EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Increasing access to ADR reports on the Web

PCWP – Wednesday 26 November 2014

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An agency of the European Union

Agenda

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

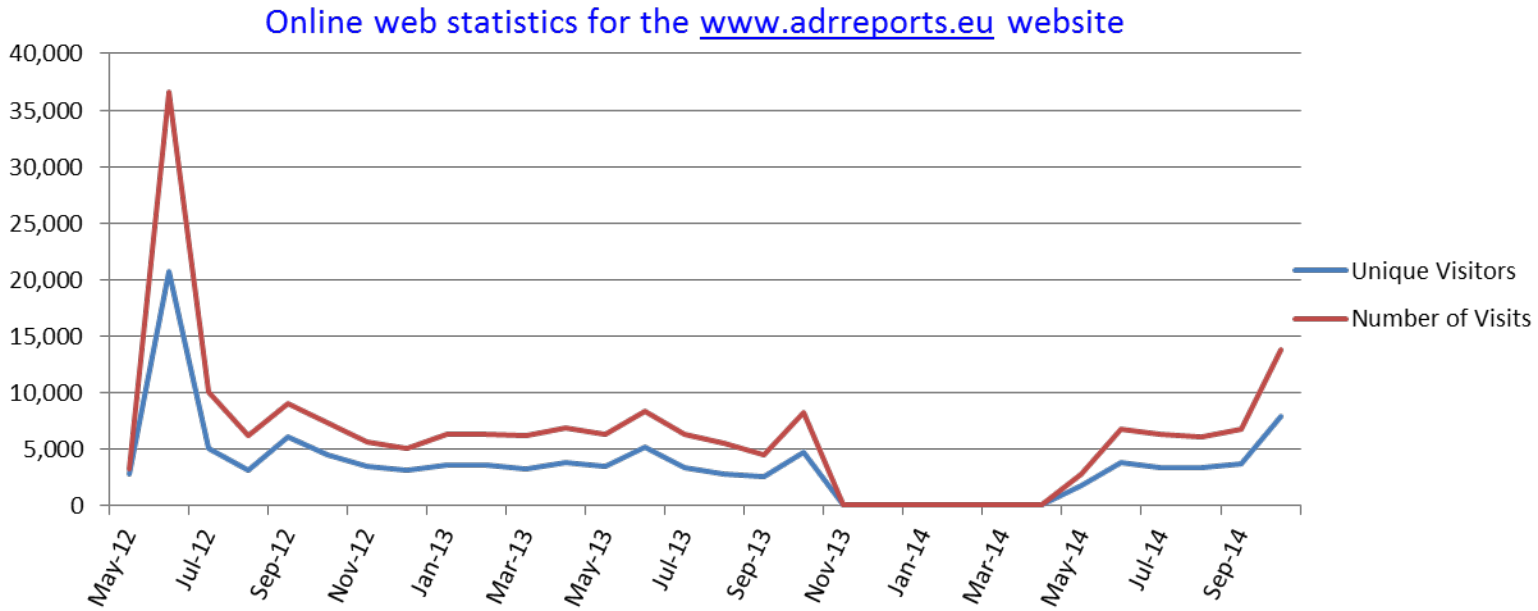
Background

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.

Since 06 October 2014, information on suspected adverse drug reactions is available for an additional 1,700 active substances contained in medicines approved in the European Union (EU).

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Number of Centrally Authorised Products (Authorised, Withdrawn, Suspended)	Number of Web reports for Centrally Authorised Products	Details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 no web reports created (122 authorised products & 68 withdrawn products)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

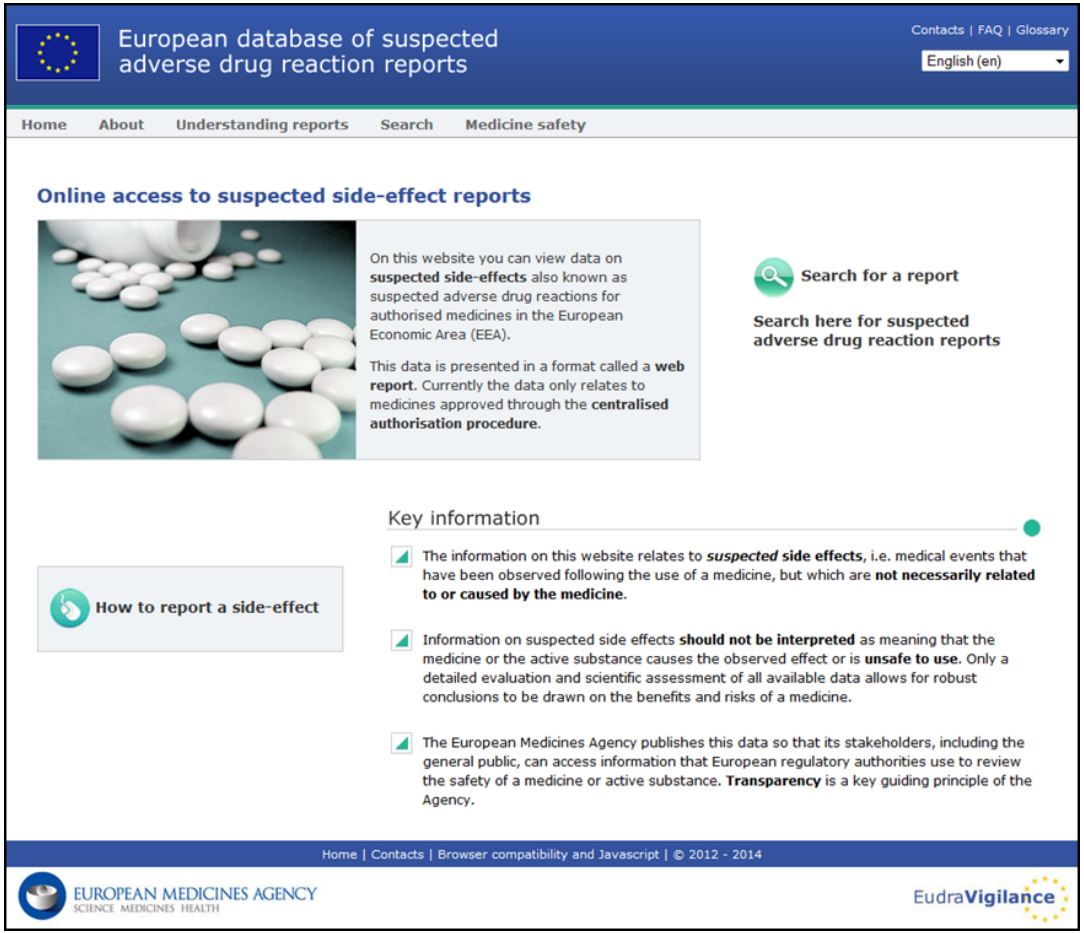
Products & Substances available – what is new ?

Substance classification	Number of Substances	Details
belongs to Centrally Authorised Products	527	Corresponding to the 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**	

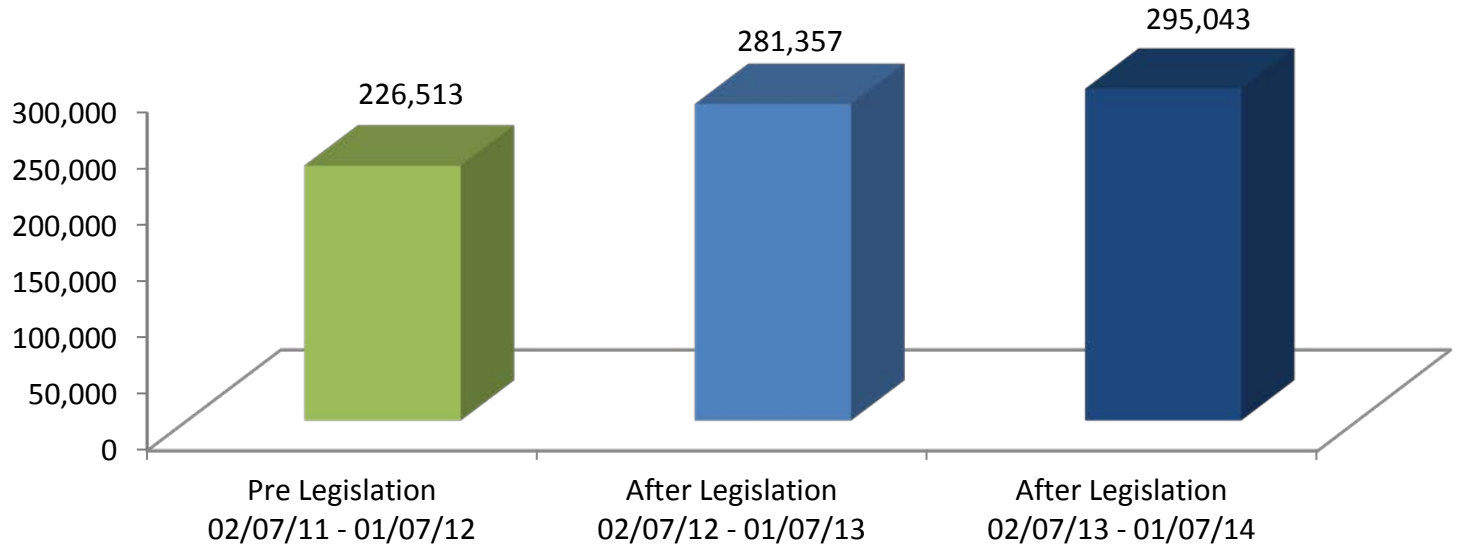
Addition of over 1,700 nationally authorised substances

ADR Website

http://www.adrreports.eu

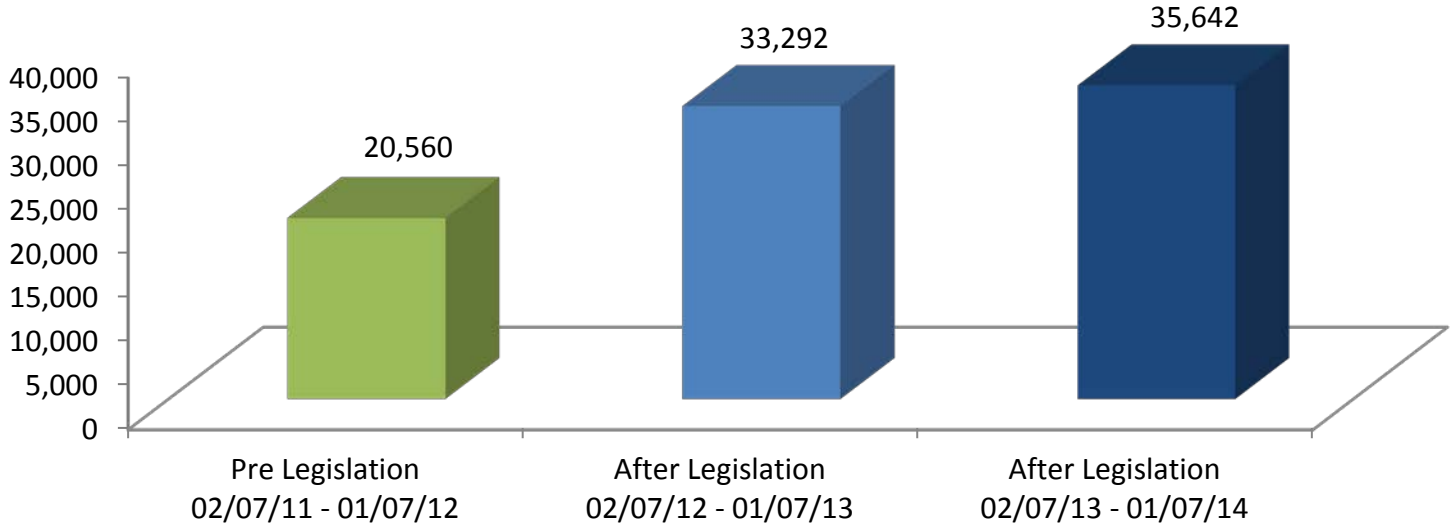


Spontaneous reporting in EEA*



* Number of ICSRs received in EudraVigilance before de-duplication

Spontaneous reporting by patients in EEA*



* Number of ICSRs received in EudraVigilance before de-duplication

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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