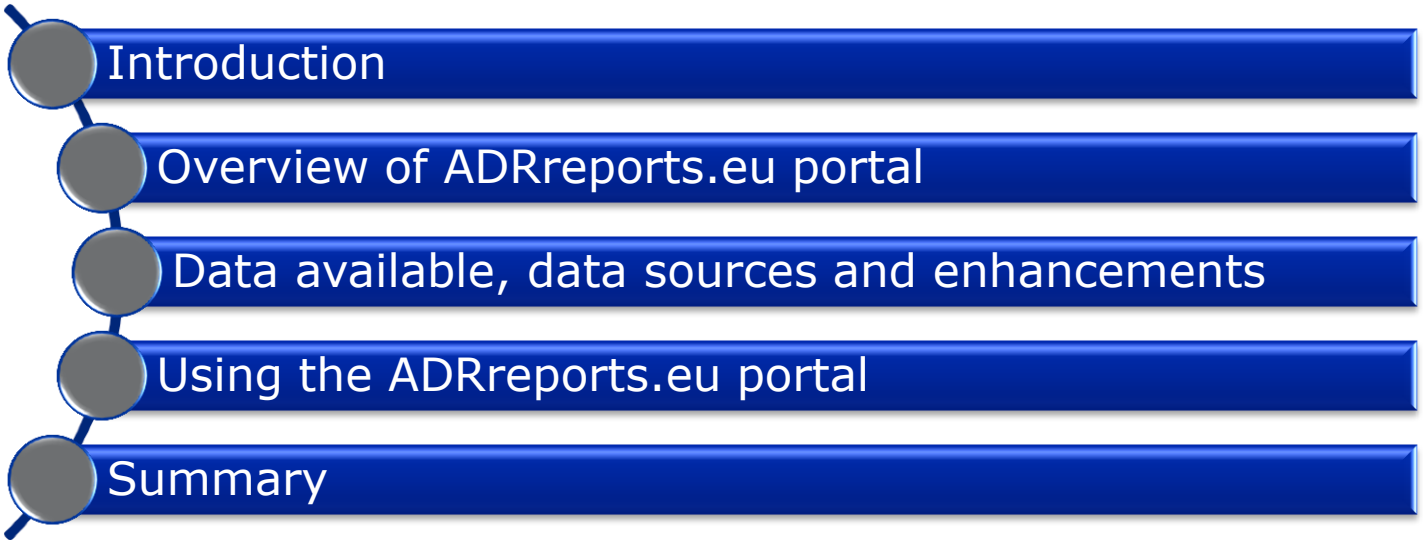
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ADRreports.eu portal

Training Module EV-M6

This module provides an overview of the new ADRreports.eu portal and guides users on how to make best use of its features

Content Summary



- Introduction
- Overview of ADRreports.eu portal
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Introduction: Target Audience

Target audience for this training module:

- Patients and the general public
- Healthcare professionals
- Drug safety experts (public and private sector)
- Academia

Introduction: Learning objectives

At the end of module EV-M6 you should be able to:

- Understand the utility of the ADRreports.eu portal and what information it contains
- Understand the enhancements to the portal
- Understand the potential use of the portal
- Understand where to obtain further information

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Adverse drug reactions in the European Economic Area

- The European Medicines Agency (EMA) plays a key role in the safety monitoring of medicines in the European Union (EU) - this is known as pharmacovigilance. The Agency's main role in this area is to support the coordination of the European pharmacovigilance system and to provide advice on the safe and effective use of medicines.

- As part of this responsibility, the Agency is responsible for the development, maintenance and co-ordination of EudraVigilance, a system for reporting suspected cases of adverse reactions to a medicine. For more information please visit the EMA website).

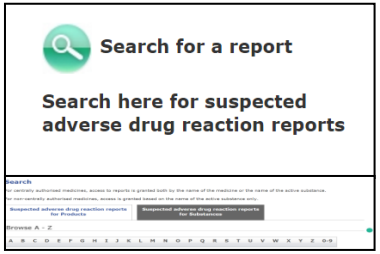
- Data from EudraVigilance are published in the European database of suspected adverse drug reaction reports. (ADRreports.eu portal).
  - This portal allows users to view the total number of individual suspected side effect reports (also known as Individual Case Safety Reports, or ICSRs) submitted to EudraVigilance for each centrally authorised medicine. Users can view these reports by age group, sex, type of suspected side effect and outcome.
  - Reports for common drug substances used in nationally authorised medicines are available since October 2014.

How is the ADRreports.eu portal organised?

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.**

Normally carried our by healthcare professionals. Patients can report adverse reactions through their national competent authorities

The information on the portal 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**.



A browsing tab will appear allowing you to select data for a specific product or substance

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.

Disclaimer

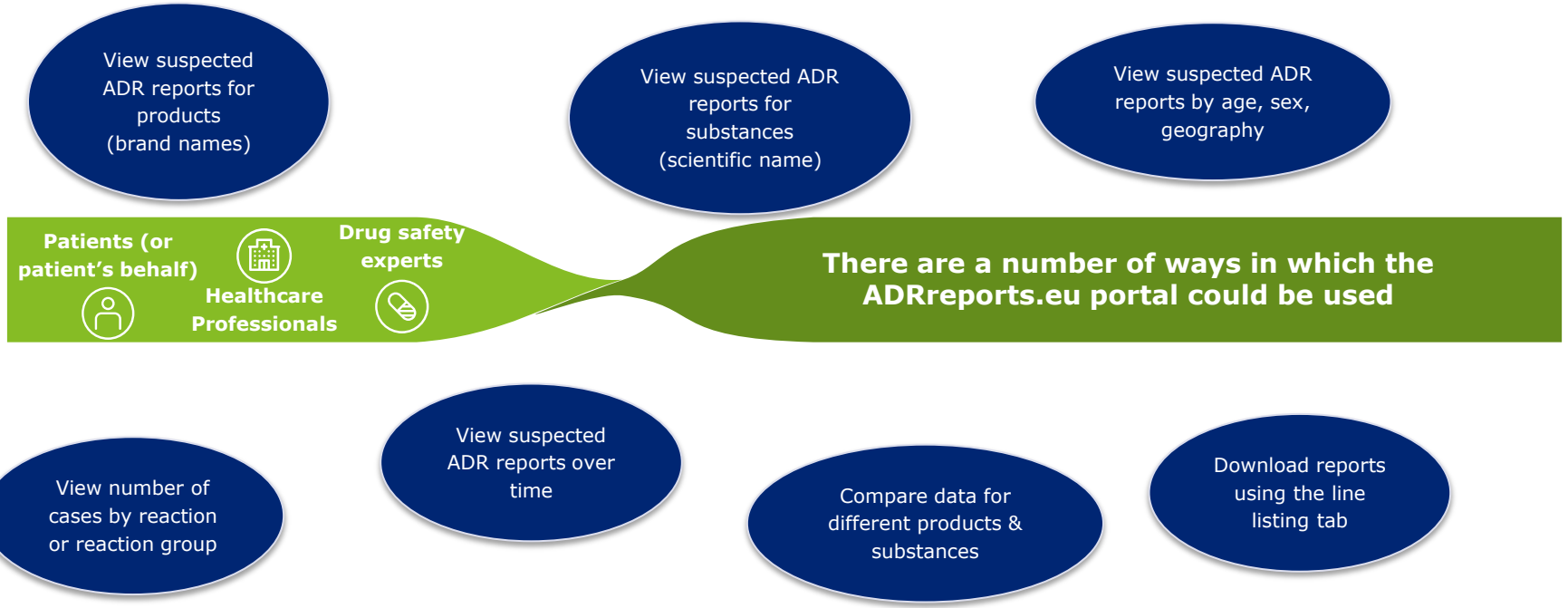
A disclaimer will appear the first time you will access a report. The key points to note are:

- The information on the portal **does not reflect any confirmation of a potential link between the medicine and the observed effect(s)**.
- **Patients and consumers should not stop or change medication without prior consultation with a healthcare professional**.
- The information on the portal concerns **only** suspected associations that **reflect the reporter's observations and opinions**. The number of suspected side effects in EudraVigilance **should not** serve as a basis for determining the **likelihood of a side effect occurring**.
- The side-effect reports in EudraVigilance do not represent all available information concerning the benefits and risks of a medicine and **should not be used in isolation by healthcare professionals** to make decisions regarding a patient's treatment regimen; other sources of information, including the product/prescribing information, should be consulted first.
- **Patients and consumers should not stop or change medication without prior consultation with their prescribing healthcare professional**.

What information can I find on this website?

- You can view information on **reports of suspected side effects** for authorised medicines in the European Economic Area (EEA). This information is presented in a **format called a web report**.
- All information on suspected side effects on the portal is derived from **EudraVigilance**, a database designed for collecting reports on suspected side effects.
  - The data in EudraVigilance is submitted electronically by **national medicines regulatory authorities** and by the **pharmaceutical companies** that hold the marketing authorisation for the medicines (National medicines regulatory authorities receive reports from healthcare professionals and also patients or other persons).
- The portal was launched to comply with the **EudraVigilance Access Policy**, which was developed to improve public health by supporting the safety-monitoring of medicines and to increase the European Medicines Agency's level of transparency.

How can I use the ADRreports.eu portal?



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Availability of information

The following information can be accessed through the ADRreports.eu portal web reports:

- Aggregated data outputs based on predefined queries
- **Individual Case Safety Report (ICSR) line listings** (based on core ICSR data elements)
- **ICSR forms** (for individual case review)

How has the ADR website been enhanced?

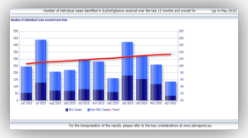
As of November 2017, the ADRreports.eu portal contains **3 additional tabs** allowing the general public to:

- ✓ View the number of cases received over time
- ✓ View the number of cases received in a particular geography
- ✓ Download data using various criteria (age, sex, time, geography) in an excel file for further analysis

Viewing a web report

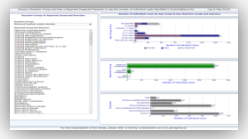
1. Number of individual cases

7. Line listing New!



2. Number of individual cases received over time New!

Each report will contain 7 tabs with different data views



6. Number of individual cases for a selected reaction

3. Number of individual cases by EEA countries New!

5. Number of individual cases for a selected reaction group

4. Number of individual cases by reaction groups

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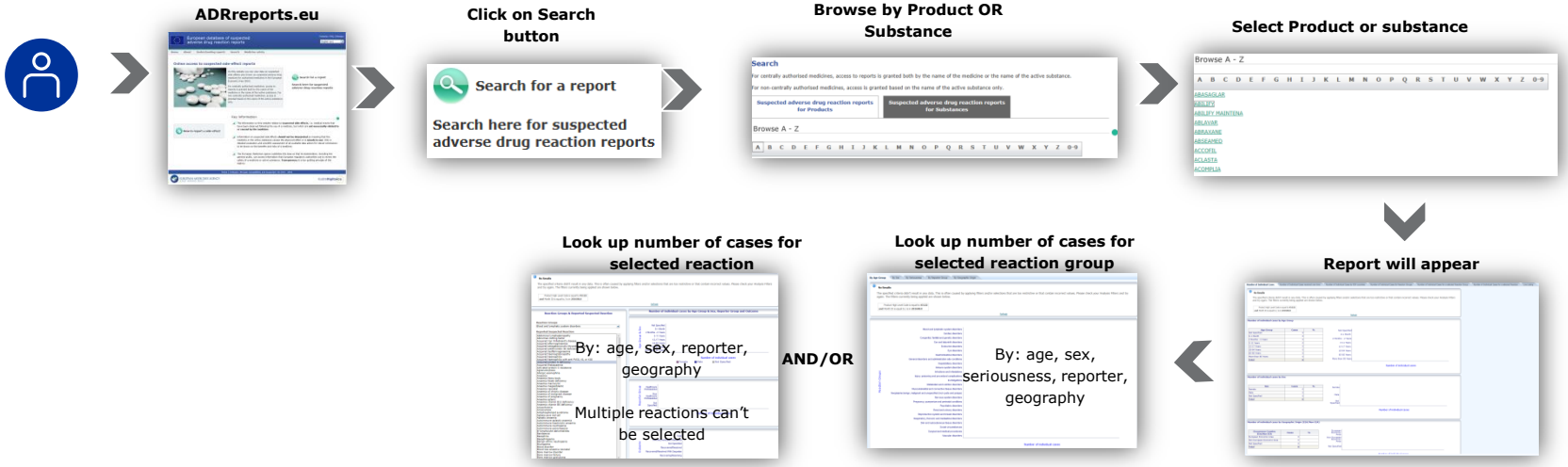
Example of using the ADRreports.eu portal to look up adverse reaction for particular reaction groups



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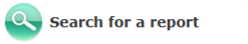
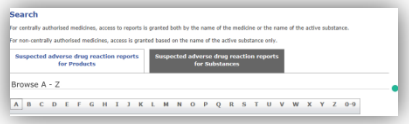
Example of using the ADRreports.eu portal for comparison purposes

ADRreports.eu

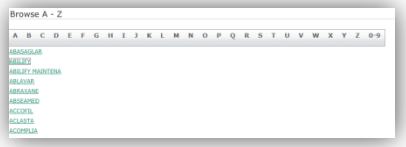
Click on Search button



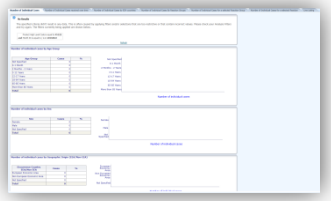
Browse by Product OR Substance



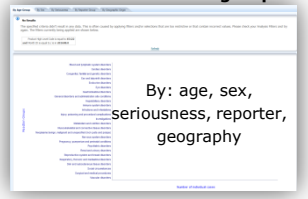
Select Product or substance



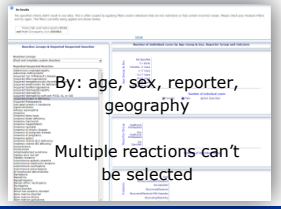
Report will appear



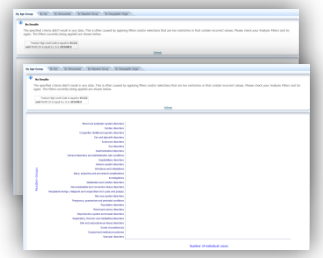
Look up number of cases for selected reaction group



Look up number of cases for selected reaction



Compare products/substances by looking up different reports

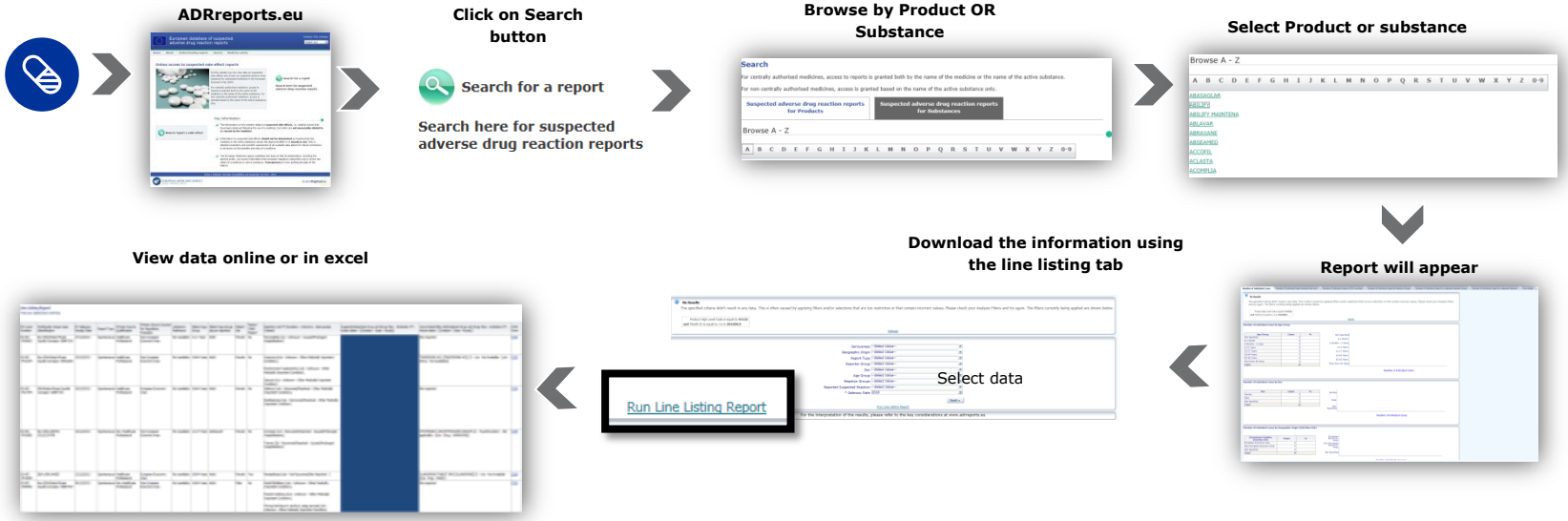


Look at the trends of adverse reactions over time/by geography

AND/OR

AND/OR

Example of using the ADRreports.eu portal to perform detailed analysis



Further support

If you have any questions on the ADRreports.eu portal please refer to the following support channels:

- ✓ Download the 'EudraVigilance - European database of suspected adverse reactions' guide *(Accessed via: Understanding reports > Viewing a web report)*
- ✓ Consult 'Ask EMA' from the corporate website to request further data in different formats (will be shared in line with EV Access Policy)
- ✓ Contact the EMA Service Desk for technical queries from the portal: EMA Service Desk portal

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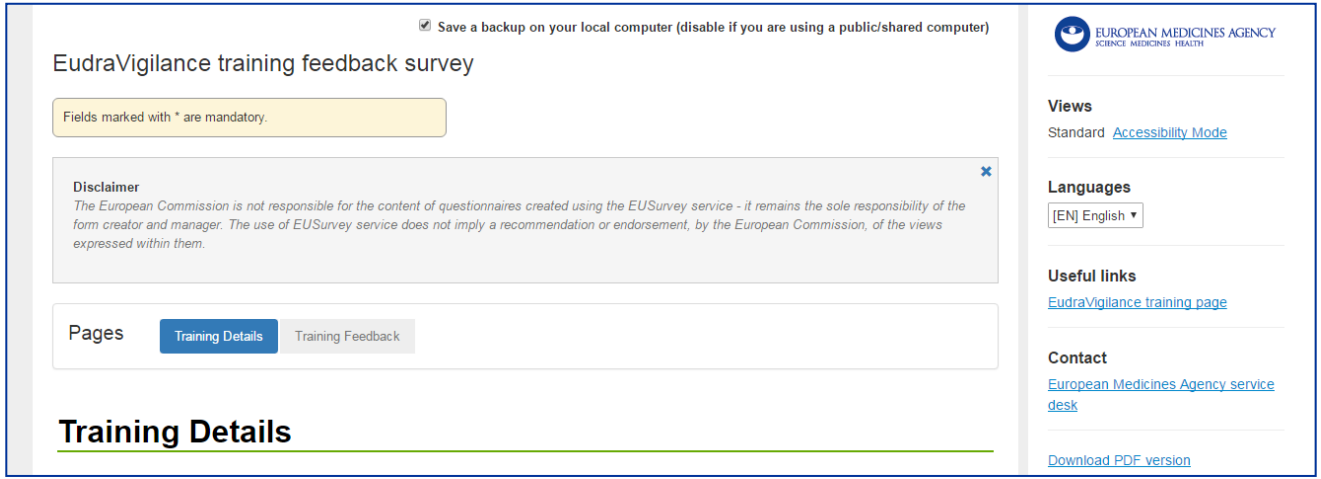
In this module you have learned to:

- Understand the utility of the ADRreports.eu portal and what information it contains
- Understand the enhancements to the ADRreports.eu portal
- Understand the potential use of the portal
- Understand where to obtain further information

Feedback

- Please provide us with feedback on this E-learning module and any attendant guidance documents you have viewed by taking the EMA training survey.

- The survey is accessible via this link.



Supporting documents

Title	Link
Revised Access Policy	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199048.pdf
User Manual	

Acronyms

Acronym	Description
ADR	Adverse Drug Reaction
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
EV	EudraVigilance
ICSR	Individual Case Safety Report

Thank you for your attention

Further information

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