Medical Device Regulatory Update

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

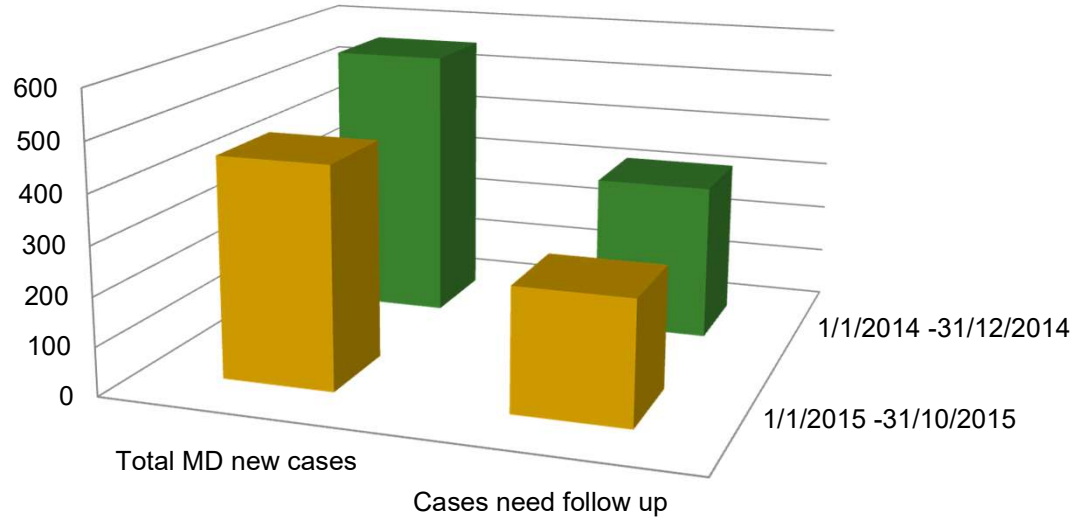
12 November 2015

Matters related to Legislative Proposal

- The Government has commissioned the ECRI Institute to conduct a study on the control of use of selected medical devices in Hong Kong. The consultant is expected to complete the study in the first quarter of 2016.

MD Listing under MDACS

Result of Initial Screening



	Total MD new cases	Cases need follow up
1/1/2015 -31/10/2015	450	251
1/1/2014 -31/12/2014	558	319

MD Listing under MDACS

Result of Initial Screening

- Successful rate is not encouraging (45%)
- Check completeness & correctness of application before submission
- Enrolling in our workshop especially for new comers – 2 Dec 2015
- It is an evening workshop at Lecture Theater 2, Esther Lee Building, Chinese University of Hong Kong, Sha Tin

MD Listing under MDACS

Result of Initial Screening

- LRP shall be the applicant and hub of communication, not the "Overseas Office" or "Consultant".
- There is NO Listing Workshop at our MDCO office.

MD Listing under MDACS

Section as shown in medical device listing application form*	Suggestions
A001	- Ensure the legal manufacturer's information is consistent with the ISO certificate in section A003: 1. name 2. address
A002	Check validity of certificate especially if it is near expiry.
A003	Check validity of certificate especially if it is near expiry.
B001 (Contact Person)	- If there are more than 1 contact person, please feel free to provide details of other contacts in order not to miss any reply sending from MDCO. - Should provide Hong Kong contact numbers.
B001 (Business Registration Certificate)	- Check validity of certificate especially if it is near expiry. - Full BR number is required.
B002 (Designation Letter)	- Should exactly follow the content of the letter suggested by MDCO and do not make any amendments. - Legal manufacturer's name and address should be the same in A001 & ISO 13485. - LRP's name and address should be the same on BR. - Designation letter should be in legal manufacturer's letterhead. - Product name should be the same in marketing approvals/IFU.
B004 (SOPs)	MDCO found a number of SOPs submitted are not complete or acceptable. It is too brief and not clear on roles and steps. SOPs should be prepared to address the specific situation of each organisation. LRP Panel suggests members should review their SOPs to align its content with SOPs of their global team and their partners e.g. distributor. It will be very helpful to trial run the SOPs especially the SOP on recall to ensure the SOP work practically
C001 (Brand Name)	- MDCO confirmed it is OK to leave it blank if there is no brand name - Product name should be the same in designation letter.
C003 (AMDN Code)	AMDNS is almost the same as UMDNS. Members should just copy the GMDN code here. Companies should also be aware that the AMDN code of listed product may also be changed during renewal if MDCO considers the original AMDN code not appropriate.

MD Listing under MDACS

Section as shown in medical device listing application form*	Suggestions
C005 (Intended Use)	The intended use should be complete preferably with intended medical purposes for what kind of patients and it is intended to be used by whom. If any accessory is required for proper functioning of the device, it should be mentioned. There should be no marketing message.
C009 (Manufacturing Site)	- Name and address should be provided. - Related ISO 13485 should be submitted for checking.
C013 (Instruction for Use)	- Correct product name. - Both Eng and Chi are required for consumer products.
C013 (Device Labelling)	- Should be provided.
C013 (Sample of Special Listing information)	- Should be provided.
C014 (Licenses)	- Should be provided if applicable
C015 (CAB Certificate)	Missing signature, post title and name of organisation are common
C016 (Risk Assessment Report)	Missing signature, post title and name of organisation are common. Use of electronic signature should be clearly indicated.
C017 (Clinical Evaluation Report)	Missing signature, post title and name of organisation are common. Use of electronic signature should be clearly indicated.
D001 (Marketing Approvals)	- Should provide at least one certificate. - For EC Certificate, EC Full Quality and EC Doc are required for listing Class II/III devices. - For Class IV and IVD Class D, EC Design is also required.
D001 (ER & EP)	- If earliest approval obtained on or after 1/1/2005, ER/EP is required. - For EP (i.e. MD-CCL), it should be prepared by the LRP and original (stamped with company chop) is required.

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
- 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
- Elimination of 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

MD Listing under MDACS

Expiration of Listing

- A large no. of MD listings (~500) will expire in 2015 – renewal applications received in 2014 >360 cases
- LRP/Importer/LM to submit application for renewal at least 3 months before expiry
- Need to submit a new application – if application is submitted after expiry or if there is a major change
- No reminder for renewal will be issued
- Enquiry for renewal is NOT a formal renewal request
- Remember to give application/listing no. in all correspondences

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 (0 LRPs and 3 importers so far), 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

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

MDACS Development

Change of Staff

- New Research Officer reported duty

MDACS Development

Relocation of Office

- Tentatively around March 2016
- New office at TaiKoo Shing CP3

Thank you !