The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Mutual Recognition Agreements and Reliance in the Regulation of Medicines

Information Gathering Session

AGENDA

Wednesday, 29 May 2019

3:30pm CEST, 2:30pm BST, 9:30am EDT, 7:30am MDT, 6:30am PDT

Contact Kelly Choi (KChoi@nas.edu) to register for this event

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3:30pm CEST **OPENING REMARKS**
Alastair Wood, Committee Chair

3:35 pm **REMARKS BASED ON GUIDING QUESTIONS**

Belén Escribano
Head of Pharmaceutrical Inspection and Enforcement Department
Spain's Agency for Medicines and Health Products (AEMPS)

3:55 pm **DISCUSSION WITH THE COMMITTEE**

Respondents:

Manuel Ibarra Lorente
Head, Area of Inspection of Standards of GMP and GLP

R. San José Rodriguez
Department of Inspection and Control of Medicines

Jesús Díaz Hernández
Technical Advisor, Quality Unit and Secretariat Technical Inspection Committee
Department of Drug Inspection and Control

4:30 pm *Adjourn*

GUIDING QUESTIONS

Opportunities/Efficiencies

- What opportunities do you envisage for greater reliance on information from trusted counterpart regulators in the future?
- What efficiencies have or could result from such reliance agreements/approaches
- 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

Impediments

- What are possible impediments to reliance?

Risk/benefits

- What areas pose the greatest risk or benefit?
- How would you prioritize those areas?

Confidentiality

- How do you ensure confidentiality given peer assessment with varying levels of security (cyber and other threats)?
- Has there ever been a breach of confidential information and if so, how was it handled?

Are you aware of regulatory agencies other than your own within the EU, that have such reliance? Please tell us about them.