Medical Device Regulatory Update

Medical Device Control Office
Department of Health
The Government of Hong Kong SAR

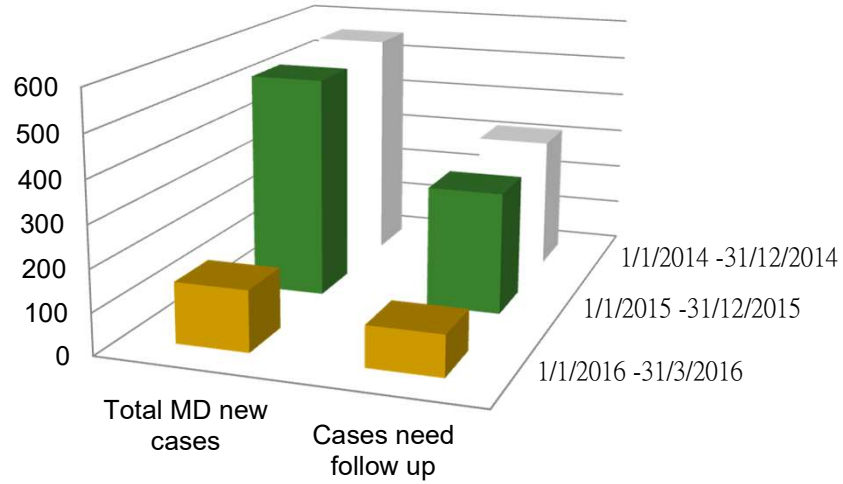
27 May 2016

Matters related to Legislative Proposal

- The consultancy study by the ECRI Institute on the control of use of selected medical devices in Hong Kong is approaching the final stage and anticipated to be completed by 2016 Q2.

MD Listing under MDACS

Result of Initial Screening



	Total MD new cases	Cases need follow up
1/1/2016 -31/3/2016	146	98
1/1/2015 -31/12/2015	532	293
1/1/2014 -31/12/2014	558	319

MD Listing under MDACS

Possible change

Renewal of listed equipment

- The renewal will be mainly an administrative process, through provision of essential document (business registration & etc)
- 'Change' will be handled separately and to be submitted when situation arise

MD Listing under MDACS

Possible change

Notification of Renewal application

- Currently, the status of the listed equipment will be indicated in the MDCO website;
- There is an intention to indicate the status of renewal application in addition to the validity of listed equipment

MD Listing under MDACS

Application Form

- Please double check before submission
- Unwelcomed examples like:
  - Indication of single use when the equipment is more than $500K
  - Indication of non-invasive when the equipment is supplied with sterilized transducer pack that to be inserted inside the patient body
- By registered mail

MD Listing under MDACS

Long Lasting Applications

- Results of ineffective communication from both parties
- Piecemeal question and answer process leading to follow up questions
- Encourage to clear the long lasting cases by both parties. Initial result is promising
- Withdraw application as appropriate
- Bigger achievement is anticipated

MD Listing under MDACS

Intended use of medical devices

- Intended use ≠ Direction of use
  ≠ Sale leaflet
- Indication of single use as appropriate
- Avoid beauty jargon
- Concise and Precise

MD Listing under MDACS

Intended use of medical devices

Length of Intended Use (character)

From listed cases:

- Occurs most frequently - Below 200 characters
- Over 70% is below 400 characters
- Around 10% is more than 600 characters
- Some of them are unreasonably long and up to 3,000 characters or more

MDACS Development

Full/Surveillance Inspections

- Full inspections to all applicants applying for listing as LMs or Importers
- Conduction of surveillance inspections (2015) to listed importers/LRPs , major observations cover:
  - Control of documented procedures
  - Procedures to include timing of report & CAPA
  - Keeping of complete records and its retention time
  - Storage and segregation of goods
- Tentatively 5 surveillance inspections in 2016, likely to increase number of surveillance inspections.

MDACS Development

Listing of Distributors

- Commenced on 30 April 2015
- Guidance Note GN-09 posted under MDCO website

MDACS Development

Listing of Distributors (recap)

- Requirements similar to listing of Importers, need:
  - Application form & BR
  - Documented procedures
  - Local manned office (where distribution operations are performed),
  - At least 1 device listed (list of devices to be submitted)
- Valid for 3 years

MDACS Development

Listing of Distributors

- Documented Procedures

(Mandatory)

- Distribution procedures and records
- Handling, Storage and Delivery of MDs

(If applicable)

- Complaints handling
- Product alerts, modifications and recalls
- Managing reportable adverse incidents in HK
- Tracking of specific medical devices
- Maintenance and services arrangements

MDCO Development

New office at Room 604, 6/F, CityPlaza Three, 14 Taikoo Wan Road, Taikoo Shing, Hong Kong.

New electronics engineer, Ms Kay S.K. Wong joined MDCO on 1 April 2016.

Thank you !