



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Access to EudraVigilance data – demonstration

8 May 2012

Healthcare Professionals' Working Group

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Agenda

- Introduction
- Implementation update
- Website survey
- Website demonstration



Introduction

Goals of Access Policy

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

- Overview

⇒ 4 stakeholders groups / access

- Timelines

⇒ stepwise implementation with - centrally authorised products (Phase 1)
- all medicinal products (Phase 2)

- Implementation

⇒ involvement of representatives from the PCWP and the HCPWG



Implementation update (Phase 1) (1)

Activities since last meeting

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



Implementation update (Phase 1) (2)

Activities since last meeting (continued)

- Integration of the web reports within the website ✓
- Stakeholders testing with representatives from PCWP & HCPWG ✓
- Website performance testing ✓
- Communications strategy for website launch for stakeholders ✓
- Go Live ✗



Implementation update (Phase 1) (3)

Go Live

- ⇒ 1 - Live website in English -> **by end of May**
- ⇒ 2 - Live website in all EU languages -> **by end of June**

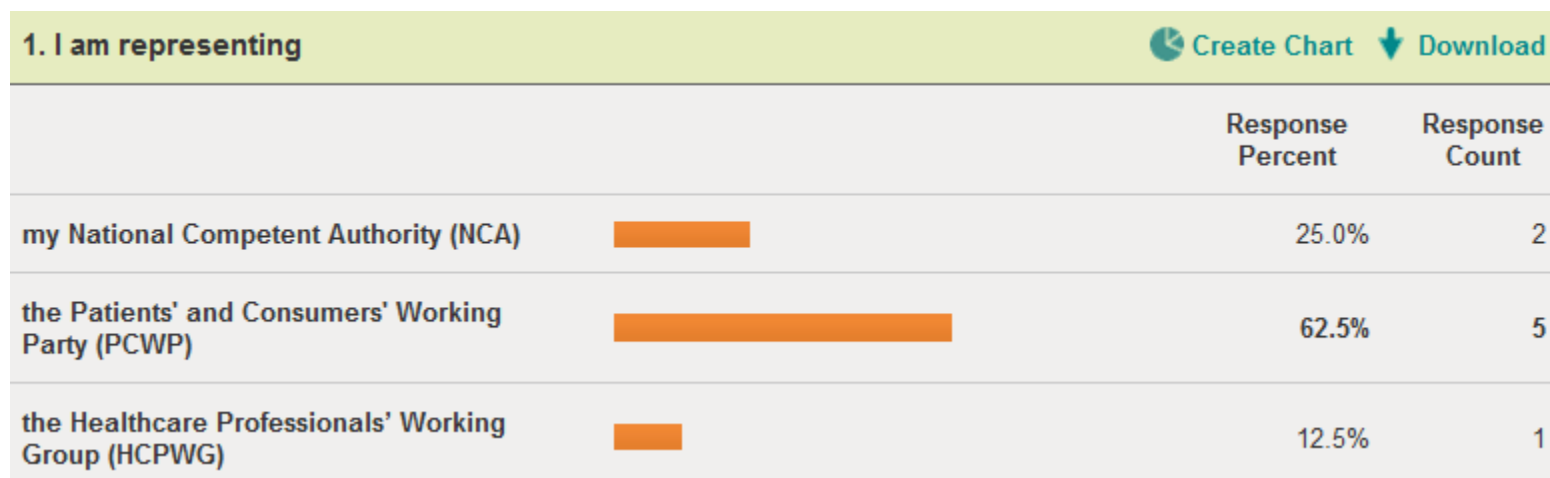


Website survey – results (1)

- Testing of the website by NCAs, PCWP and HCPWG from 19-28 March 2012
- Provision of
 - ⇒ Website (not all functionalities available)
 - ⇒ Scenarios to facilitate the testing
 - ⇒ journalist, patient & healthcare professional looking for information
 - ⇒ Survey to complete to collect feedback



Website survey – results (2)





Website survey – results (3)

PAGE: TEST SCENARIO 1

2. You are a journalist looking for the number of adverse drug reaction (side-effect) reports for the medicine Zyprexa. You want to: (1) find the web report on Zyprexa (2) understand more about the source of the data available in the web report on the website Please try to carry out both of these tasks through the website and then answer the questions below.



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	Very easy	Easy	Neither easy nor difficult	Difficult	Very difficult	N/A	Rating Average	Response Count
How easy was it to find the web report on Zyprexa?	42.9% (3)	28.6% (2)	14.3% (1)	14.3% (1)	0.0% (0)	0.0% (0)	2.00	7
How easy was it to find information on source of the data on the website?	14.3% (1)	42.9% (3)	28.6% (2)	14.3% (1)	0.0% (0)	0.0% (0)	2.43	7



Website survey – results (4)

PAGE: TEST SCENARIO 2

3. You are a patient taking the medicine Olanzapine, you have found the web [Create Chart](#) [Download](#) report on the website showing all the adverse drug reaction (side-effect) reports for Olanzapine, but you now want to learn more about understanding the report. Please try to carry out this task through the website and then answer the question below.

	Very easy	Easy	Neither easy nor difficult	Difficult	Very difficult	N/A	Rating Average	Response Count
How easy was it to find information on the website about understanding the report?	0.0% (0)	33.3% (2)	33.3% (2)	16.7% (1)	16.7% (1)	0.0% (0)	3.17	6



Website survey – results (5)

PAGE: TEST SCENARIO 3

4. You are a healthcare professional and one of your patients informed you about a side-effect. You would like to report the suspected adverse drug reaction (side-effect) to the health authority in your country but you are not sure how. Through a Google search you have arrived at the home page of this website and have started to click around to find the information you need. Please try to find out about reporting side-effects through the website and then answer the question below.



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	Very easy	Easy	Neither easy nor difficult	Difficult	Very difficult	N/A	Rating Average	Response Count
How easy was it to find the information on reporting a side effect?	16.7% (1)	33.3% (2)	50.0% (3)	0.0% (0)	0.0% (0)	0.0% (0)	2.33	6



Website survey – results (6)

5. How would you rate the usability of the website?							Create Chart	Download
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Rating Average	Response Count	
The website is easy to use (the navigation is simple and intuitive)	33.3% (2)	16.7% (1)	50.0% (3)	0.0% (0)	0.0% (0)	2.17	6	
The information is well organised and structured	16.7% (1)	83.3% (5)	0.0% (0)	0.0% (0)	0.0% (0)	1.83	6	
The website is visually appealing - nice look and feel (images, colors,...)	33.3% (2)	50.0% (3)	16.7% (1)	0.0% (0)	0.0% (0)	1.83	6	
Most people would learn to use the website very quickly	16.7% (1)	33.3% (2)	33.3% (2)	16.7% (1)	0.0% (0)	2.50	6	



Website survey – results (7)

6. How would you rate the written content of the website ?

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	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Rating Average	Response Count
The terminology used is easy to understand	0.0% (0)	66.7% (4)	16.7% (1)	16.7% (1)	0.0% (0)	2.50	6
The website provides the correct level of information	0.0% (0)	50.0% (3)	50.0% (3)	0.0% (0)	0.0% (0)	2.50	6
The website answers all my questions	0.0% (0)	0.0% (0)	66.7% (4)	33.3% (2)	0.0% (0)	3.33	6



Website survey – results (8)

7. How would you rate the usability of the web report (for Zyprexa, for example) that can be found on the website?



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	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Rating Average	Response Count
The way the data is displayed in the web report is user-friendly	16.7% (1)	66.7% (4)	0.0% (0)	16.7% (1)	0.0% (0)	2.17	6
The web report provides the information I am looking for	16.7% (1)	16.7% (1)	16.7% (1)	50.0% (3)	0.0% (0)	3.00	6



Website survey – results (9)

8. Overall, how would you rate the 'European database of suspected adverse drug reaction reports' website ?

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		Response Percent	Response Count
Very poor		0.0%	0
Poor		0.0%	0
Average		16.7%	1
Good		66.7%	4
Very good		16.7%	1



Website survey – results (10)

9. Please provide us with any comments and feedback you may have on the website.

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Response
Count

[Show Responses](#)

5

- Terminology – sometimes too complicated
 - ⇒ mainly due to technical terms (e.g. reactions names)
- Functionality – sometimes too complicated
 - ⇒ web report contain a lot of information



Website – demonstration

- Website name: European database of suspected ADR reports
- Website URL: www.adrreports.eu