders of medical devices to apply for listing under the MDACS.

Moreover, under an established mechanism, the DH has been closely monitoring safety alerts of medical devices issued by relevant regulatory authorities, including the local ones and those in other regions, as well as the World Health Organization, and taking appropriate actions according to actual circumstances. These include contacting local suppliers to follow up on necessary arrangements, notifying relevant stakeholders (e.g. the HA, private hospitals and professional healthcare institutions) through different means, and publishing safety alert summaries and special alerts on its website.

Taking the incident mentioned in the question involving insufflation devices as an example, the DH has, upon noting the relevant overseas safety alert, promptly made an announcement on its website and taken the initiative to inform stakeholders including the HA and relevant private healthcare facilities (e.g. private hospitals). As a preventive measure, all public and private healthcare facilities have temporarily suspended the use of the devices in question to safeguard patient safety.

For private hospitals, pursuant to the Private Healthcare Facilities Ordinance (Cap. 633), the DH has promulgated the Code of Practice for Private Hospitals (the Code) which sets out various requirements on the use of medical devices by hospitals. This includes, each hospital must keep a register in respect of all medical equipment; all equipment must be appropriately procured, and properly installed, operated, maintained, and calibrated according to the manufacturer's recommendation; all equipment must conform to health and safety requirements; there must be procedures for cleaning, disinfection, packaging, sterilisation, transportation and storage of reusable medical equipment; and staff using medical equipment must have completed training. Compliance with the Code is a condition for issuance and renewal of licence to a private hospital. The Director of Health will take appropriate regulatory actions for non-compliance with the Code (including requirements related to the use of medical devices).

As stated in the 2023 Policy Address, the Government will set up a preparatory office next year to study the potential restructuring and strengthening of the current regulatory and approval regimes for medicine, medical devices and medical technology. The office will put forward proposals and steps for the establishment of the Hong Kong Centre for Medical Products Regulation (CMPR) which will be a step towards the transition to the "primary evaluation" approach in approving applications for registration of pharmaceutical products, and explore the upgrading of the CMPR as a standalone statutory body in the long run. This will help accelerate the launching of new drugs and medical devices to the market, and foster the development of research and development and testing of medical products and related industries. Looking ahead, the regulation of medical devices will fall within the scope of the CMPR's work. The Government will consider the legislative timetable for regulating medical devices in tandem with the progress of establishing the CMPR, thereby further enhancing the overall regulatory regime for medical products in Hong Kong.

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To prepare for these related tasks, the HHB and the DH are now conducting a comprehensive review of the proposed legislative framework having regard to the latest international trends in regulation of medical devices in recent years, and will study various aspects of the regulation of high-risk medical devices, including traceability, maintenance and operation procedures, such that the legislative proposal may be introduced in due course. The DH will continue to promote and enhance understanding of the public, users and the industry on the MDACS, with a view to having more medical devices listed under the system and making better preparations for the transition to a statutory regulatory regime in future.

Note: The GHTF was established in 1992 by regulatory authorities and trade representatives of the United States of America, Canada, Australia, Japan and the European Union to harmonise the standards and principles for the regulation of medical devices. It was disbanded in 2011, and a new IMDRF was formed to build on the work of the GHTF. The IMDRF aims to accelerate international medical device regulatory harmonisation and convergence, and its current members include China, Australia, Brazil, Canada, the European Union, Japan, Russia, Singapore, South Korea, the United Kingdom and the United States of America.