Medical Device Regulatory Update

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

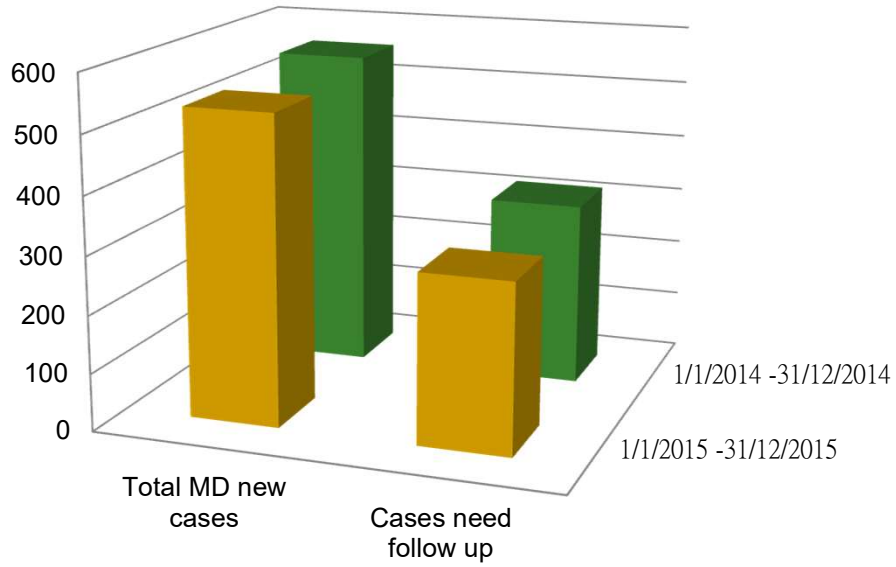
19 February 2016

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 in progress and views from stakeholders have been collected. The study is expected to be completed by 2016 Q1.

MD Listing under MDACS

Result of Initial Screening



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

MD Listing under MDACS

Result of Initial Screening

- Successful rate is still less than 50% (45%)
- Check completeness & correctness of application before submission
- Enrolling in our workshop especially for new comers – 13 April 2016
- 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

Result of Initial Screening

- Application Form (e.g. incorrect manufacturer's/LRP information, no/incorrect AMDNS code, incorrect applicant's name, etc)
- Related to ISO 13485 (e.g. not available, expired)
- Related to BR (e.g. not available, branch certificate)
- Related to LRP letter (e.g. not available, incorrect address, no device name, incorrect format, etc)

MD Listing under MDACS

Result of Initial Screening

- Marketing Approvals, Essential Requirements Checklist, etc (e.g. not available, incorrect device name

- Others (including risk analysis, clinical evaluation, IFU, device label, special listing information)

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

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 , 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

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

Relocation of Office

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

Thank you !