The National Academies of
SCIENCES • ENGINEERING • MEDICINE

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

Wednesday, 26 June 2019
3pm CEST, 2pm BST, 9am EDT, 7am MDT, 6am PDT

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

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3 pm CEST	**WELCOME** Alastair Wood, Committee Chair
3:10 pm	**OPENING REMARKS** Suzette Kox, Secretary General International Generic and Biosimilar medicines Association
3:25 pm	**DISCUSSION WITH THE COMMITTEE**
4:00 pm	*Adjourn*

GUIDING QUESTIONS

Briefly describe the work of IGBA

- What further forms/uses of reliance would in your view enhance the availability of generics?
- Would/could increased reliance affect drug shortages?
- Can you comment on the Swiss form of reliance in the availability/approval of generics and do you think that is a model that should be adopted elsewhere?
- Given the increased complexity of for example biosimilars how could reliance improve access?

Additional Questions

- Do you think regulators should move towards more mutually recognizing the reference products used in their respective jurisdictions?
- How can your industries better demonstrate to regulators that you are dealing with the same reference product, even if sourced from another country?
- Would ISO IDMP standard for product identification that both EU and US FDA seem to accept help in this?