The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Mutual Recognition Agreements and Reliance in the Regulation of Medicines

Information Gathering Session

AGENDA

May 28, 2019

7:00 amPDT; 10:00amEDT; 3:00pm London; 4:00pm Brussels/Geneva

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

4:00 pm (CEST) **OPENING REMARKS**
Alastair Wood, Committee Chair

4:05 pm **REMARKS BASED ON GUIDING QUESTIONS**
Petra Doerr, Head of Management Services and Networking, Swissmedic
Raimund T. Bruhin, Executive Director, Swissmedic

4:25 pm **DISCUSSION WITH THE COMMITTEE**

5:00 pm *Adjourn*

GUIDING QUESTIONS

• How have MRAs/reliance approaches been developed and utilized at Swissmedic?
• What has been your experience with such agreements/reliance approaches?
  o When MRAs are implemented, what are the public health impacts, resource savings and/or redirection, e.g., to areas of higher risks?
  o 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 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?
• 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.