The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Mutual Recognition Agreements and Reliance in the Regulation of Medicines Information Gathering Session

AGENDA

Monday, 29 July 2019
11amEDT, 9am MDT, 8am PDT, 5pm CEST, 4pm BST

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

---

11am EDT **WELCOME**
Alastair Wood, Committee Chair

Committee Introductions

- Katherine Bond
- Barbara Koremenos
- Others TBD

11:10 am **OPENING REMARKS**
David R. Gaugh, Sr Vice President for Sciences and Regulatory Affaires
Association for Accessible Medicines

Lisa Parks, VP for Sciences and Regulatory Affairs.
Association for Accessible Medicines

11:30 am **DISCUSSION WITH THE COMMITTEE**

12:00 noon *Adjourn*

GUIDING QUESTIONS
Briefly describe the work of AAM **Mutual Recognition Agreement/Reliance questions** • What role do/could MRAs/reliance have in facilitating the availability of generic medicines? • Can you envisage additional roles for such reliance? • Some countries (e.g., Switzerland) rely on approval of generics in other jurisdictions—please comment on that model • Should generics already approved by other stringent regulators (e.g., Canada, the EU) undergo a different path (accelerated) to approval in USA? • Can you comment on the "reference listed product" as a potential barrier to generic drug approval? **GMP Inspections** • Would reliance on third country inspections (e.g., EU inspections of China/India sites improve the inspection system? • Can you comment on supply chain challenges as it relates to generics and biosimilars?