Information Day on the New Identification of Medicinal Products (IDMP) International Standards and ICH M5/M2

22 September 2011 | Course # 11524

Implementation of Electronic Submission of Medicinal Product Information in the EU (Article 57(2) Requirements of the New Pharmacovigilance Legislation)

23 September 2011 | Course # 11547

Programme Committee

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FDA, CBER, US

Details of these Information Days

Location: European Medicines Agency
Canary Wharf
7 Westferry Circus
London E14 4HB, UK

Capacity: Each event is limited to 120 participants

Course Overview

The European Medicines Agency (EMA) is organising this public awareness event to inform medicines regulatory authorities, pharmaceutical companies and IT vendors about the five new international Identification of Medicinal Product (IDMP) Standards and the intended implementation at ICH level (Topic M5). At the ISO TC 215 meeting in May 2011, the resolution was adopted that the Identification of Medicinal Products (IDMP) progresses to Final Draft International Standard (FDIS), a major step forward in finalising the five IDMP standards by beginning of 2012.

On Day 1, experts from the EMA (European Medicines Agency), US FDA (Food and Drug Administration) and EDQM (European Directorate for the Quality of Medicines & Healthcare), who have been strongly involved in the standards development and in the drafting of the ICH Implementation Guide will provide participants with a detailed update on the latest version of the ISO IDMP standards and their implementation in the EU within the ICH framework. The use of the standards in the new ISO ICSR (corresponding to the ICH E2B (R3) topic) will be also addressed.

On Day 2, the requirements, the timeframe and the process for the implementation of the new ISO IDMP standards in the context of the provisions laid down in Article 57(2), second subparagraph of Regulation (EC) No 726/2004 and the electronic submission of medicinal product information by marketing authorisation holders to the Agency will be addressed.

Key Topics

- Background on the IDMP topic and the international standards development in the context of ICH M5 and International Standardisation Organisations
- Main principles of the five IDMP standards, their concepts, data elements and messaging formats
- The information exchange process between regulators and pharmaceutical companies
- The electronic submission process of medicinal product information for medicinal products for human use authorised or registered in the Union
- The EVMPD and the transition towards the implementation of the IDMP and ICSR standards

Learning Objectives

At the conclusion of this course, participants should be able to:

- Understand the ongoing international standardisation work on IDMP
- Recognise the main new features of the five IDMP standards
- Prepare medicines regulatory authorities in the EU, IT vendors and pharmaceutical companies for the implementation of the new IDMP standards and the adaptation of their regulatory product management and pharmacovigilance systems
- Understand the requirements for the electronic submission of medicinal product information by marketing authorisation holders to the Agency in compliance with the new pharmacovigilance legislation

Who Will Attend

- Regulatory affairs staff of pharmaceutical companies
- Representatives of IT departments of medicines regulatory authorities, pharmaceutical companies, and service providers
- EU Qualified Persons responsible for Pharmacovigilance (EU QPPVs)
- Pharmacovigilance staff of pharmaceutical companies and medicines regulatory authorities
- Medicinal product management software vendors
- Sponsors of Clinical Trials

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22 September 2011

At the ISO TC 215 meeting in May 2011, the resolution was adopted that the Identification of Medicinal Products (IDMP) progresses to Final Draft International Standard (FDIS), a major step forward in finalising the five IDMP standards by beginning of 2012. The Information Day on 22 September will be dedicated to provide participants with a detailed update on the latest version of the ISO IDMP standards by the ISO editorial team from the US Food and Drug Administration (FDA), the European Directorate for the Quality of Medicines & Healthcare of the Council of Europe (EDQM) and the European Medicines Agency (EMA). A guest speaker from the ISO Central Secretariat will provide an overview of this project from a standards development and management perspective.

The Identification of Medicinal Products (IDMP) standards were developed in response to a worldwide demand for internationally harmonised specifications for medicinal products. The IDMP standards support the primary objectives of the regulation of medicines and pharmacovigilance to exchange medicinal product information in a robust and reliable manner. Unique identifiers produced in conformance with the IDMP standards are aimed to support applications where it is necessary to reliably identify and trace the use of medicinal products.

In May 2005, the first ICH M5 guideline in relation to the identification of medicinal products was released for public consultation. The ICH Steering Committee has taken a key decision that technical specifications should no longer be solely within ICH, but should be created in collaboration with Standards Development Organisations (SDOs) to enable wider interoperability across the regulatory and healthcare communities. The International Organisation for Standards (ISO), Health Level 7 (HL7), the European Committee for Standardisation (CEN), the Clinical Data Interchange Standards Consortium (CDISC) and the International Health Terminology Standards Development Organization (IHTSDO) have collaborated to form a Joint Initiative through which a single, common standard for the IDMP could be advanced. GS1 recently also joint this initiative.

IDMP is one of a group of five standards which together provide the basis for the unique identification of medicinal products. The group of standards comprises:

- ISO FDIS 11615 Health Informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated medicinal product information
- ISO FDIS 11616 Health informatics – Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information
- ISO FDIS 11238 Health Informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances
- ISO FDIS 11239 Health Informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
- ISO FDIS 11240 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement

The Identification of Medicinal Products (IDMP) supports the activities of medicines regulatory agencies worldwide by jurisdiction. These include a variety of regulatory activities related to development, registration and life cycle management of medicinal products as well as pharmacovigilance and risk management.
ICH representatives have been heavily involved in this project in addition to other experts from beyond the ICH community. The overall standard will make use of HL7 messaging tools capable of supporting the entire life cycle management of medicinal products.

ICH will define the way that this standard should be used by the publication of an ICH Implementation Guide. One major use case will focus on the support of coding medicinal product information for the new ICSR E2B(R3) standard.

23 September 2011

In the context of the new pharmacovigilance legislation published on 31 December 2010, one of the first deliverables is the implementation of the requirements as set out in Article 57, paragraph 2, second subparagraph of Regulation (EC) No 726/2004.

This refers in particular to the obligation of marketing authorisation holders to submit electronically information on medicinal products for human use authorised or registered in the Union to the Agency at the latest by 2 July 2012. These provisions apply independent of the authorisation procedure of the medicinal product. Furthermore, marketing authorisation holders are required to electronically submit medicinal product information for new or varied, suspended or revoked marketing authorisations for which the decisions have been adopted in the Union after 2 July 2012 to the Agency.

In compliance with the provisions as set out in Article 57(2), second subparagraph, the Agency will publish an electronic format and detailed guidance for marketing authorisation holders.

The objective of this Information Day is to provide participants with a detailed outline of the requirements as regards the electronic submission of medicinal product information including the business processes and the technical aspects that need to be taken into account by marketing authorisation holders.

The timeframe and the process for the implementation of the new the ISO IDMP standards in the context of Article 57(2), second subparagraph and its use by marketing authorisation holders taking into account this new international harmonisation work and the technical and scientific progress will be also addressed.

AGENDA – 22 SEPTEMBER 2011

New Identification of Medicinal Products (IDMP) International Standards and ICH M5/M2

08:00 **REGISTRATION**

08:45 **Welcome**
Peter Arlett, European Medicines Agency, EU
Chairpersons for the whole day:
Sabine Brosch and Vada Perkins

09:00 **Session 1**

THE DEVELOPMENT OF THE IDMP STANDARDS IN THE CONTEXT OF INTERNATIONAL ORGANISATION FOR STANDARDS (ISO)

This session will provide participants with an introduction to the five IDMP standards, which together with the Individual Case Safety Report (ICSR), are the first topics to go through this new standardisation process, whereby the International Organisation for Standards (ISO), Health Level 7 (HL7), the European Committee for Standardization (CEN), the Clinical Data Interchange Standards Consortium (CDISC) and the International Health Terminology Standards Development Organization (IHTSDO) agreed to form a Joint Initiative. Participants will be also briefed about the ISO processes and steps in developing standards in the context of the Joint Initiative.

Speaker: Ian Shepherd, Convener of ISO TC 215 WG6, UK
Discussant: Tim Buxton, Head of Sector ICT Development, EMA, EU

09:30 **Session 2**

ISO FDIS 11240 HEALTH INFORMATICS — IDENTIFICATION OF MEDICINAL PRODUCTS — DATA ELEMENTS AND STRUCTURES FOR THE UNIQUE IDENTIFICATION AND EXCHANGE OF UNITS OF MEASUREMENT

Taking into account that there are currently different approaches applied for expressing units of measurement, it was necessary to establish a single standardised vocabulary that can be used as an international reference for unit concepts, concept definitions where applicable and concept identifiers. This session will give participants the opportunity to familiarize with the latest updates on this FDIS. The aim is to ensure that terms and identifiers currently used to represent units of measurement in the drug regulatory, pharmacovigilance and healthcare environments are mapped in a standardised and traceable way to the underlying metrological concepts. This will help ease implementation of the standard without impacting on the unit terms currently in use.

Speaker: Aniello Santoro, EMA, EU
Discussant: Christof Gessner, DIN to ISO TC 215, DE, Germany (via conference call)

ISO FDIS 11239 – HEALTH INFORMATICS — IDENTIFICATION OF MEDICINAL PRODUCTS — DATA ELEMENTS AND STRUCTURES FOR THE UNIQUE IDENTIFICATION AND EXCHANGE OF REGULATED INFORMATION ON PHARMACEUTICAL DOSE FORMS, UNITS OF PRESENTATION, ROUTES OF ADMINISTRATION AND PACKAGING.

This session will address the identification of pharmaceutical dose form, unit of presentation, routes of administration and packaging in the context of the IDMP FDIS. The essential elements for the specification, translation and versioning of the specified controlledterms will be described including recommendations concerning the mapping of terms that are already used by stakeholders to the concepts arising from the implementation of this standard.

Speaker: Christopher Jarvis, EDQM, Council of Europe

10:45 **COFFEE BREAK**

11:15 **Session 3**

ISO FDIS 11238 HEALTH INFORMATICS — IDENTIFICATION OF MEDICINAL PRODUCTS — DATA ELEMENTS AND STRUCTURES FOR THE UNIQUE IDENTIFICATION AND EXCHANGE OF REGULATED INFORMATION ON SUBSTANCES

This session will provide a detailed overview of the FDIS that has been developed to define the concepts required for the unique identification of substances at an international level. Furthermore, the concept of a specified substance has been elaborated allowing to capture more detailed characteristics of substances. This can relate to e.g. intermediate products that contain multiple substances or specified substances of diverse origin and taking into account features such as physical forms, constituents, components, marker substances, additives, impurities, manufacturing information, critical production processes, etc.
Various examples for different substance classes will be also presented to illustrate the specific concepts to be applied according to the FDIS. The use of HL7 messages for the information exchange on substances will be also discussed.

Speaker: Lawrence Callahan, FDA, USA
Discussants: Ilaria del Seppia, EMA, EU, Panagiotis Telonis, EMA, EU

12.45 LUNCH BREAK

13:45 Session 4

ISO FDIS 11616 HEALTH INFORMATICS — IDENTIFICATION OF MEDICINAL PRODUCTS — DATA ELEMENTS AND STRUCTURES FOR THE UNIQUE IDENTIFICATION AND EXCHANGE OF REGULATED PHARMACEUTICAL PRODUCT INFORMATION

This session will focus on the presentation of the data elements, structures, and their relationships to uniquely identify and exchange regulated pharmaceutical product information. This refers to both packaged and administered pharmaceutical products. The standard will be applicable to regulatory and pharmacovigilance activities worldwide. The association with the other IDMP and HL7 messaging standards will be also described.

Speaker: Vada Perkins, FDA, CBER, US
Discussant: Paolo Alcini, EMA, EU

14.30 ISO FDIS 11615 HEALTH INFORMATICS — IDENTIFICATION OF MEDICINAL PRODUCTS — DATA ELEMENTS AND STRUCTURES FOR THE UNIQUE IDENTIFICATION AND EXCHANGE OF REGULATED MEDICINAL PRODUCT INFORMATION

This session will be dedicated to provide participants with an overview of the main changes introduced in the FDIS. ISO FDIS 11615 has been developed to characterise and uniquely identify regulated medicinal products for human use during their entire life cycle from development, to approval and marketing. More specifically, the standard establishes definitions and concepts and describes data elements and their structural relationships, which are required for the detailed description and unique identification of medicinal products.

Furthermore, to support the successful information exchange in relation to the unique identification and characterisation of medicinal products, the use of HL7 messaging will be also addressed.

Speaker: Sabine Brosch, EMA, EU
Discussants: Panagiotis Telonis, EMA, EU, Shafiq Ur-Rehman, EMA, EU

15.15 COFFEE BREAK

15.30 ISO FDIS 11615 HEALTH INFORMATICS — IDENTIFICATION OF MEDICINAL PRODUCTS — DATA ELEMENTS AND STRUCTURES FOR THE UNIQUE IDENTIFICATION AND EXCHANGE OF REGULATED MEDICINAL PRODUCT INFORMATION

To be continued

16:30 SESSION 5

THE ISO IDMP AND INDIVIDUAL CASE SAFETY REPORT (ICSR) STANDARDS

This session will provide an overview of the new pharmacovigilance legislation and its interface with the IDMP and ICSR ISO standards. It will further provide an insight on how the IDMP standards will b applied for adverse reaction reporting and signal detection in pharmacovigilance.

Speaker: Anja van Haren, MEB, NL
Discussants: Vada Perkins, FDA, US

17:15 END OF THIS INFORMATION DAY

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04 July 2011 | London, United Kingdom | ID 11591

IDMP Information Day at the European Medicines Agency
22-23 September 2011 | London, United Kingdom | ID 11524

ICSR Information Day at the European Medicines Agency
16 November 2011 | London, United Kingdom | ID 11525

ICSR Technical Implementation Training at the European Medicines Agency
17 November 2011 | London, United Kingdom | ID 11526

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency
13 September 2011 | London, United Kingdom | ID 11552
6 December 2011 | London, United Kingdom | ID 11553

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AGENDA – 23 SEPTEMBER 2011

Implementation of Electronic Submission of Medicinal Product Information in the EU (Article 57 Requirements of the New Pharmacovigilance Legislation)

08:00 **REGISTRATION**

08:45 **Welcome**

Peter Arlett, European Medicines Agency, EU
Chairpersons for the whole day:
Sabine Brosch and Paolo Alcini

09:00 **Session 1**

THE PROCESS OF ELECTRONIC SUBMISSION AND VALIDATION OF MEDICINAL PRODUCT INFORMATION

This session will provide participants with an overview of the business processes that apply for the electronic submission of medicinal product information to the Agency as set out in Regulation (EC) No 726/2004, Article 57(2) second subparagraph.

Speaker: Ilaria Del Seppia, EMA, EU
Discussant: Krishna Caulee

THE NEW EUDRAVIGILANCE PRODUCT REPORT MESSAGES (EVPRMS)

This session will focus on the description of the enhanced EVPRM which supports the electronic submission of information on medicinal products for human use authorised or registered in the Union. The EVPRM data elements and their use will be presented.

Speaker: Sabine Brosch, EMA, EU
Discussant: Ilaria Del Seppia, EMA, EU

10:30 **COFFEE BREAK**

11.00 **Session 2**

THE NEW EVPRM AND PRACTICAL EXAMPLES

Participants will be provided with various examples as to how to populate the EVPRM taking into account different types of medicinal products authorised or registered in the Union.

Speaker: Krishna Caulee, EMA, EU

THE NEW EVPRM - QUESTIONS AND ANSWERS

This session is dedicated to address implementation questions as received from marketing authorisation holders in the context of the new EVPRM. This session will also address the process of updating information that has been previously submitted by marketing authorisation holders, in accordance with the provisions set out in volume 9A of The Rules Governing Medicinal Products in the European Union, part III, chapter 11.6.

Speaker TBC

12.30 **LUNCH**

13:30 **Session 3**

DESCRIPTION OF SUBSTANCE CHARACTERISTICS – ESSENTIALS TO BE TAKEN INTO ACCOUNT

Participants will have the opportunity to learn as to how to describe the characteristics of a substance taking into account various substance classes such as chemicals, polymers, proteins, nucleic acids and structurally diverse materials (e.g. vaccines, advanced therapies).

Speaker: Ilaria Del Seppia, EMA, EU

PRACTICAL EXAMPLES – DESCRIPTION OF SUBSTANCE CHARACTERISTICS

Participants will be provided with various examples as to how to describe substances taking into account different substance classes.

Speaker: Lawrence Callahan, FDA, US

15.00 **COFFEE BREAK**

15:30 **Session 4**

THE PROCESS OF ELECTRONIC SUBMISSION AND VALIDATION OF SUBSTANCE INFORMATION

This session will provide participants with an overview of the business processes that apply for the definition of the characteristics of substances in relation to medicinal products authorised or registered in the Union. The validation approach of the substance information as received electronically from marketing authorisation holders will be also presented.

Speaker: Ana Cochino, EMA, EU
Discussants: Ilaria Del Seppia, EU, Carmela Mastrandrea, EMA, EU

MEDICINAL PRODUCT INFORMATION MANAGEMENT FROM AN FDA PERSPECTIVE AND COLLABORATION WITH EMA

Participants will be updated on the management of medicinal product information from an FDA perspective. Furthermore the areas of collaboration between FDA and EMA working jointly on the harmonisation of their business processes will be also addressed.

Speaker: Vada Perkins, FDA, US

IMPLEMENTATION OF THE ISO IDMP STANDARDS IN THE EU AND THE US

The implementation planning of the ISO IDMP standards will conclude this two days event.

17:00 **END OF THIS INFORMATION DAY**

REGISTRATION FORM
European Medicines Agency Information Days | EMA, London, UK

Registration includes participant material, coffee breaks and sandwich lunch. Each event is limited to 120 participants.

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