The Hong Kong Association of the Pharmaceutical Industry
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HKAPI responses to the Proposed Regulatory Framework for Medical Devices

1. Introduction:

Formed in 1968, the Hong Kong Association of the Pharmaceutical Industry (HKAPI), represents 41 international companies engaged in the research and development of pharmaceuticals including the world's top 20. As some of our members also involve in the import and regional distribution of medical devices, HKAPI would like to express our perspective on the proposed regulatory framework for medical devices.

2. General Comments:

2.1 HKAPI supports that there is a need to develop a regulatory framework for medical devices to protect public health while ensuring continued access to the new medical technologies for the benefits of patients.

2.2 HKAPI also supports the principle that such regulatory framework should adopt a risk-based approach whereby the level of control would be proportionate to the degree of risk classified for medical devices in accordance to the schedule of the International Medical Devices Regulators Forum ("IMDRF").

This ensures a strong foundational regulatory framework while harmonizing with international medical device regulations.

3. Recommendations:

In addition, the Association would like to propose the following recommendations for the consideration of the regulatory authorities in formulating the framework for medical devices.

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3.1 Validity period of medical devices

> *19. Registration of a medical device will be granted for a period of **three years**, and can be renewed every **three years**. Moreover, a registered medical device can only be supplied for the purpose(s) as approved by the DH.*

Considering the current validity period of medical device listing approval under Medical Device Administrative Control System (MDACS) administered by the Medical Device Control Office (MDCO) is five years, we would like the government to consider maintaining the validity as five years for the following reasons:

In most circumstance, there would not be major changes made to a marketed device and in the case of any major change to the information that has been submitted in relation to the application, the local responsible person (LRP) needs to notify the MDCO within 10 calendar days of the change and the MDCO has the discretion to require the LRP to submit a new application for the device based on the information submitted. This together with the stringent requirement of having a Quality Management System (QMS) in place would mitigate any safety risk concerns arising from changes to medical devices.

Besides, in view of the extensive number of medical devices available in the market and the transitional arrangement to be implemented if changing the registration of a medical device from the current five year to a period of three years, we are concerned that this would create huge administrative burden to both the registration certificate holders and the regulatory authorities.

HKAPI recommends - Validity period of medical devices should be five years

3.2 Validity period of registration and licensing of traders

> *23. In line with validity period of medical device registration, the validity period of all trader registrations will be aligned to **three years**, which can also be renewed every **three years**.*

In line with our comments regarding the registration and listing of medical devices above, HKAPI would suggest the government to consider granting a validity period of five years to all trader registrations. Currently, the validity period for different trader registrations is not aligned, for example, the validity period of local manufacturer registrations is five years while for distributor registration is three years. As there is an effective delisting mechanism in place for all traders and the fact that all traders are required to notify the MDCO as soon as possible if there are changes to the information submitted after the application is approved

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should alleviate concerns on safety.

HKAPI recommends - Validity period of five years for all trader registration

3.3 Standardization of control over advertisements

27. As for advertisement, misleading or fraudulent advertising of medical devices will be prohibited. Promotion of medical devices for use other than their approved use is also forbidden.

Under the existing regulations, the advertisements or commercial promotional materials of medical products shall not contravene the Undesirable Medical Advertisement Ordinance (Cap. 231). While we agree that misleading or fraudulent advertising of medical devices shall be prohibited, we suggest that advertisement control should also follow a risk-based approach in accordance with the UMAO. The level of advertisement control should be proportionate to the level of risk as identified by the regulatory and use control assessment.

HKAPI recommends – Risk based approach to advertisement control

3.4 Already established labelling requirements

27. To provide users with essential information for the proper and safe use of medical devices and to identify the traders which have been engaged in the supply of medical devices concerned, medical devices will also be required to meet the corresponding labelling requirement.

As MDCO has already established guidelines to the labelling requirement of medical devices, we would suggest that the regulatory authorities to maintain the current requirement and practices as traders already have operating procedures in place to comply with these requirements. We are concerned that any changing of the current labelling requirements could lead to unnecessary relabeling or redressing work. Future going, the implementation of any labelling requirement and changes should be discussed with the industry to facilitate transition..

HKAPI recommends – Maintain current requirements and practices established by MDCO

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3.5 Qualifications and training for use control of specific medical devices

> *30 (b) – users must be supervised on site by a registered medical practitioner or be a personnel who has successfully completed the relevant training programme as recognized by the Government.*

While use control will be imposed on specific medical devices, the proposed regulatory framework will not restrict the use of any medical devices by a registered HCP for purposes within the scope of his professional practice. As patient safety is our utmost concern, HKAPI recommends that all users, including registered HCPs, should possess the relevant qualifications and attend relevant training programmes especially for highly specialized and high risk medical devices to ensure a high level of technical competency and patient safety. Furthermore, we would like to inquire the requirement that constitutes a Government-recognized training programme and the process in which respective programmes can become recognized. Such information can further assist manufacturers of medical devices to develop quality and Government recognized training programme.

HKAPI recommends – All users should possess relevant qualifications and attend training programmes

4. Requests for clarifications

Further to the above recommendations, we would like to seek clarifications on the following proposed requirements.

4.1 Registration and licensing of traders

> *21. Traders including authorized representatives ("ARs"), local manufacturers, importers and distributors of medical devices must be registered with or have obtained a licence from the DH before they can supply medical devices in Hong Kong…"*

HKAPI would like more clarity and guidance on the definition, roles and liabilities of authorized representatives (ARs) as referenced in the proposed regulatory framework. For example, whether the roles and obligations of ARs will be different from the established "local responsible person" registered under the MDACS.

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4.2 Quality Management System

22. Local manufacturers will be required to conform to Quality Management System ("QMS") certification requirements.

HKAPI would like to have further guidance to the QMS certification requirements proposed and we would suggest the regulatory authorities to follow internationally recognized standards such as ISO 13485 when drafting its QMS requirements to reduce redundancy and confusion due to separate requirements.