



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

Suspected adverse drug reaction reports  
for Products

Suspected adverse drug reaction reports  
for Substances

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

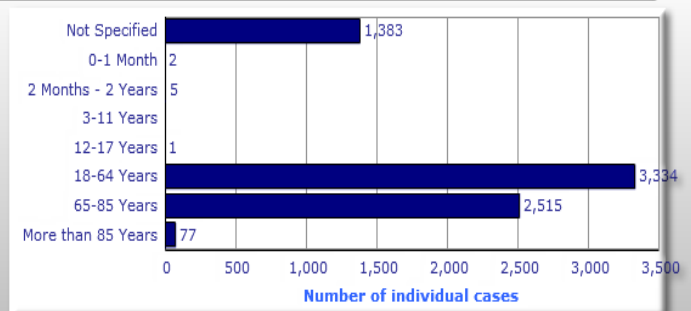
[XAGRID](#)[XARELTO](#)[XELEVIA](#)[XELODA](#)[XENICAL](#)[XEPLION](#)[XERISTAR](#)[XGEVA](#)[XIAPEX](#)[XIGRIS](#)[XOLAIR](#)[XYREM](#)

Number of Individual Cases
 Number of Individual Cases by Reaction Groups
 Number of Individual Cases for a selected Reaction Group
 Number of Individual Cases for a selected Reaction

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

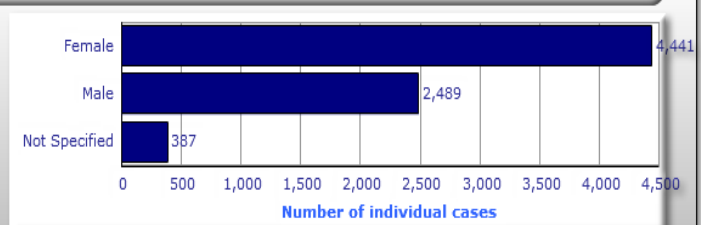
Number of individual cases by Age Group

	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>



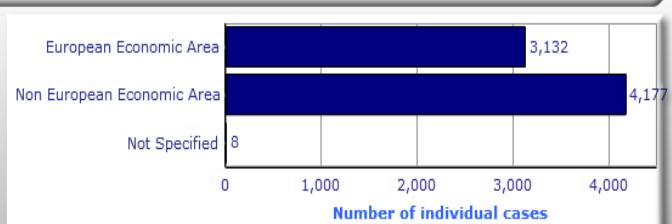
Number of individual cases by Sex

	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>

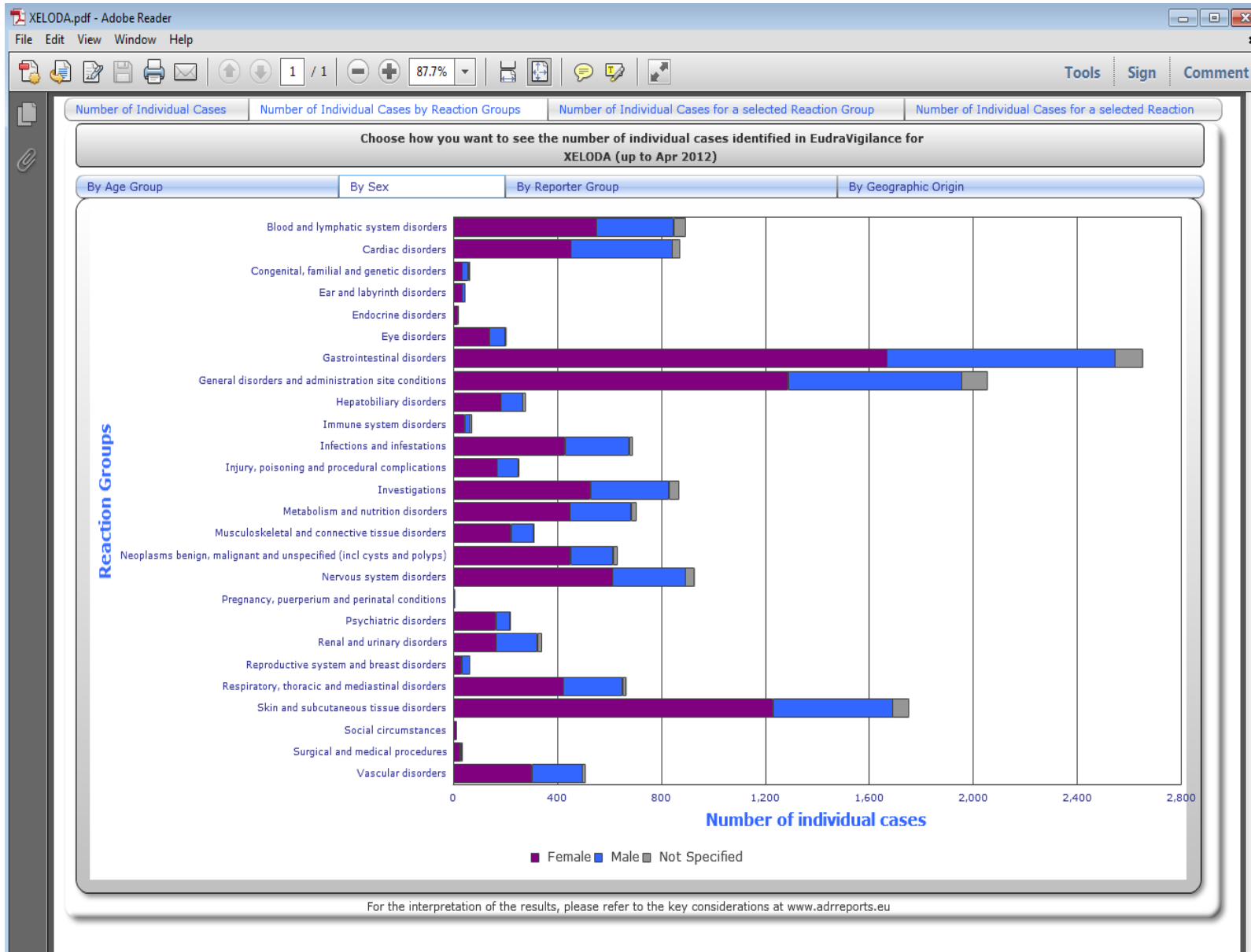


Number of individual cases by Geographic Origin (EEA/Non-EEA)

	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)

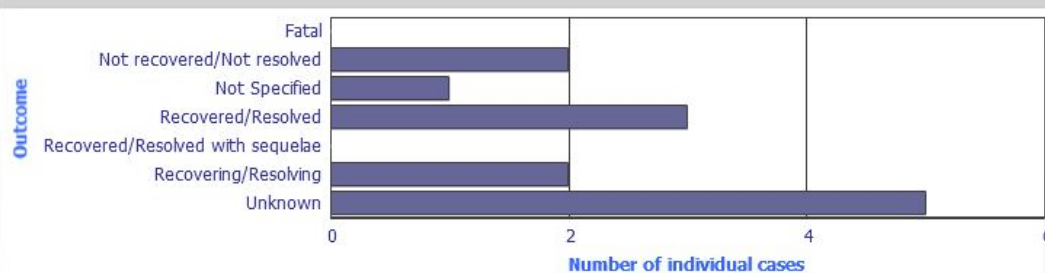
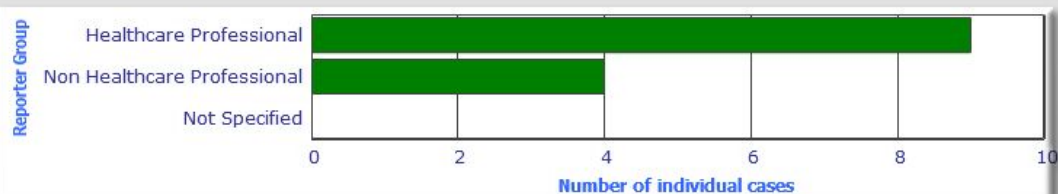
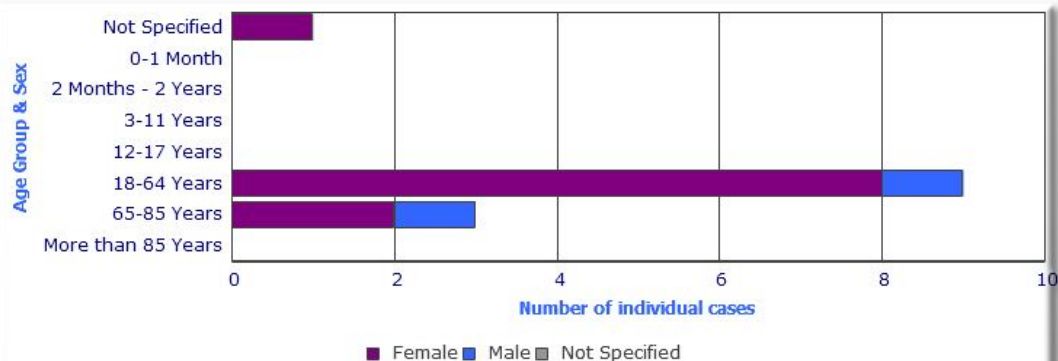
### Reaction Groups

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

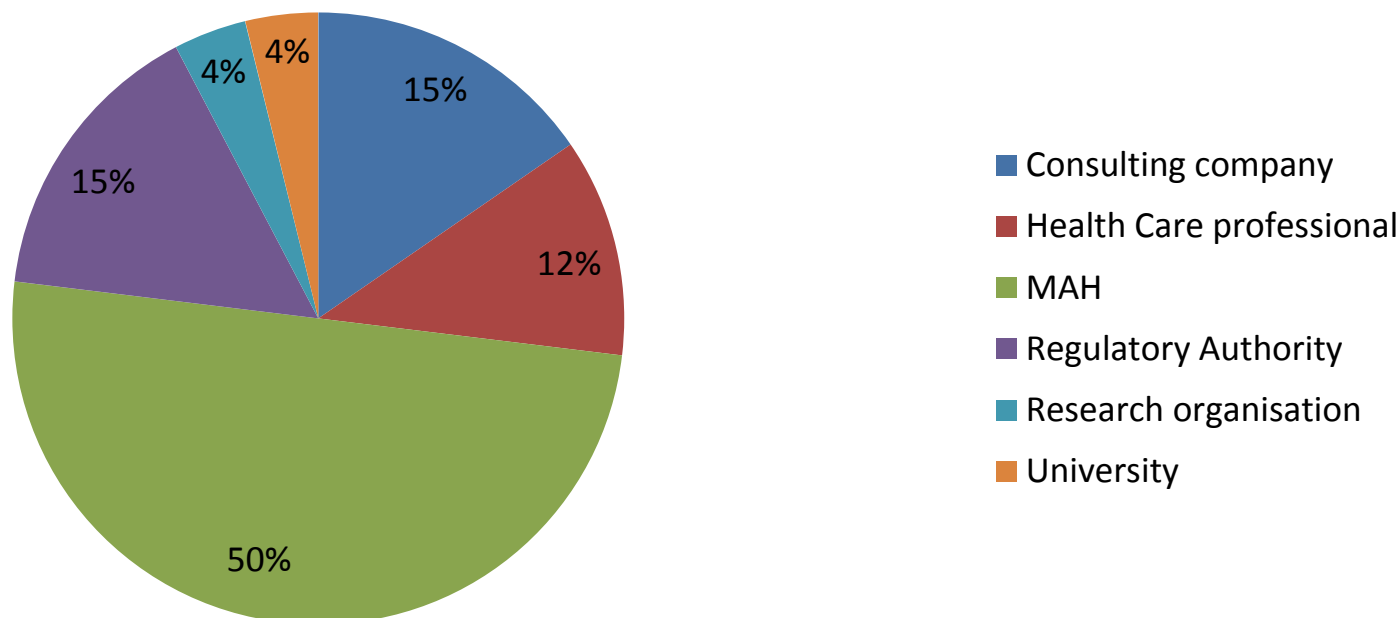
### Number of individual cases by Age Group & Sex, Reporter Group and Outcome



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