LRP Panel – Medical Device listing

Guidance document on listing preparation

Version 2017.1

Prepared by LRP Panel with input from MDCO, Industry and Academic

LRP Panel was informed by MDCO in the past panel meetings of the common problems observed during product listing in HK. We would like to summarize the common problems and suggestions in the following table. Members may consider using the checklist below to double check your listing application before submission:

Section as shown in medical device listing application form*	Suggestions
A001	Ensure the manufacturer information is consistent with the ISO certificate in section A003
A002	Check validity of certificate especially if it is near expiry
A003	Check validity of certificate especially if it is near expiry
B001 (Contact Person)	If there are more than 1 contact person, please feel free to provide details of other contacts in order not to miss any reply sending from MDCO
B001 (Business Registration Certificate)	Check validity of certificate especially if it is near expiry
B002 (Designation Letter)	Should exactly follow the content of the letter suggested by MDCO and do not make any amendments
B004 (SOPs)	MDCO found a number of SOPs submitted are not complete or acceptable. It is too brief and not clear on roles and steps. SOPs should be prepared to address the specific situation of each organisation. LRP Panel suggests members should review their SOPs to align its content with SOPs of their global team and their partners e.g. distributor. It will be very helpful to trial run the SOPs especially the SOP on recall to ensure the SOP work practically
C001 (Brand Name)	MDCO confirmed it is OK to leave it blank if there is no brand name
C003 (AMDN Code)	AMDNS is almost the same as UMDNS. Members should just copy the GMDN code here. Companies should also be aware that the AMDN code of listed product may also be changed during renewal if MDCO considers the original AMDN code not appropriate.
C005 (Intended Use)	The intended use should be complete preferably with intended medical purposes for what kind of patients and it is intended to be used by whom. If any accessory is required for proper functioning of the device, it should be mentioned. There should be no marketing message.
C015 (CAB Certificate)	Missing signature, post title and name of organisation are common
C016 (Risk Assessment Report)	Missing year version for international or national safety standards, signature, post title and name of organisation are common. Use of electronic signature should be clearly

	indicated.
C017 (Clinical Evaluation Report)	Missing signature, post title and name of organisation are common. Use of electronic signature should be clearly indicated.
D001 (Marketing Approvals in Foreign Countries)	Ensure the product name and models align with the submitted foreign marketing approval.

*Note: re. Form MD-C2&3&4 (Jul 2011 Edition)

Special thanks for the contributors below

- MDCO
- SY Lam (ex-MDCO)
- Raymond Tong, Jack Wong, Tammy Wong (LRP Panel)
- Linda Chan, Chan Hoi Yan, Kwan Yi (Industry)