Regulatory Affairs Task Force

Name	Company
Gwenael Meneux (Sponsor)	**AstraZeneca**
Karen Yuen (Lead)	**GSK**
Kim Lee	Novartis
Tony Chow	Bayer
Linda Chan	BMS
Ivy Ting	Ferring
Susanna Yim	Janssen

<table>
<tr><td>Objective</td><td colspan="5">Keep on building a world-class Regulatory framework and efficient process for Patient early access</td></tr>
<tr><td rowspan="2">Endpoint</td><td colspan="3">Expedite</td><td>Adapt</td><td>Educate</td></tr>
<tr><td>NCE registration - Early submission:
•Explore opportunity to expand scope of “1 CPP” exception (high unmet medical needs)
•Clear guidance fm DH on NCE of COVID-19 related products
•Concept of Good reliance pathway for NCE registration is adopted</td><td>Change of Particulars
•One-month stop-clock mechanism for CORP review
•Expediting review for new indications application
•Multiple manufacturing sites for vaccines and biologics
•Approval by DH of ePI (Package Insert) as an additional option for Industry</td><td>Macao regulatory:
•Enhance the transparency of the licensing system and expedite the process</td><td>To ensure the regulatory environment could cope with medical advancement
•Medical Device Legislation
•Monitor the implementation of the Advanced Therapies Products (ATP) Legislation</td><td>Promote Regulatory best practices
•Build more competent regulatory affairs professionals for the industry
•Further enhance the good submission practice</td></tr>
<tr><td>Future State</td><td colspan="5">Pharma industry seen as an important partner in healthcare delivery in both HK & Macau
Regulatory requirements shaped to cope with medical advances
Efficient regulatory system being able to protect public health, while also conducive to pharma industry</td></tr>
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