

Regulatory forum

Newsletter - HK Medical Device

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First Jointed Regulatory Forum

Medical Devices will be regulated in Hong Kong very soon. Before the enactment of legislation, an administrative control system called Medical Device Administrative Control System (MDACO) within Department of Health (DOH) has been set up to provide framework for listing of medical devices, adverse incident reporting, listing of importers, listing of local manufacturers and recognition of Conformity Assessment Bodies (CAB)

Regulatory forum among 10-15 companies has been established since 2006. In order to maintain a regular gathering of regulatory and non-regulatory staff in medical device fields, and create a platform for different trade associations and DOH to introduce their roles and updates the medical device regulatory development,



a jointed forum of Medical Device Control Office (MDCO), Hospital Authority (HA), BSI (British Standards Institution, a recognized CAB in HK and notified body in Europe), Hong Kong Medical and Healthcare Device Manufacturers Association (HKMHDMA with focus on local medical device companies), Hong Kong Association of Pharmaceutical Industry (HKAPI with more than 44 multinational companies as members) was formed on 18 Jan 08.

On 18 Jan, we have 47 participants who are Regulatory, commercial, engineers or pharmacists from local industries, multinational industries, distributors, legal firms, publishers, Hong Kong Productivity Council, MDCO, HA or CAB participated.



This forum will be arranged regularly every 3-4 months so that regulators, biggest buyers e.g. HA, industries, industry trade associations and CAB can discuss their needs, concerns, HK & regional regulatory trends.

Organization Introduction



After introduction of the forum history and objectives, each organization provided their roles and functions. Detail can be found from their websites:

MDCO www.mdco.gov.hk

HA www.ha.org.hk

HKMHDMA www.medicaldevice.org.hk

HKAPI www.hkapi.hk

BSI (British Standards Institution)

www.bsi-global.com/en/ProductServices/Medical

*** more organizations are welcome to join**

HK Medical Device listing experience sharing



Christine Tsai (Regulatory Affairs & Quality Assurance Manager from Boston Scientific HK Ltd) was invited to share her experience on listing her companies' products including drug eluting stents.

Christine has more than 10 years marketing experiences in Pharmaceuticals and Medical Devices industry before RAQA. Boston Scientific has more than 50 listing approvals received from MDCO up to now



Regarding Drug eluting stent listing, companies need to aware that they should submit their listing application to MDCO and pharmacological data of the drug concerned may be required. Besides, company may need to apply for Wholesale Poison Licence if the drug concerned is classified as Poison in Hong Kong.

Contact BSI (the forum Convener) if you need a copy of presentation

AHWP update



Asian Harmonization Working Party (AHWP)'s objectives are to forge a common direction for the harmonization of medical device regulation in Asia, encourage increased understanding on the benefits of harmonization and facilitate a linkage with the Global Harmonization Task Force (GHTF).

Jack and Andros (industry representatives in Technical Committee of AHWP) provided an introduction of AHWP and brief update on Asia Regulatory changes including Singapore, Malaysia, Thailand, Philippines, India, Saudi and China.

Andros Chan (representative of HKMHDMA) also recommend participants to attend AHWP meetings to gain knowledge and network



Ms Huang Jin (Vice Secretary of Shenzhen Association of Medical Devices) also provided her insight of China regulatory. She also stressed the regulatory system in HK so far is very logical, easy to understand and communication with trade is excellent. Participants agreed with thanks.

A new China Medical Device Regulation was posted on website for comment. The following is the exact internet link where you can find the draft of the regulation:

www.sfda.gov.cn/WS01/CL0014/25388.html

MDCO update and discussion



Mark Lau (Senior Electronics Engineer, MDCO) informed that the Regulatory Impact Assessment was completed and pending final report. MDCO aims for submission of report to Legislative Council Q1 2008.

The Regulatory Impact assessment includes a series of focus group discussion with key stakeholders and even household survey to understand the impact of mandatory medical device regulation in Hong Kong.

There may be potential new changes including IVDD listing, Class I product listing/notification. Updates will be provided during coming forums.

Some key questions and answers of the forum:

Q: Any estimation on timing of mandatory regulatory listing?

A: MDCO stressed that it is not easy to predict the time for Legislative Council to discuss and pass the regulation. Monica Wong (Principal Medical and Health Officer, MDCO) highly recommended industry to list their products ASAP and mentioned that the Secretary for Food and Health accorded a high priority to the introduction of medical device regulation and Trade Facilitation Unit also budgeted the Regulatory Impact Assessment.

Q: The HK essential principle form's format is very different from EU essential principle form. It can take lots of time to fill in HK's essential principle form

A: *Mark Lau explained that the HK's form follows GHTF. MDCO allows company to provide essential principle form in EU format with a letter declare their product also follow the GHTF's principle as mentioned in HK's form will do.*

Q: Medical Device Listing in Hospital Authority includes technical assessment. Listing in MDCO also include technical assessment. Will duplicate technical assessment be eliminated in HA if a product got MDCO listing. This will help quicker listing in Hospital Authority

A: *Andy Chung (Biomedical Engineer, HA) mentioned HA needs to understand the technical detail of the product they purchase, and not aware any duplication. Monica suggested MDCO and HA will discuss the idea suggested during their coming internal meeting and will provide updates in future forums*

Other Issues

Forum's terms of reference agreed:

- maintain a regular gathering of regulatory and non-regulatory staff in medical device fields, and
- create a platform for different trade associations and DOH to discuss and updates the medical device regulatory development in HK

2 School of Pharmacy students in CUHK (supported by BSI) also created a report of HK Medical Device Industry Overview with list of HK medical device distributors. The report was distributed to the participants on 18 Jan. Contact me if you need a copy

Coming AHWP meeting will be in March. Please note 3-4 Mar is AHWP meeting, 5-7 Mar is APEC training. Detail can be found by the following link:

http://asiahwp.org/upload/id254/APEC%20Training_KL_2008.pdf

Next forum will be around end Mar/early Apr. Convener will inform the participants ASAP

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