LRP Panel 33rd Meeting

Date: Nov 9, 2018

Time: 2pm~5pm

Venue: Room 10, Bamboo Hong Kong, Star House, TsimShaTsui

Approval time experience from industry

new registration - 9-12 months (4 months approval also mentioned by members)
Change - 6-9 months (4-12 months approval also mentioned by members)

Formal listing approval Certificate available time

Challenge: industry aware it takes around 4 weeks to get the above once board approval was done
Next steps: MDCO will review the time required and explore chance to shorten this steps

Submission of Change: suggestion

Challenge: no clear documentation requirement and different regulators have different expectation
Next steps: Tammy kindly pass MDCO our last change guidance document for any update and then we will share with industry as guidance document

Registration requirement database

We aim to roll out a free platform to share APAC medical device registration requirement database
Jack will pass the above to YS (to comment HK content and overall design) and Raymond (to discuss how to roll out)

Trial Scheme for Provisional Approval

- latest flow chart and criteria was updated by YS
- MDCO will evaluate when to roll out and any chance to have a pilot first

Forum promotion

MDCO will mention related organization and activities during coming MDCO workshop. Any interested parties can contact Raymond, Tammy or me to attend the coming one (date TBC)

EU MDR impact to HK

- YS mentioned that MDCO is in observation stage and will adjust HK requirement if required
- Jack mentioned that EU MDR will have big impact to industry (e.g. label change, product classification change, notified body name or number change, and even product being deleted due to additional clinical data requirement)

IVD

- guidance document on listing of Class B and C will be available for comment in Dec
- voluntary listing of Class B and C targeted to roll out in 1Q 2019