The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Mutual Recognition Agreements and Reliance in the Regulation of Medicines

Information Gathering Session

AGENDA

Wednesday, 24 July 2019/Thursday, 25 July 2019

(Wednesday evening) 7:30pm EDT, 5:30pm MDT, 4:30pm PDT

(Thursday morning) 7:30am Singapore

Please contact Kelly Choi (kchoi@nas.edu) to register for this event

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7:30pmET **WELCOME**

Alastair Wood, Committee Chair

Committee Introductions

- Martha Brumfield
- David Beier
- Barbara Koremenos
- Others TBD

7:40pm **OPENING REMARKS**

Please address:

- What MRAs does HSA have?
- What do the MRAs cover (do you have MRAs for the "approval" of drugs)?
- How do these MRAs work?

Assoc Prof Chan Cheng Leng,
Group Director, Health Products Regulation Group,
Health Sciences Authority of Singapore (HSA)

Ms Jessica Teo, Division Director,
Audit and Licensing Branch, HPRG, HSA

Ms Agnes Chan, Director,
Therapeutic Products Branch, HPRG, HSA

Ms Chua Siew Wei, Deputy Director,

Stakeholder Engagement Office, HPRG, HSA

8:00 pm **DISCUSSION WITH THE COMMITTEE**

8:30pm *Adjourn*

ADDITIONAL GUIDING QUESTIONS TO CONSIDER

Formal Agreements & Informal Arrangements
• What formal agreements does HSA have, and with which countries?
• What informal arrangements does HSA have, and with which countries?
• What has been your experience with such agreements/reliance approaches?
  o What was your experience with ACSS Consortium?
Outcomes of MRAs
• When MRAs are implemented, what are the:
  o Public health impacts;
  o Resource redirection/savings or costs;
  o Impacts to HSA's technical, scientific and regulatory competencies
Confidentiality
• How do you ensure confidentiality?
• Has there ever been a breach of confidential information and if so, how was it handled?
Opportunities/Challenges
• What opportunities do you envisage for greater reliance on information from trusted counterpart regulators in the future?
• What efficiencies could result from such reliance agreements/approaches?
• What are the impediments to such reliance?
• What specific areas could be subject to such reliance?
  o What are the risks/benefits?
  o How would you prioritize the specific areas that you propose?
Other issues
• How does HSA handle approval of generics that are already being sold in a country similar to Singapore (will any of the information be accepted from a previous ruling/report)?