EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of the EudraVigilance Access Policy for Centrally Authorised Products - Phase 1

(Access to EudraVigilance data)

Monday 27 February 2012

4th Stakeholders Forum

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Agenda

- Introduction
- Implementation update

Introduction (1)

3rd Stakeholders Meeting

Goals of Access Policy

⇨ support public health, support signal detection, inform healthcare professionals and the general public

- Overview

⇨ stakeholders groups and access

- Timelines

⇨ stepwise implementation with

- centrally authorised products (Phase 1)
- all medicinal products (Phase 2)

Introduction (2)

- Implementation

⇨ best format for publication of data with involvement of representatives from the PCWP and the HCPWG

- EudraVigilance data quality

⇨ data management contract ongoing

- Demo

⇨ draft web report (dashboard)

Implementation update (1) – phase 1

Activities since last meeting

- Implementation of the web report (ICT) √
  ⇨ development, testing and defects fixing
- Website design √
- Website build (ICT) √
- Migration of the business intelligence software to a newer version
  ⇨ publication of the web reports using interactive PDFs (ICT) ongoing

Implementation update (2) – phase 1

Activities – next steps

- Integration of the web reports within the website (ICT)
- Stakeholders testing with representatives from PCWP & HCPWG
- Website performance testing (ICT)

Go Live

- Website available in all EU languages

  ⇨ current orientation is

  1 - Live website (English) ~ 20 April

  2 - Live website (all EU) ~ 01 June