The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Mutual Recognition Agreements and Reliance in the Regulation of Medicines

Information Gathering Session

AGENDA

Monday, 10 June 2019/Tuesday, June 11 2019

(Monday evening) 6pm EDT, 4pm MDT, 3pm PDT, 11pm BST, 12am CEST

(Tuesday morning) 8am ACT

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

8am ACT **WELCOME**
Alastair Wood, Committee Chair

Committee Introductions

- David Beier
- Gavin Huntley-Fenner
- Larry Gostin
- Others TBD

8:10 am **OPENING REMARKS**
Kaylene Raynes, Director – Applications & Advisory Management
Therapeutic Goods Administration (TGA)
Health Products Regulation Group
Australian Government Department of Health

8:25 am **DISCUSSION WITH THE COMMITTEE**

Dr Jane Cook, First Assistant Secretary
Medicines Regulation Division,
Prescription Medicines Authorisation

Adrian Bootes, Branch Head
Prescription Medicines Authorisation

Tracey Duffy, First Assistant Secretary,
Medical Devices and Product Quality Division

Joe Hlubucek, Project Manager
Council of Academic Public Health Institutions Australia (CAPHIA)

9:00am *Adjourn*

GUIDING QUESTIONS
Experiences with MRA/reliance • How have MRAs/reliance approaches been developed and utilized at TGA? • What has been your experience with such agreements/reliance approaches? • When MRAs are implemented, what are the public health impacts, resource savings and/or redirection, e.g., to areas of higher risks? • Over time, what if any are the impacts to an NRA's technical, scientific and regulatory competencies? **Confidentiality** • How do you ensure confidentiality given peer assessment with varying levels of security (cyber and other threats)? • 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** • Is it likely that such reliance agreements/approaches could/would accelerate the drug development and market authorization process by reducing inefficiencies and redundant work—tell us how and by how much—specific illustrations would be helpful • How does TGA handle approval of generics that are already being sold in a country similar to Australia (will any of the information be accepted from a previous ruling/report)?