The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Mutual Recognition Agreements and Reliance in the Regulation of Medicines

Information Gathering Session

AGENDA

Friday, 31 May 2019

1pm EDT, 11am MDT, 10am PDT, 6pm BST, 7pm CEST

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

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1pm EDT **OPENING REMARKS**
Alastair Wood, Committee Chair

1:10 pm **OPENING REMARKS**
Kimby Barton, Director, Health Products Inspection & Licensing

1:25 pm **CLARIFYING POINTS & DISCUSSION BASED ON GUIDING QUESTIONS**

- Linsey Hollett – Acting Director General, Health Product Compliance Directorate (HPCD)
- Kimby Barton – Director, Health Product Inspection and Licensing Division (HPIL)
- Stephen McCaul – GMP Manager
- Stéphanie Anctil – MRA Officer (HPIL)
- Louise Kane – Manager, MRA and International Affairs Program
- Celina Bak, Acting Associate Director - Health Product Compliance and Risk Management (HPCRM)
- Ann Kourtesis – Acting GMP Manager – Foreign sites
- Joy Bregg – Acting GMP Manager – Domestic
- Kim Dayman-Rutkus – Senior Policy Advisor , Policy and Regulatory Strategies Directorate

2:30/3:00pm *Adjourn*

GUIDING QUESTIONS

Experiences with MRA/reliance

- How have MRAs/reliance approaches been developed and utilized at Health Canada?
- 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?
    - What are the risks/benefits?
    - 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 Health Canada handle approval of generics that are already being sold in a country similar to Canada (will any of the information be accepted from a previous ruling/report)?