LRP Panel 39th Meeting

Date: Apr 16, 2021

Time: 3pm~5pm

Venue: Zoom

LRP Panel discussed topics

Personnel updates

- 9 to 7 vetting officers, 2 vetting officers left on 1 April 2021

Statistics (Please refer to attached DH's presentation slides)

Despite the pandemic, the number of listing applications received and approved in 2020 were close to those in 2019.

Key Updates

- Updated Guidance Notes and the corresponding Forms will be published in mid Apr 2021; old forms will not be accepted three months after
- Extension of 3 existing trial schemes Some changes in requirements for expedited approval of Class II/III/IV, LRPs are encouraged to join the trial scheme(s) with one or two of their products)

Reminders

- submit renewal application (at least 3 months) before the expiry date. MDD will follow this rule strictly
- 15% of the email address given from the traders are undeliverable. Please update your contact to MDD in order to avoid missing important update
- LRPs are reminded that certificates submitted must be valid, it is common problem that expired/out-dated certificates are given

Notice

- Some medical devices (e.g. contact lens, condoms) may be regulated by the Consumer Goods Safety Ordinance, which has different requirements on labelling/IFU from MDACS. Meeting MDACS' requirements on labelling does not necessarily mean that compliance with the Consumer Goods Safety Ordinance

Update on legislation of medical device regulation

- Administration more focus on fighting with COVID-19 pandemic and other issues
- MDD continue to work on refinement of the bill
- LRP Panel will consider rendering support to the proposed legislation as appropriate

Q: MDD review during COVID - variation parts seems taking longer time (> 6 mths)

A: Industry may expect potential delay due to manpower situation mentioned above. Helpful to provide comparison table on the change proposed which could help speed

up approval.

Q: Regards on the renewal process, it is quit concerning when the MD is regulated, any passed expiry license will be terminated. I wonder if MDD consider follows Pharm regulation that the DOH send us notification 6 months ahead to ensure license owner can apply renewal on time.
A: Timely submission of renewal applications is the sole responsibility of the listing certificate holder. MDD currently does not have the resources to issue/follow up reminders

Q: Reviewer ask to simply the intended use for record only
A: It is the Approval Board's intention to keep the "Intended Use" accurate and precise. Content which is of precaution, indication or promotion nature may normally be removed. However, for trade facilitation, such revision will only be reflected in MDD's database, and corresponding change to the IFU is not mandatory.

Q: I have a question about the registration of medical device which will be co-packed with a drug product with different pharm company. what is the registration strategies regarding this subject?
A: It may be considered combinational product. In view that pharmaceutical products are regulated while medical device is not, traders are suggested to first enquire Drug Office if registration with them is needed.