The National Academies of
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Mutual Recognition Agreements and Reliance in the Regulation of Medicines

Information Gathering Session

AGENDA

Monday, 10 June 2019

1pm EDT, 11am MDT, 10am PDT, 6pm BST, 7pm CEST

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

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1 pm EDT **OPENING REMARKS**
Alastair Wood, Committee Chair

1:05 pm **REMARKS BASED ON GUIDING QUESTIONS**
Janet Woodcock, M.D.
Director of the Center for Drug Evalution and Research
Food and Drug Administration (FDA)

1:25 pm **DISCUSSION WITH THE COMMITTEE**
In your view

- What were the questions that you wanted this study to answer?
- What were the information gaps that you wanted the report to fill?
- What are the current constaraints on the agency relying on the work of others?
- What are the current constraints on the agency sharing information with others?
- If there were no constraints (legal or otherwise) how would you like to see reliance working
    - What are the constraints to achieving that
    - What changes would be needed to achieve that
- Straw man for discussion as an illustration
        - A generic already approved in US. Another manufacturer applies for authorization for a generic already approved by EMA.
            - What could reliance contribute?
            - Would this accelerate approval?
            - Role in alleviating shortages
            - Different for oral (bioavailability) versus IV (no bioavailability issues)
- What is your vision for requesting this study?
- What is your goal for the report?

- What would be your dream within regulation and reliance assuming resources are not a limitation?

2:00 pm *Adjourn*

GUIDING QUESTIONS

• 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?
  o What changes in law would be required to allow the FDA to share data?
  o How might confidentiality be ensured?
  o How do you avoid Freedom of Information Act with sensitive information?
• 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?
  o Increasing complexity of supply chains and manufacturing?
• 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
• Do the current human resources match the projected need regarding expertise and numbers? How might reliance aid this process?