



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Increasing access to ADR reports on the Web

8th Stakeholders forum – 15 September 2014

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Data Collection and Management

An agency of the European Union





Agenda

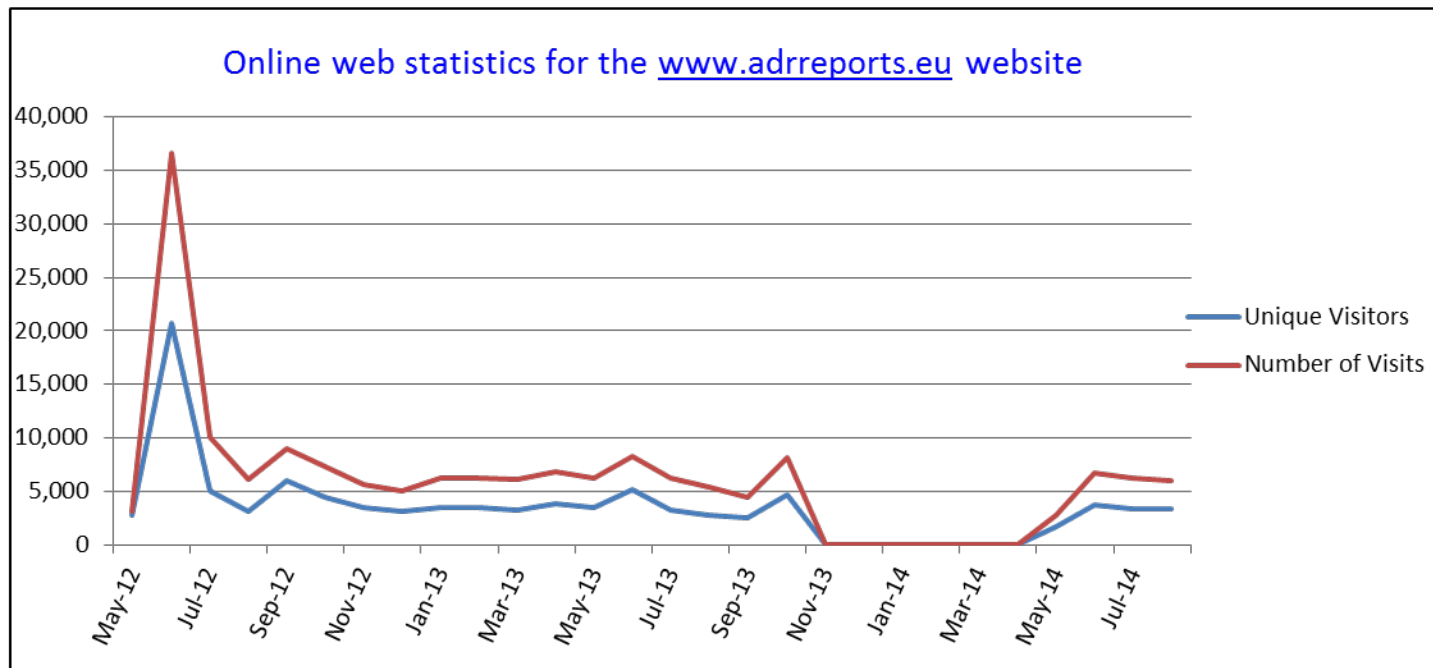
- Background
- Website usage
- Products & Substances available – what is new ?
- ADR Website – web reports and patient guidance
- What's next ?

Background

The EudraVigilance Access Policy was created to define the level and mean of access to EudraVigilance data by the multiple stakeholders – Member States, Marketing Authorisation Holders & Sponsors, Healthcare professionals and the general public.

The access to EudraVigilance data for Healthcare professionals and the general public was implemented with the creation of the www.adrreports.eu website that provides aggregated data for suspected adverse drug reactions for Centrally Authorised Products (CAP) and is available online since May 2012.

Website usage



➡ **Average of 4,400 unique visitors & 7,700 visits per month**

Products & Substances available – what is new ?

Number of Centrally Authorised Products (Authorised, Withdrawn, Suspended)	Number of Web reports for Centrally Authorised Products	Details
910	720	No data received in EudraVigilance for 190 Centrally Authorised Products -> no web reports created (122 authorised products & 68 withdrawn products)


Web reports for Centrally Authorised Products are automatically added when data are received in EudraVigilance

Products & Substances available – what is new ?

Substance classification	Number of Substances	Details
belongs to Centrally Authorised Products	527	Corresponding to 720 Centrally Authorised Products
belongs to Nationally Authorised Products	1,724	965 monitored by Member States 759 from the Periodic Safety Update Reports & Union Reference Date (EURD)
Total	2,251	

➡ **Addition of over 1,700 nationally authorised substances**



ADR Website

<http://www.adrreports.eu>

= > online in the coming weeks



European database of suspected adverse drug reaction reports

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English (en)

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Online access to suspected side-effect reports



On this website you can view data on **suspected side-effects** also known as suspected adverse drug reactions for authorised medicines in the European Economic Area (EEA).

This data is presented in a format called a **web report**. Currently the data only relates to medicines approved through the **centralised authorisation procedure**.



Search for a report

Search here for suspected adverse drug reaction reports



How to report a side-effect

Key information

- ✓ The information on this website relates to **suspected side effects**, i.e. medical events that have been observed following the use of a medicine, but which are **not necessarily related to or caused by the medicine**.
- ✓ Information on suspected side effects **should not be interpreted** as meaning that the medicine or the active substance causes the observed effect or is **unsafe to use**. Only a detailed evaluation and scientific assessment of all available data allows for robust conclusions to be drawn on the benefits and risks of a medicine.
- ✓ The European Medicines Agency publishes this data so that its stakeholders, including the general public, can access information that European regulatory authorities use to review the safety of a medicine or active substance. **Transparency** is a key guiding principle of the Agency.

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EudraVigilance

What's next ?

Revision of the EudraVigilance Access Policy

- Public consultation ongoing -> comments until 15 September 2014
 - Currently the policy foresees for the public and the healthcare professionals
 - Increased level of transparency and volume of information published online
 - Inclusion of Line Listings and access to a set of data fields from the safety report
- ⇒ More detailed information available online for more substances

What's next ?

Dependencies

- Validation of the medicinal product information submitted by the pharmaceutical industry

⇒ Improve data quality and the addition of more substances overtime

- Implementation of the new ISO data standard for the reporting of safety information

⇒ Few changes to be expected in the web reports layout (e.g. seriousness, origin,...)



Thank you for your attention

Further information

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