

LRP Panel Discussion Highlights (28 Apr 2017)

Listing and improvement noted

- More effective process time in the listing application: We observed approval time significantly improve since one year ago. Some companies also experience listing approval in a few months when there was a well prepared application. We will continue to have the MDCO colleagues to join our LRP meeting to promote the good practice to our LRP members in preparing their submission.
- Board meeting schedule: MDCO actively monitor the various stages of the vetting process including board meeting schedule to ensure applications are timely processed.
- Renewal process: A new and innovative renewal process was rolled out which separate product change application from renewal application. Industry really found it is an effective way and make the process more smooth and clear.
- Listing screening: The MDCO staff provide screening and comments on the listing application is very professional. They provide timely response to the application and offer useful advice on preparing the application.

Ideas to be considered

- Allow application of listing while waiting for other licence approval (e.g. Radiation certificate approval), so that company can submit application earlier and supplement the radiation certificate around 3-4 months after submission
- When new regulation implemented, allow medical device parts importation for product maintenance even the product is not registered. It allow continue maintenance service.
- Arrange regulatory and/or technology training from industry to MDCO in University
- Allow company presentation on product/technology to reviewer if required
- Fast track listing criteria to be developed

Others

- As discussed, LRP Panel will try to draft a guideline on Product change for MDCO to comment
- We also understand Legal manufacturer name change will be considered as new listing. Provision of old listing details could facilitate the easy retrieval of useful relevant information for evaluation of the new listing.