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

10:00 am OPENING REMARKS
Alastair Wood, Committee Chair

10:05 am PRESENTATIONS
Experts in managing issues of safety and risk will share their perspective regarding the processes that are triggered when a problem arises with a product associated with a mutual recognition agreement. Presentations will be 10 min each.

Mutual Recognition Agreements - Risk and Safety Management
David Vladeck, Georgetown Law/former FTC invited

10:30 am Break

10:45 am Q&A WITH COMMITTEE

11:45 am PUBLIC COMMENT

12:00 pm Adjourn to closed session

OPEN SESSION

1:30 pm RECONVENE
Alastair Wood, Committee Chair

1:35 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 10 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
Mary Ann Slack, FDA
Pierre Sabourin, Health Canada
Julio Sánchez y Tépoz, ALó ProSciences/former COFEPRIS, Mexico
João Paulo Ortega Terra, ANVISA, Brazil

2:15 pm  Q&A WITH COMMITTEE
3:45 pm  PUBLIC COMMENT
4:00 pm  Adjourn