The National Academies of
SCIENCES • ENGINEERING • MEDICINE

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 FACILITATED 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)

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

Georgios Balkamos, International Relations Officer
European Commission (EC)

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

11:00 am 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

3:15 pm  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