The National Academies of
SCIENCES · ENGINEERING · MEDICINE

Committee on Mutual Recognition Agreements in the Regulation of Medicines
AGENDA
April 1, 2019

Members' Room
The National Academy of Sciences
2101 Constitution Ave. NW
Washington, DC 20418

OPEN SESSION

1:00 pm **OPENING REMARKS**
Alastair Wood, Committee Chair

1:05 pm **PRESENTATIONS**
Regulatory leaders will share their perspectives regarding their motivations and process for pursuing recognition and reliance mechanisms in drug regulation, especially mutual recognition agreements. Presentations will be 20 min each and guided by the following questions:

Initiation
– What were the motivations to pursuing and/or entering into an agreement?
– What types of information or decisions were to be relied upon or recognized?
– How did you approach the protection of sensitive information?
– What benefits, costs, and risks did you forsee before entering into an agreement?

Implementation and Impacts
– What have been some major challenges and opportunities when implementing agreements?
– What have been the benefits, costs, and challenges resulting from the agreement for:
  · public health?
  · regulatory efficiencies and the ability to redirect resources?
  · regulatory expertise and competencies?
  · economics?

Recognition and Reliance in Medicines
Dara Corrigan, Fresenius Kabi/former FDA
Mary Ann Slack, FDA
Pierre Sabourin, Health Canada   *invited*
Julio Sánchez y Tépoz, ALó ProSciences/former COFEPRIS, Mexico
João Paulo Ortega Terra, ANVISA, Brazil   *invited*

Recognition and Reliance in Other Industries
David Vladeck, Georgetown Law/former FTC

2:30 pm **DISCUSSION**

3:30 pm **PUBLIC COMMENT**

4:00 pm *Adjourn open session*