Medical Device Regulatory Update

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

8 August 2014

Legislative proposal

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

- Consultancy study on use control of selected medical devices being arranged

MD Listing under MDACS

Observations from submissions

- ***Quality of Applications*** *(Application form)*
  - Quality of applications and staff employed by LRP in making submission remain major concerns
  - No improvement in correctness/completeness of applications despite repeated reminders/advices
  - LRP shall be the applicant, not the “Overseas Office” or your “Consultant”

MD Listing under MDACS

Observations from submissions

- ***Quality of Applications*** *(Application form)*
  - Items inappropriate or not acceptable
    e.g. AMDNS no./term, intended use, device classification, make/brand/model
  - Items commonly omitted e.g.
    Contacts – should include emails/tel. of all persons need to know
    Product details – include all system components, accessories and full list of product codes (should be found from submitted marketing approval, CFG or EC DoC)

MD Listing under MDACS

Observations from submissions

- ***Quality of Applications*** *(Key documents)*
  - Documented procedures of LRP/Importer (for new LRPs/Importers and renewals)
  - Designation letter (missing or not follow template, no signature/company chop/date/letterhead)
  - Special listing info (missing or incorrect)
  - EC DoC, EP, ER (with EP DoC), risk assessment / clinical evaluation (not provided or without signatures/post)
  - Written confirmation required from manufacturer on docs adopting electronic signature

MD Listing under MDACS

Observations from submissions

- ***Quality of Applications*** *(Others)*
  - Initial Screening – application **NOT** accepted for processing if outstandings not submitted/cleared before deadline (currently 3 reminders max)
  - Common Issues related to Applicants:
    - Not familiar with application procedures
    - Lack of proper training/handing over
    - Do not read the instructions/GNs and check for completeness before submission
    - Often make careless mistakes
    - Fail to provide valid docs/acceptable answers before deadlines, applications will be closed

MD Listing under MDACS

Observations from submissions

- **Risk class of submitted certificate different from MDACS (GHTF)**
  - Classification of catheter in contact with common iliac is of a lower risk level class IIb according to EU certificate, but should be class IV under MDACS.

- **Intended areas of applications too broad or undefined**
  - For e.g. device is suitable for " general/other intraoperative procedures including peripheral procedure", if "general/other" is not defined, the device is classified as a higher risk device.

MD Listing under MDACS

Expiration of Listing

- LRP/Importer/LM to submit application for renewal at least 3 months before expiry
- A large no. of MD listings (~500) will expire in 2014 – about 50 renewal applications received per month recently
- 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

MD Listing under MDACS

Compliance with MDACS Requirements

LRP shall

- fulfill the obligations under MDACS and maintain effective communication channels with parties concerned
- inform MDCO of safety recalls/alerts/adverse events and provide details **asap**
- report changes **asap** including change of address/ contact details/LRP, discontinuation of sales, and other changes affecting SEQ of device

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

MDACS Development

Listing of Distributors

- Draft GN for Listing of Distributors being prepared
- 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 being/to be distributed
- Valid for 3 years
- Would consult the trade when draft is ready (draft to be posted on MDCO website)
- Expected to be launched in 2015

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)
- List would be sent to the trade for comments

MDACS Development

- ***MD Classification Program***

  http://www.mdco.gov.hk/english/faq/question.html

- Now posted under MDACS
- No need to login
- You are welcome to give it a try!

Thank you !