Government’s response on medical device regulation

In regard to media enquiries on the Consumer Council's recommendations on medical device regulation today (January 15), the Health Bureau (HHB) and the Department of Health (DH) gave the following response:

Existing regulatory regime

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 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.

Among others, 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 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.

Follow-up actions

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 various means, and publishing safety alert summaries and special alerts on its website.

Since 2019, the DH has received a total of five complaints on medical devices listed under MDACS which all concerned quality issues of the products. Upon investigation, there was no evidence indicating that the products had quality issues.

The DH has noticed that three complaint cases were mentioned in the article published by the Consumer Council today regarding the purchase of medical devices. The department has proactively communicated with the Consumer Council on the cases concerned and taken appropriate follow-up actions. According to the information provided by the Consumer Council, one of the cases concerns the recalling arrangement of the respirator parts purchased through parallel import, while the other two are complaints related to the terms of sales and after-sales services of medical devices and do not carry any safety, quality and performance implications of the respective medical devices.

Future legislative works

The Government has all along been planning for legislation on the regulation of medical devices. However, the progress was affected by the COVID-19 epidemic. As stated in the 2023 Policy Address, the Government will set up a preparatory office this 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 new 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.

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, 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 the 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.