Medical Device Regulatory Update

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

11 Nov 2014

Legislative proposal

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

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

MD Listing under MDACS

Observations from submissions

- ***Quality of Applications*** *(Overall)*
  - No improvement in quality of applications received
  - **Check** correctness/completeness of applications carefully before submission
  - Withdraw application if requisite information / docs could not be provided within a reasonable short period (say 6 weeks)
  - LRP shall be the applicant and hub of communication, not the “Overseas Office” or “Consultant”. Some LRPs have no involvement and roles of parties unclear.

MD Listing under MDACS

Observations from submissions

- ***Quality of Applications*** *(major observations)*

  - Wrong/unacceptable AMDNS no./term, intended use, device classification, make/brand/model
  - Incomplete/Incorrect contact information
  - Missing/Incomplete product details
  - Incomplete/unacceptable documented procedures

MD Listing under MDACS

Observations from submissions

- ***Quality of Applications*** *(major observations)*
  - Missing/unacceptable designation letter
  - Missing/Incorrect Special listing info
  - Missing/No signature - EC DoC, EP, ER (with EP DoC), risk assessment, clinical evaluation
  - No confirmation on adoption of electronic signature

MD Listing under MDACS

Expiration of Listing

- A large no. of MD listings (~500) will expire in 2014 – renewal applications received in past few months on the high side > 50 cases per month
- 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 started in June, 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

- Draft GN for Listing of Distributors completed
- Two briefing sessions will be held at 3/F Lecture Room, Ngau Chi Wan Municipal Services Building:

  Briefing Session No.1 (conducted in Cantonese) :
  25 November 2014
  3:30 p.m. to 5:30 p.m.

  Briefing Session No.2 (conducted in English) :
  26 November 2014
  3:30 p.m. to 5:30 p.m.

  Details and enrolment method available from
  http://www.mdco.gov.hk/english/events/events_20141125.html

MDACS Development

Listing of Distributors

- 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
- Expected to be launched in mid 2015

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

Ref Standards to be adopted for listing

- 1st List of Reference Standards compiled:
  - *Basic (general) standards*
  - *Group standards*
  - *Product specific standards*
- Assessment of MD listing applications based on the list of standards (e.g. EP / ER, clinical evaluation, risk assessment, type test/approval)
- There is no comment received from LRP panel members

Thank you !