The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Mutual Recognition Agreements and Reliance in the Regulation of Medicines

Information Gathering Session

AGENDA

Tuesday, 7 May 2019

5 PM CEST, 4 PM BST, 11am EDT, 9am MDT, 8am PDT

Contact Kelly Choi (KChoi@nas.edu) to register for this event

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5pmCEST **OPENING REMARKS**
Alastair Wood, Committee Chair

5:05 pm **REMARKS BASED ON GUIDING QUESTIONS**
Agnes Saint-Raymond
Head of International Affairs Division
Head of Portfolio Board
European Medicines Agency (EMA)

Tania Teixeira
EMA Liaison Official
U.S. Food and Drug Administration

5:25 pm **DISCUSSION WITH THE COMMITTEE**

6:00 pm *Adjourn*

GUIDING QUESITONS

• How have MRAs/reliance approaches been developed and utilized at the EMA?
• 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?

- What opportunities do you envisage for greater reliance on information from trusted counterpart regulators in the future?
- What efficiencies have or 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?
- 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
- Are you aware of regulatory agencies other than your own, that have such reliance? Please tell us about them.