



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



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"



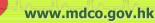


Observations from submissions

- **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)





Observations from submissions

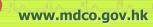
- **Quality of Applications** (Key documents)
 - Documented procedures of LRP/Importer (for new LRPs/Importers and renewals)
 - Designation letter (missing or not follow template, no signature/company chop/date/letterhead)
 - Special listing info (missing or incorrect)
 - EC DoC, EP, ER (with EP DoC),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





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





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.



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!



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