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# TTIP and Medicinal products

# State-of-play after Round 8

**74th Pharmaceutical Committee**
**17 March 2015**

Health and Food Safety

European Commission

# GMP INSPECTIONS: EU OBJECTIVES

- Mutual Recognition Agreement
- The EU and its 28 Member States recognised as a single system
- Domestic and third country inspections

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# BACKGROUND ON GMP inspections

- Interest from both regulators
- EU has positive experience with Mutual Recognition Agreements: Canada, Japan, Switzerland, Australia/new Zealand, (Israël – recently concluded)
- MRA with US was concluded in 1999 but was never implemented
- FDA does not recognise GMP inspections from third countries
- Existing collaboration: EMA/FDA strategy to develop reliance (2011), Joint inspections, sharing of inspection reports, PIC/S

# GMP Inspections Process

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## TTIP negotiations rounds

**Negotiators:**

- USTR/FDA

- DG TRADE/DG SANTE with the support of EMA

**Oversight of Regulator to Regulator activities:**

- State-of-play at each round

- Objectives/Actions for next round

## Regulator to Regulator activities: the Mutual Reliance Initiative

- **Participants**
  - EU Team: EMA, SANTE, UK, PL, FR, HR – Report to Inspector's Group
  - FDA Team

- **Work through:**
  - Exchange of e-mails
  - Regular phone conferences
  - Face-to-face meetings (1 meeting on 14-17 Nov. 2014)

# GMP inspections
# Evaluation of FDA

| | |
|---|---|
| **Using existing experience** | • **PIC/S evaluation**<br>• **API audit 2013** |
| **First list of 14 questions submitted on 17 Nov. 2014** | • **Overview of current legislation/technical standards/administrative arrangements**<br>• **Changes since PIC/S assessment**<br>• **Oversight of manufacturers for export**<br>• **Internal process to conclude on compliance**<br>• **Consistency with PIC/S, etc.** |
| **Audit currently scheduled for September 2015** | • **Headquarters (White Oack)**<br>• **District offices** |

# GMP inspections
# Evaluation of the EU

| | |
|---|---|
| **EU and its 28 Member States** | • **a single system** |
| **Joint Audit Program: a key element** | • **Positive feedback from the audit of Sweden**<br>• **FDA to observe the 7 JAP - PIC/S audits of Member States in 2015:**<br>• **EL, DE, HR, HU, CZ, IT, UK**<br>• **Commission finance MS auditors for 2015** |
| **Extensive information shared with FDA** | • **Previous JAP audit reports**<br>• **Previous PIC/S assessments**<br>• **Audits of CAN (MRA) under preparation** |
| **Conflicts of interest rules** | • **FDA's review of EMA at final stage: Positive**<br>• **Rules from 24 MS collected submitted on 16 February 2015** |

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# Exchange of confidential information/trade secret

- **Type of information:**
  - GMP inspection reports
  - GCP inspection reports
  - Information submitted in applications for authorisation
  - Internal non public information

- Issue: current arrangement is not satisfactory
  - FDA "redaction" leads to delays/incomplete information
  - Regulatory cooperation sometimes prevented

- FDA has the legal authority to conclude agreements to exchange confidential/trade secret information

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# Biosimilars

- **Objectives**
  - **Implementation of US abbreviated pathway**
  - **Convergence with EU: single global development**

- **FDA guidelines**
  - Finalisation of draft FDA guidelines (clinical trials!)
  - Guideline on naming and labelling (INN)

- **First authorisation provided by FDA on 6 March 2015**

- **Regulatory collaboration**
  - EMA/FDA/CAN/JP Cluster
  - International Pharmaceutical Regulators Forum
  - WHO

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# Generics

- **Objectives**
  - Opportunities of convergence/harmonisation
  - Regulatory cooperation
- **Clinical trials**
- **Collaboration in the framework of the International Drug Regulatory Pilot (IGDRP)**
  - "Work sharing" of evaluations
  - Biowaivers, Active Substance Master File

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# Other topics

- **Paediatrics**
  - Scientific aspects to be handled in ICH
  - Paediatric Investigation Plan

- **Other points raised by the US**
  - Transparency of clinical trials
  - Price and reimbursement