31st LRP Panel Meeting on Feb 23, 2018

LRP Panel's Consultation Task Force on Regulatory Progress of Advanced Therapy

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Guidance document

- There are still many concerns on what should be required during change control process. Kindly share with MDCO reviewer to help align their expectation. LRP Panel will also share among members. Do let us know if any content need to be updated

Regulation

- It will take 2yrs+ for the MD legislation to be fully implemented even if the bill is successfully introduced into and passed by the Legislative Council
- There is no licensing requirement solely for warehouse of medical devices
- Application as an authorised representative (LRP) will be allowed even without product being registered

Listing

- YS is exploring an idea of Priority path for quality dossier with 2 or more GHTF founding countries approval (to be rolled out around Sept 18)
- Will consider CFDA approval as reference country for future listing

Appreciation

The LRP Panel found that Mr Fung and Tina provided very efficient and professional service. The team really appreciate their support and feedback.

Listing queries

- Change in name of legal manufacturer needs new registration as MDCO considered it is major and critical change

Next forum date
20 Jul, 9 Nov