Medical Device Regulatory Update

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

10 Feb 2015

Legislative proposal

- Business Impact Assessment (BIA) findings and the refined regulatory framework reported to the LegCo Health Panel in June 2014

- Arrangement of the consultancy study on use control of selected medical devices is still in progress

MD Listing under MDACS

Observations from submissions

- ***Quality of Applications*** *(Overall)*
  - Some improvements in quality observed especially those submitted by existing traders
  - Some applications are incomplete. In one case, some essential information are not provided including contact email and fax.
  - Check completeness & correctness of application before submission
  - Withdraw application if requisite information could not be provided within a short period (say >6 weeks)
  - LRP shall be the applicant and hub of communication, not the "Overseas Office" or "Consultant".

MD Listing under MDACS

Observations from submissions

- ***Quality of Applications*** *(recap of major observations)*
  - Wrong/unacceptable AMDNS no./term, intended use, device classification, make/brand/model
    - Gives 4 AMDNS terms for selection in one case
    - Provide GMDN term only
    - No knowledge of device, quote wrong AMDNS
    - Incomplete intended use by providing names of diseases only
    - Intended use has no medical purpose(s)
    - Always treat “make” as brand name

MD Listing under MDACS

Observations from submissions

- ***Quality of Applications*** *(recap of major observations)*
  - Missing/Incomplete product details
  - Incomplete/unacceptable documented procedures
  - Missing/unacceptable designation letter (change wordings)
  - Missing/No signature - EC DoC, EP, ER (with EP DoC), risk assessment, clinical evaluation

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 (2014) to listed importers/LRPs (3 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

- Two briefing sessions (25 & 26 Nov) held at Ngau Chi Wan Municipal Services Building for traders
- Draft GN posted under MDCO website for comments (up to end Dec 2014), one email received with comments on mandatory listing, doc procedures required and proof of the required procedures.
- Advice from DoJ on draft docs received late Jan
- Propose to introduce the listing on 1 April 2015

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

- Mr S Y Lam will leave the office and proceed on pre-retirement leave after 27 Feb 2015.
- Mr Y S Chan will succeed him as leader of team 2.

Thank you !