Panel Discussion
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From our survey to your pharmaceutical association, you have a plan to introduce Post-Approval Change Management Protocol, "PACMP"* in Singapore,

Question 1: ***What is the current status regarding the introduction of "PACMP"?***

** PACMP was defined in ICH Q12 TECHNICAL AND REGULATORY CONSIDERATIONS FOR PHARMACEUTICAL PRODUCT LIFECYCLE MANAGEMENT, Chapter 4 adapted on 20 Nov.2019.*

- PACMP needs careful consideration and planning before implementation. We conducted a survey of our local industry stakeholders for this purpose.
- HSA will adopt a phased approach in the implementation of ICH Q12 tailored to the readiness and needs of the industry
- HSA is currently participating in the ICMRA collaborative assessment of CMC related post-approval changes, which includes PACMP as an observer

Question 2: ***Do you see any advantages to introduce "PACMP" in your country?.***

1. Facilitate the introduction of manufacturing innovation
2. Reduce the ambiguity about studies and documentary requirements for post-approval changes
3. Increase predictability surrounding the implementation of post-approval changes
4. Allow faster implementation of post-approval variations for companies that have demonstrated enhanced product knowledge and process understanding together with an efficient pharmaceutical quality system

Question 3: ***Do you have any question/uncertainty to introduce "PACMP" in your country?***

1. Uncertainty: Need for changes in variation procedures and IT systems to allow implementation
2. Uncertainty: Needs/priorities of local industry
3. Question: Awareness and readiness among the industry and regulators
4. Question: Potential resource implications for regulators