



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Patient and Consumer organisations Training session: public web site of side effects

---

Victoria Newbould





## 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**

## News

[More news...](#)



**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.





# European database of suspected adverse drug reaction reports

[Contacts](#) | [FAQ](#) | [Glossary](#)

[Home](#) [About](#) [Understanding reports](#) [Search](#) [Medicine safety](#)

## Search

<a href="#">Suspected adverse drug reaction reports for Products</a>	<a href="#">Suspected adverse drug reaction reports for Substances</a>
----------------------------------------------------------------------	------------------------------------------------------------------------

## Browse A - Z

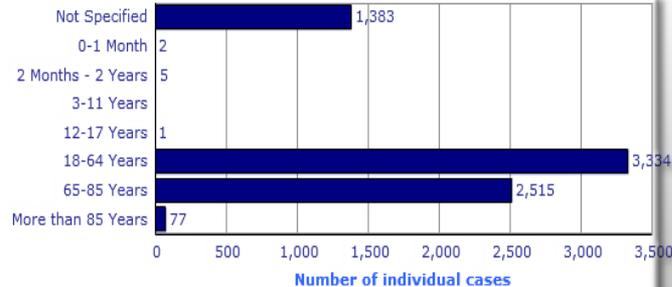
A B C D E F G H I J K L M N O P Q R S T U V W **X** Y Z

- [XAGRID](#)
- [XARELTO](#)
- [XELEVIA](#)
- [XELODA](#)
- [XENICAL](#)
- [XEPLION](#)
- [XERISTAR](#)
- [XGEVA](#)
- [XIAPEX](#)
- [XIGRIS](#)
- [XOLAIR](#)
- [XYREM](#)

The number of individual cases identified in EudraVigilance for CAP is 7,317 (up to Apr 2012)

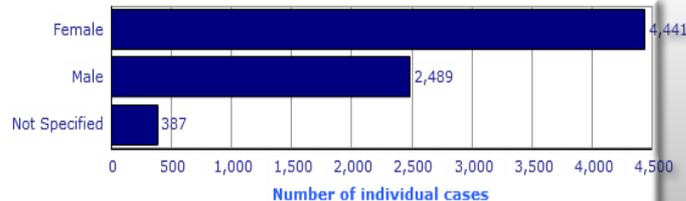
Number of individual cases by Age Group

	Cases	%
Not Specified	1,383	18.9
0-1 Month	2	0.0
2 Months - 2 Years	5	0.1
3-11 Years	0	0.0
12-17 Years	1	0.0
18-64 Years	3,334	45.6
65-85 Years	2,515	34.4
More than 85 Years	77	1.1
<b>Total</b>	<b>7,317</b>	<b>100.0</b>



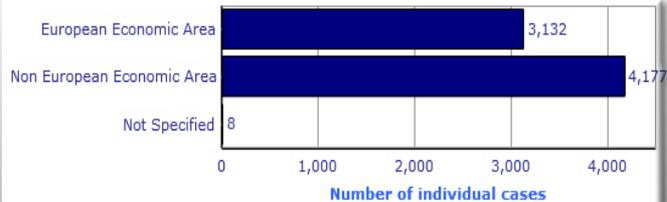
Number of individual cases by Sex

	Cases	%
Female	4,441	60.7
Male	2,489	34.0
Not Specified	387	5.3
<b>Total</b>	<b>7,317</b>	<b>100.0</b>

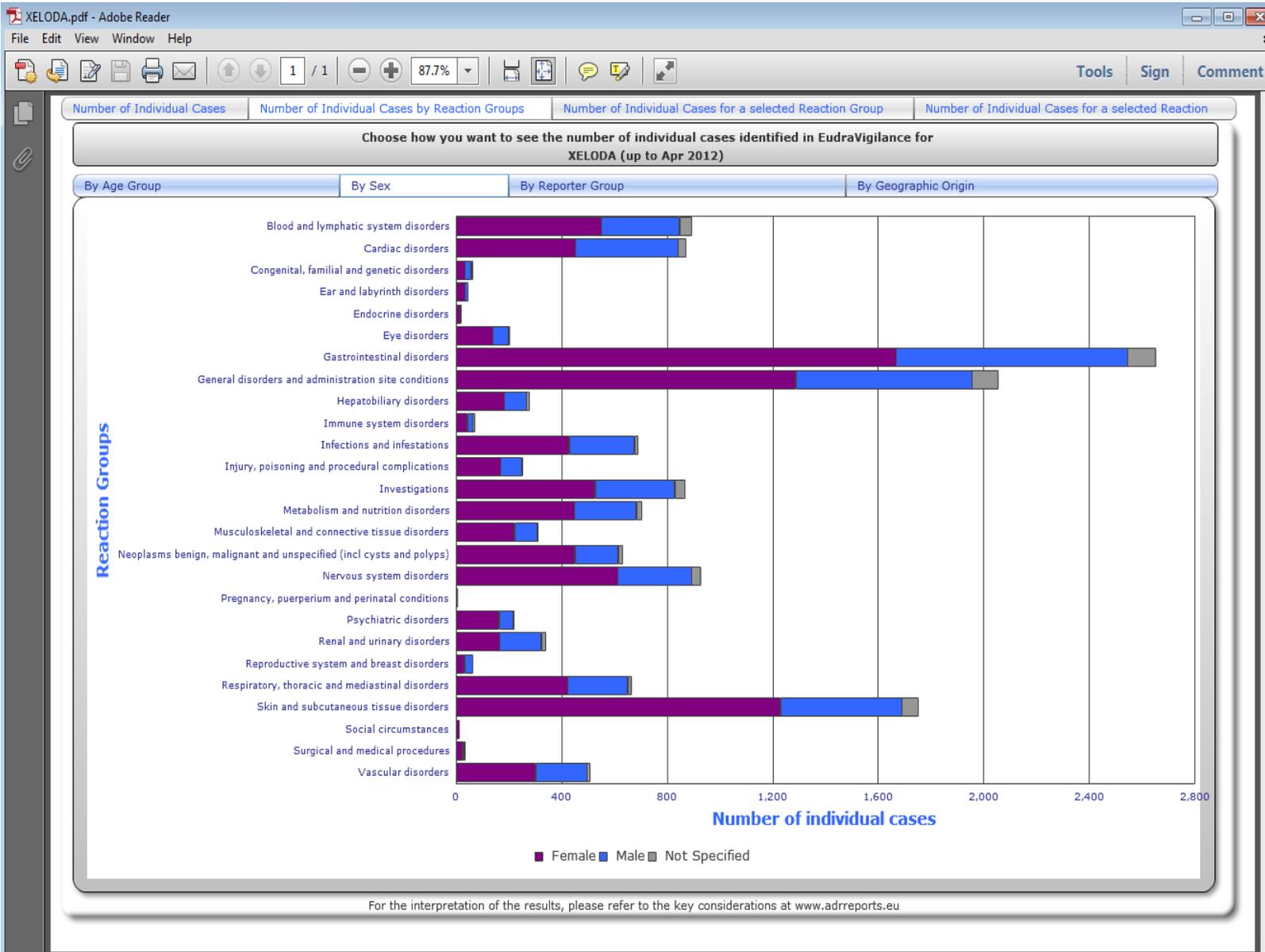


Number of individual cases by Geographic Origin (EEA/Non-EEA)

	Cases	%
European Economic Area	3,132	42.8
Non European Economic Area	4,177	57.1
Not Specified	8	0.1
<b>Total</b>	<b>7,317</b>	<b>100.0</b>



For the interpretation of the results, please refer to the key considerations at [www.adrreports.eu](http://www.adrreports.eu)





Choose a Reaction Group and then a Reported Suspected Reaction to see the number of individual cases identified in EudraVigilance for XELODA (up to Sep 2012)

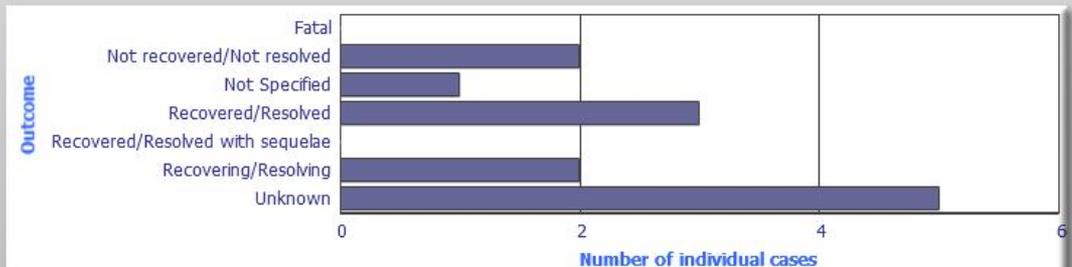
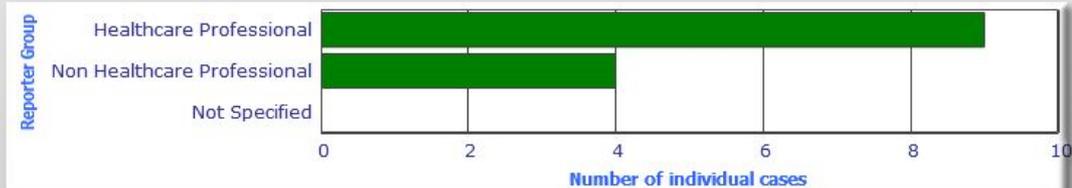
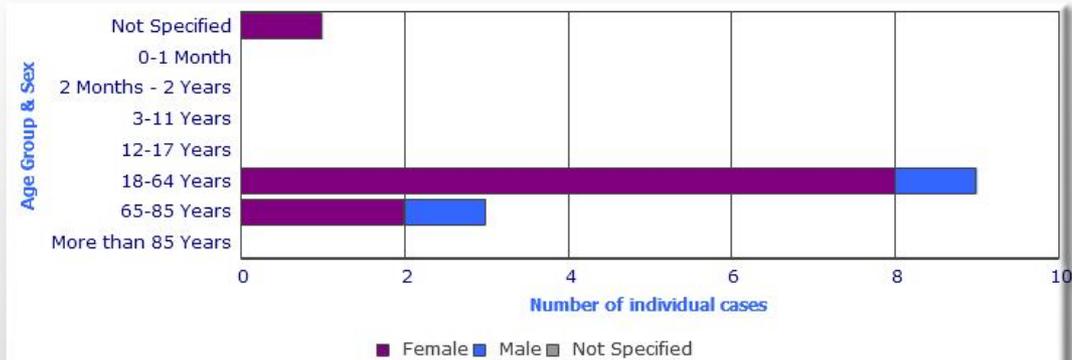
Reaction Groups

Gastrointestinal disorders

Reported Suspected Reaction

- Colitis erosive
- Colitis ischaemic
- Colitis ulcerative
- Colonic obstruction
- Colonic pseudo-obstruction
- Constipation
- Crohn's disease
- Defaecation urgency
- Dental caries
- Diaphragmatic hernia
- Diarrhoea
- Diarrhoea haemorrhagic
- Disbacteriosis
- Diverticulum
- Dry mouth**
- Duodenal perforation
- Duodenal stenosis
- Duodenal ulcer
- Duodenal ulcer haemorrhage
- Duodenal ulcer perforation
- Duodenitis
- Dyschezia
- Dyspepsia

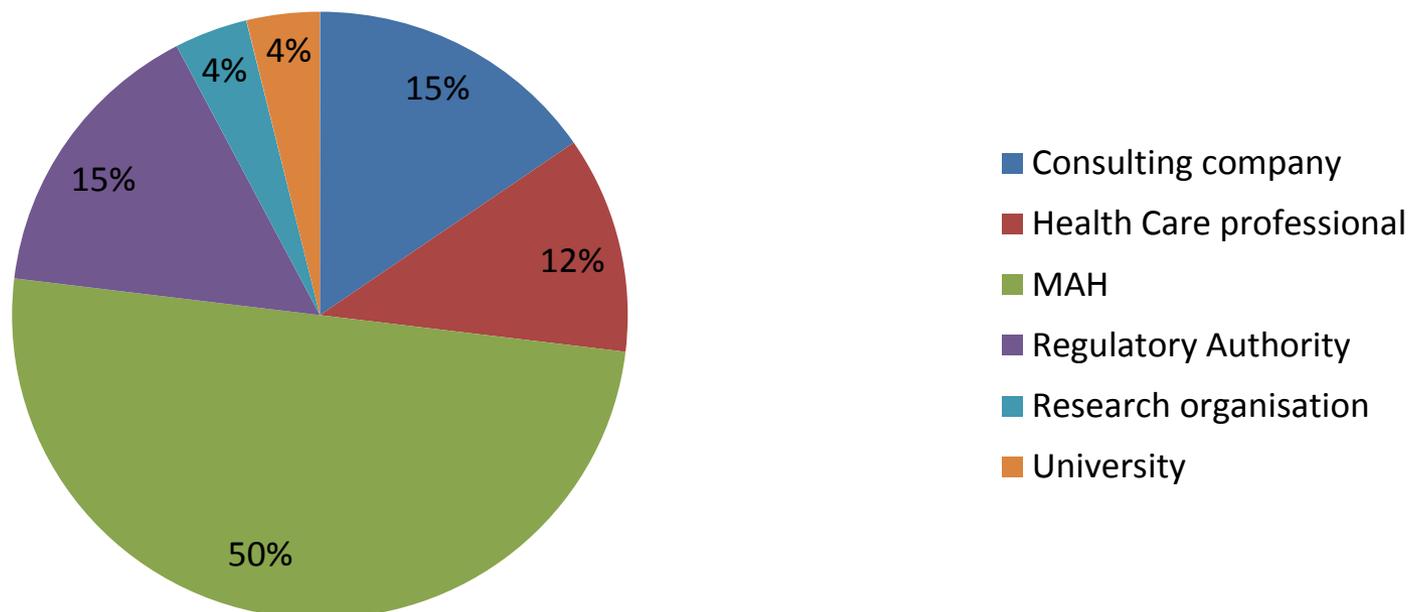
Number of individual cases by Age Group & Sex, Reporter Group and Outcome



For the interpretation of the results, please refer to the key considerations at [www.adrreports.eu](http://www.adrreports.eu)



## Organisations using web site (based on queries about website) – Promote use also by Patients and Consumers





THANK YOU