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# Mutual Recognition Agreements and Reliance in the Regulation of Medicines

## July 10, 2019

Pasteur room
Gates Foundation
62 Buckingham Gate, 5th Floor, London SW1E 6AJ

Webcast Link: https://www.bethereglobal.com/nas-071019

### Meeting Objectives:

To review and assess the use of mutual recognition/reliance agreements and informal practices of recognition/reliance, which allow regulators to use information from their counterparts at foreign drug regulatory agencies, in medicines regulation

**Wednesday, July 10**

8:00 am *Registration - coffee available*

8:30 am **WELCOME**
Mary Lou Valdez
Associate Commissioner for Diplomacy and Partnership
Office of Global Policy and Strategy
U.S. Food and Drug Administration

**OPEN SESSION**

8:35 am **OPENING REMARKS**
Alastair Wood, Committee Chair

9:00 am SESSION I: INFORMATION EXCHANGE AND USE AND SCOPE OF EXCHANGED INFORMATION

Objectives: Discuss challenges and opportunities for facilitating the exchange of information between national/regional regulatory authorities, the use of exchanged information, and the scope of exchanged information

- Challenges with the exchange of information between regulators and how they have/have not been addressed: How could things work better and what needs to be done?
- Challenges in using exchanged information in informing their own regulatory decisions and how they have/have not been addressed: How could things work better and what needs to be done?
- Opportunities for increasing the scope of regulatory activities (beyond GMP inspection reports) that would be/have been amenable to reliance on exchanged information : Are there specific areas that would be/have been relatively easy to address (e.g., API/GCP/GLP inspections; laboratory analyses for various regulatory purposes; PSUR assessment reports, bioequivalence study assessment reports, animal toxicology assessment reports, microbiology assessment reports; others).

**PRESENTATIONS WITH FACILIATATED DISCUSSIONS**

National Regulatory Agencies 10min remarks, followed by facilitated discussion

REGULATORS - PART 1

9:00 am **Chris James (virtual)**
Group Manager
Medsafe, Ministry of Health, New Zealand

**Kaylene Raynes & Adrian Bootes (virtual)**

Kaylene Raynes
Director, Applications & Advisory Management
Prescription Medicines Authorisation Branch, Therapeutic Goods Administration (TGA), Australia

Adrian Bootes
Branch head, Prescription Medicines Authorisation
Therapeutic Goods Administration (TGA), Australia

**Jörg Schläpfer & Federico Cimini**

Jörg Schläpfer, Head of Communication and Networking
Swiss Agency for Therapeutic Products (Swissmedic)

Federico Cimini, Medicinal Products, GMP- Inspection and Batch certification
Swiss Agency for Therapeutic Products (Swissmedic)

9:30am Group Discussion

**10:00 am BREAK**

10:20 am REGULATORS - PART 2

**Siu Ping Lam**
Director, Licensing Division
Medicines and Healthcare Products Regulatory Agency (MHRA), UK

**Agnes Saint-Raymond & Brendan Cuddy**

Agnes Saint-Raymond, Head of International Affairs Division
European Medicines Agency (EMA)

Brendan Cuddy, Head of Manufacturing Quality and Supply Chain Integrity
European Medicines Agency (EMA)

**Dominique De Backer**

Dominique De Backer, Director General, Health and Food Safety
European Commission (EC)

**John Lynch**
GMP Inspector & Senior Inspector
Division Health Products Regulatory Authority (HPRA), Ireland

11:00am Group Discussion

12:30 noon **LUNCH**

SESSION II: STAKEHOLDER INPUT

Input from stakeholder, 15min remarks, followed by facilitated discussion

1:30 pm **International Organization**

Emer Cooke **(virtual)**
Director, Regulation of Medicines and other Health Technologies
World Health Organization

**Facilitated discussion & questions from the committee**

2:30 pm **Industry**

**Janis Bernat & Rebecca Lumsden**

Janis Bernat
Director Biotherapeutics & Scientific Affairs
International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Rebecca Lumsden
Director – EM Regulatory Policy, Pfizer
On behalf of IFPMA

**Facilitated discussion & questions from the committee**

3:15pm **Patient Group**

Kawaldip Sehmi
Chief Executive Officer
International Alliance of Patients' Organizations (IAPO)

**Facilitated discussion & questions from the committee**

4:00 pm *Adjourn open session*