Increasing access to ADR reports on the Web

PCWP – Wednesday 26 November 2014

Presented by Steven Le Meur
Data Collection and Management Service
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

Online web statistics for the www.adrreports.eu website

Average of 4,400 unique visitors & 7,700 visits per month
<table>
<thead>
<tr>
<th>Number of Centrally Authorised Products (Authorised, Withdrawn, Suspended)</th>
<th>Number of Web reports for Centrally Authorised Products</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>910</td>
<td>720</td>
<td>No data received in EudraVigilance for 190 Centrally Authorised Products -&gt; no web reports created (122 authorised products &amp; 68 withdrawn products)</td>
</tr>
</tbody>
</table>

Web reports for Centrally Authorised Products are automatically added when data are received in EudraVigilance
## Products & Substances available – what is new?

<table>
<thead>
<tr>
<th>Substance classification</th>
<th>Number of Substances</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>belongs to Centrally Authorised Products</td>
<td>527</td>
<td>Corresponding to the Centrally Authorised Products</td>
</tr>
<tr>
<td>belongs to Nationally Authorised Products</td>
<td>1,724</td>
<td>965 monitored by Member States</td>
</tr>
<tr>
<td></td>
<td></td>
<td>759 from the Periodic Safety Update Reports &amp; Union Reference Date (EURD)</td>
</tr>
<tr>
<td>Total</td>
<td>2,251</td>
<td></td>
</tr>
</tbody>
</table>

**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*
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

steven.lemeur@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone  +44 (0)20 3660 6000 Facsimile  +44 (0)20 3660 5555
Send a question via our website  www.ema.europa.eu/contact

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