Session 4 (PV): International Collaboration

Joint US-FDA | MHRA-UK | Health Canada Good Clinical Practice & Pharmacovigilance Symposium
February 15, 2024 – 1:15 – 2:00 PM

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Regulatory Compliance and Enforcement Specialist | HC

International Collaboration

Claire Longman
Expert Pharmacovigilance Inspector
GPvP Compliance Team

MHRA

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A Global Connection

Overview

- Current projects
- International groups
- International agreements
- Working examples
- Training initiatives

- The MHRA joined the Access Consortium as a full member in January 2021.
- The aim is to share research and improve timely patient access to high quality, safe and effective medicines.
- The Consortium explores opportunities for information and work-sharing in areas.
- The Consortium has several working groups.

PROJECT ORBIS

- Provides a framework for concurrent submission and review of oncology products with other sovereign regulators.
- Coordinates the submission and review of marketing authorisations and extensions for cancer medicines with potential of benefit over existing therapies.
- Allows submission of applications among several authorities at the same time rather than sequentially.
- The scheme has already given the green light to many life-saving treatments for patients.

Other international collaborations

Bilateral agreements


U.S. Food and Drugs Administration


Health Canada


Therapeutic Goods Administration


European Medicines Agency

Proactive global communication

Communicate significant inspection findings

Ensure patient safety globally

Less burden to MAHs

Training initiatives

- China National Medical Products Administration
- Ghana Food and Drugs Authority
- UA3S programme

Summary

- Number of international collaborations
- Sharing of information
- Less burden for Industry
- Continued efforts required

Copyright information

Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Pharmacovigilance Practices (GPV) Expert Circle

Sherry Bous, PharmD
Director, Division Enforcement and Postmarketing Safety
United States Food and Drug Administration

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Agenda

1. Brief history of PIC/S Good Pharmacovigilance Practices (GPV)
2. PIC/S GPV Expert Circle Organization
3. Goals
4. Working Group Outputs
5. Summary

Brief History for PIC/S GPV

2014

Established PIC/S Working Group on Good Clinical Practices (GCP) and GPV

- Facilitate technical co-operation and harmonization of practices
- Capacity building and information sharing, including and participation in the PIC/S Joint Visits Program

2021

Proposal to dissolve GCP and GPV Working Group and create two separate Expert Circles

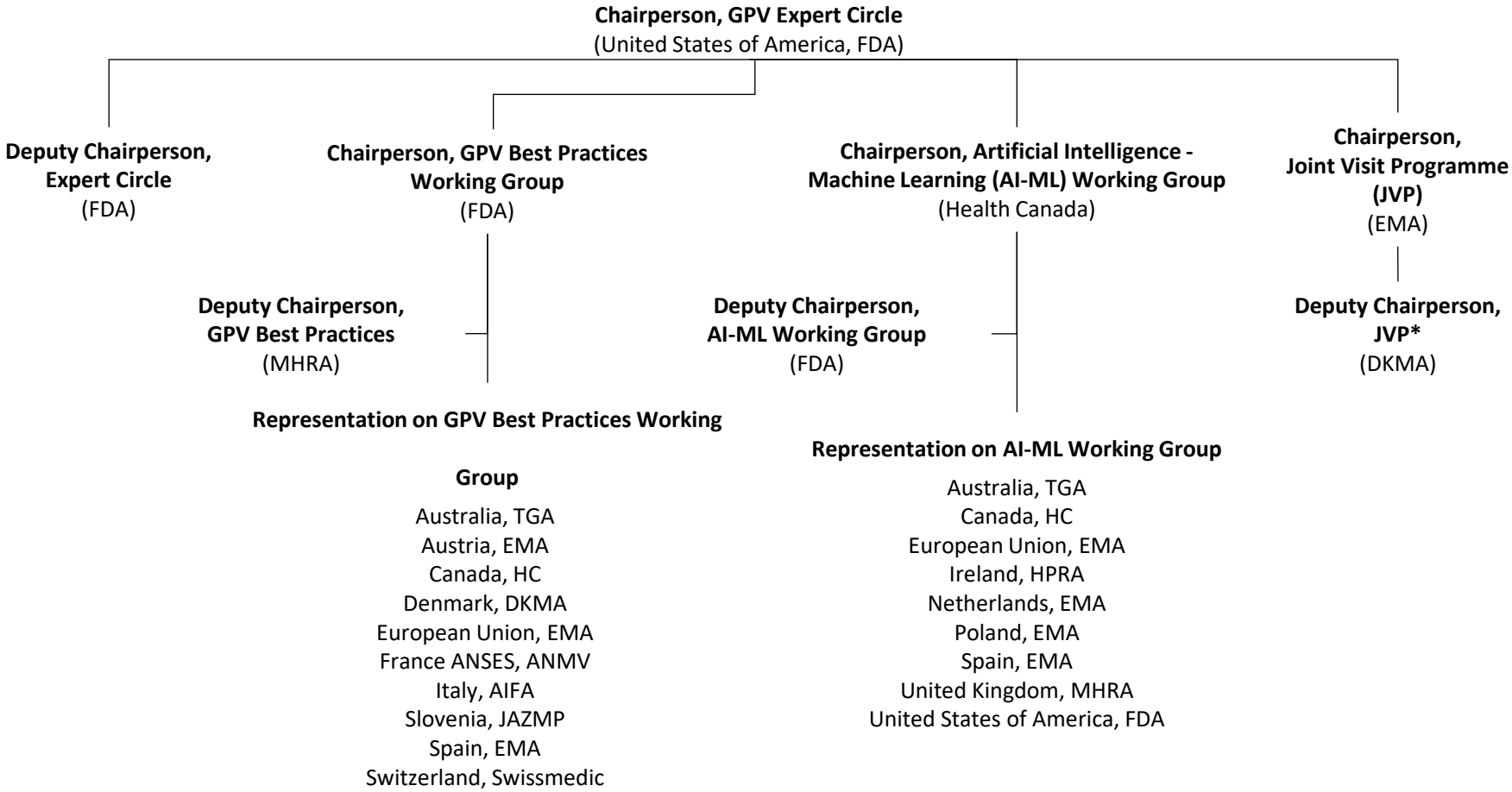
- GCP (clinical trials) and GPV (pharmacovigilance) have differing technical priorities
- The Expert Circles would work independently but collaborate on objectives and technical topics of interest to both groups

2022

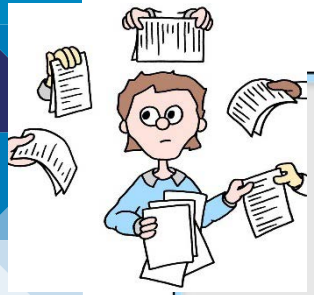
PIC/S Expert Circle for GPV established by the PIC/S Committee

- Facilitate the discussions and the exchange of information among inspectors specialized in GPV
- Meet regularly to develop draft guidance, recommendations, etc. and offer training

PIC/S GPV Expert Circle Organization



Goals



DEVELOP EXPERTISE

Establish a network of experts in technical topics covering GPV and increase understanding of relevant topics of interest

TRAIN

Design, develop and execute a training program for GPV Inspectors

NETWORK

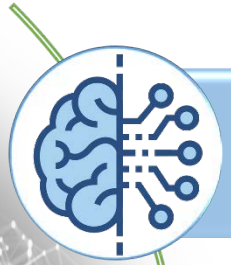
Develop a communication system between PIC/S Participating Authorities to facilitate discussions

REPRESENT

Develop and maintain a common approach and interpretation of the international guidelines

Outputs

Establish a formal network of GPV inspectors to assist in knowledge sharing, dissemination and review of GPV related policies and documents



AI-ML Workgroup

Design, develop, and execute an Expert Circle meeting focused on providing training and opportunities to obtain knowledge and competence to inspect key topics in a harmonized manner for inspectors

Best Practices Workgroup

Design and develop documents for publication on the PIC/S website and PIC/S Inspectorates' Academy

Joint Visit Program

Coordinate and execute joint visits with inspectors from 3 different countries to provide opportunities for training, sharing learning and experiences, and harmonizing inspection procedures and techniques

AI-ML Workgroup

- **Design, develop, and execute the Expert Circle meeting**
- *May be open to regulatory attendees outside the Expert Circle*
- Facilitates discussions on specific issues amongst experts
- Provides training for experts and non-experts so that GPV inspectors can obtain the required knowledge and competence to inspect key topics in a harmonized manner

GPV Best Practices Workgroup

- Design and develop documents for publication *on the PIC/S website and PIC/S Inspectorates' Academy*
- Provides an opportunity for broader access to GPV activities in PIC/S
- Helps build capacity among PIC/S Participating Authorities that are still developing their inspection programs

Joint Visit Program

- 32 GCP/GPV groups were formed in 2017/2018
- On hold during the pandemic due to travel restrictions where some groups have completed their visits remotely
- Provides an opportunity to compare and harmonize inspection procedures and techniques across different regulators
- Plans:
  - ✓ New call for volunteers from participating authorities for the JVP triplicate groups once it is restarted under the new GPV Expert Circle
  - ✓ Participating authorities may choose a remote or face to face JVP

Summary

- PIC/S Expert Circle for GPV established by the PIC/S Committee
- Goals are to Develop Expertise, Train, Network, and Represent
- Workgroups formed to establish a formal network of GPV inspectors
- Assist in knowledge sharing, dissemination, and review of GPV related policies and documents
- Provides an opportunity to compare and harmonize inspection procedures and techniques across different regulators

U.S. FOOD & DRUG ADMINISTRATION

Thank You!

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Health Canada's Good Pharmacovigilance Practices (GVP) Joint Inspection Experiences

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Paul Baillargeon
Regional Regulatory Compliance and Enforcement Specialist
Health Product Compliance Directorate
Regulatory Operations and Enforcement Branch (ROEB)

Overview

PIC/s Joint Visits Program

Health Canada Joint Inspection with EMA during COVID-19 pandemic

Lessons Learned

Summary

Joint Visits Program

Objectives

- Provide training
- Harmonization of inspections
- Maintain mutual confidence

Organization

- Carried out by inspectors from three different Health Authorities (HAs)
- Three visits per group over 24 months, one in each participating country
- The host HA is observed by the other members during a regular GVP inspection

Joint Visits Program

- In 2018, MHRA, US-FDA and Health Canada were paired in a group
- Inspections were conducted between December 2018 and March 2021
- Considering the context of COVID-19 the last inspection led by Health Canada was conducted virtually

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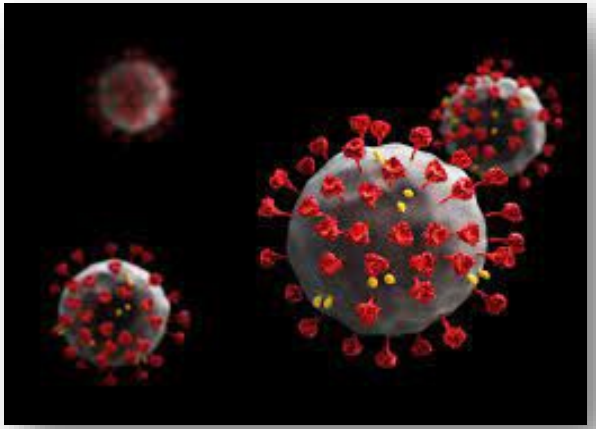
Joint Visits Program

Program Areas Assessed

- HA structure
- Regulations and guidance documents
- Site and product selection
- Inspection process:
  - Scope
  - Pre-inspection activities
  - Inspection (*e.g.*, opening, interviews, document review, closing)
  - Report Issuance
  - CAPA plan assessment
  - Tools used by inspectors

Change in Global Context



- COVID-19 pandemic required HAs to get creative, leverage opportunity and work jointly with trusted regulators
- Lockdown in jurisdictions and global travel restrictions

Joint GVP inspection

Health Canada conducted its first joint GVP Inspection in 2021 with the European Medicines Agency (EMA)

Approach

- Pre-inspection meeting
- Virtual inspection - 10 days
- Daily briefings between inspectors
- Shared IT tools (shared drive, log of requests)
- Dedicated sessions on specific requirements by HA
- Inspection report issued by each agency
- CAPA assessed in partnership

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Health Canada's Lessons Learned

Regarding PIC/s joint visits and the EMA joint inspection:

- PV requirements are similar across jurisdictions visited and their assessment can be divided amongst regulators (Divide and conquer)
  - Case reception, assessment, coding, reporting
  - Annual Summary Reports preparation
  - Review of IT systems used in PV
  - Pharmacovigilance System Master File (PSMF)
  - Qualified Person for Pharmacovigilance (QPPV)
  - Unusual Failure in Efficacy (UFIE)
  - Notification of foreign action

Health Canada's Lessons Learned

- Advantages
  - ✓ Confidence and collaboration is increased between HAs
  - ✓ Resources can be shared between HAs
  - ✓ Reduction in travel costs
  - ✓ More efficient inspection process for MAHs
- Challenges
  - ✓ Technological constraints
  - ✓ Virtual inspections take more time for HA

Summary

Takeaways

Joint inspections are not only possible, but successful

Invaluable opportunity for inspectors to share best inspection practices

Globalization helps align international GVP expectations