Patient reporting update

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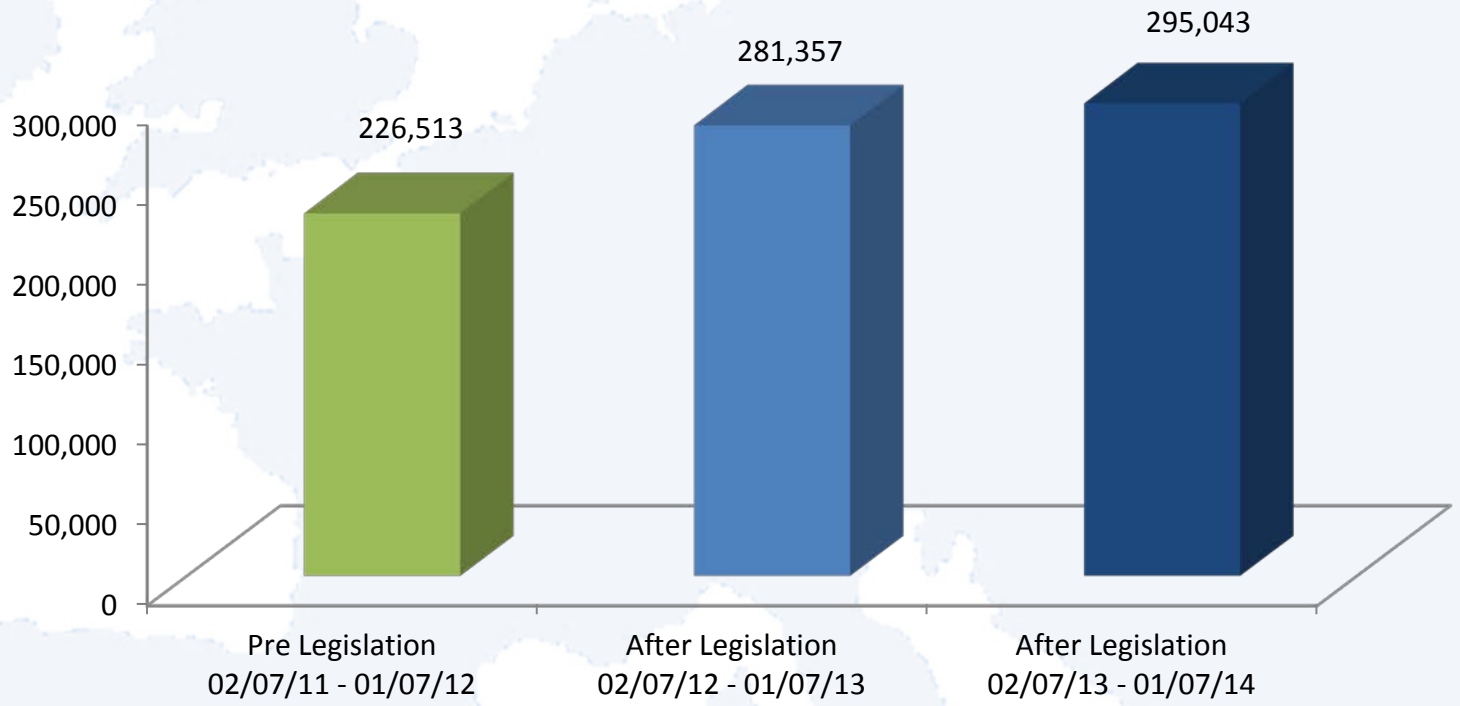
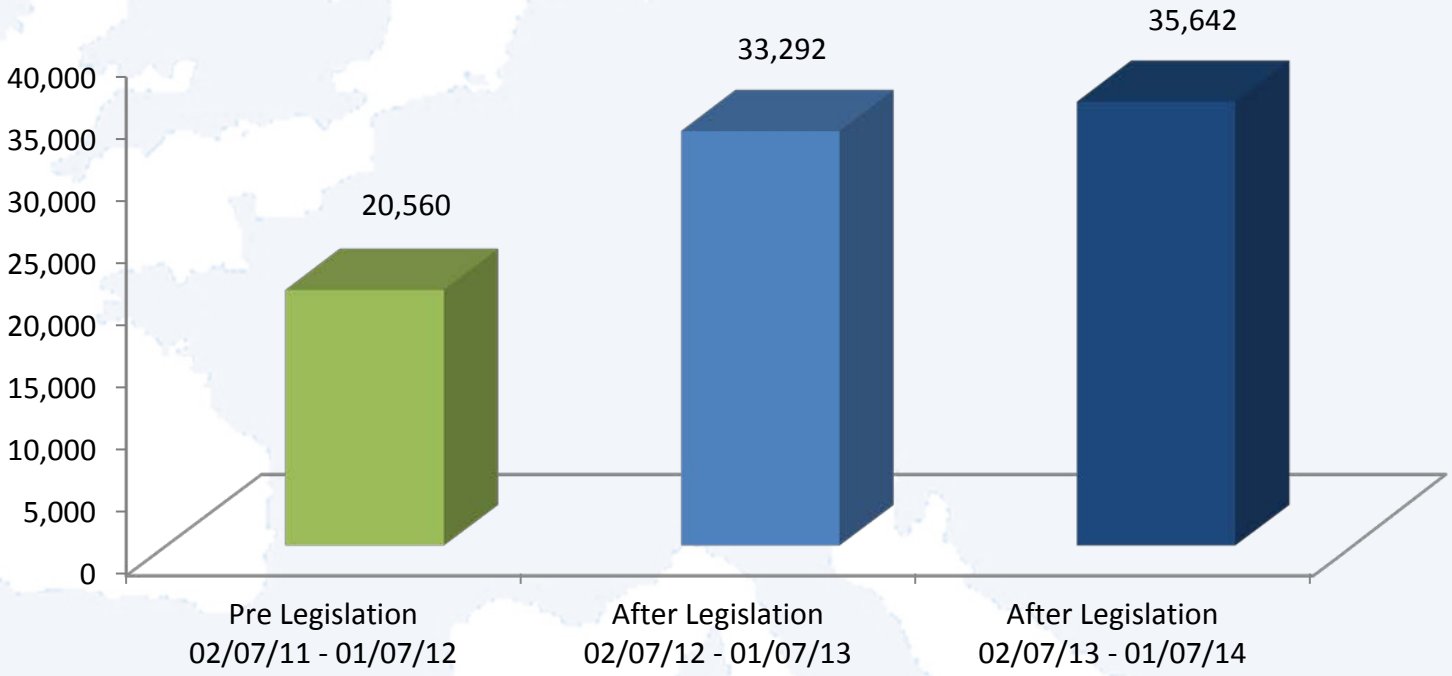
8th Pharmacovigilance stakeholders' forum EMA, 15/06/2014

Spontaneous reporting in EEA*
(data provided by EMA)



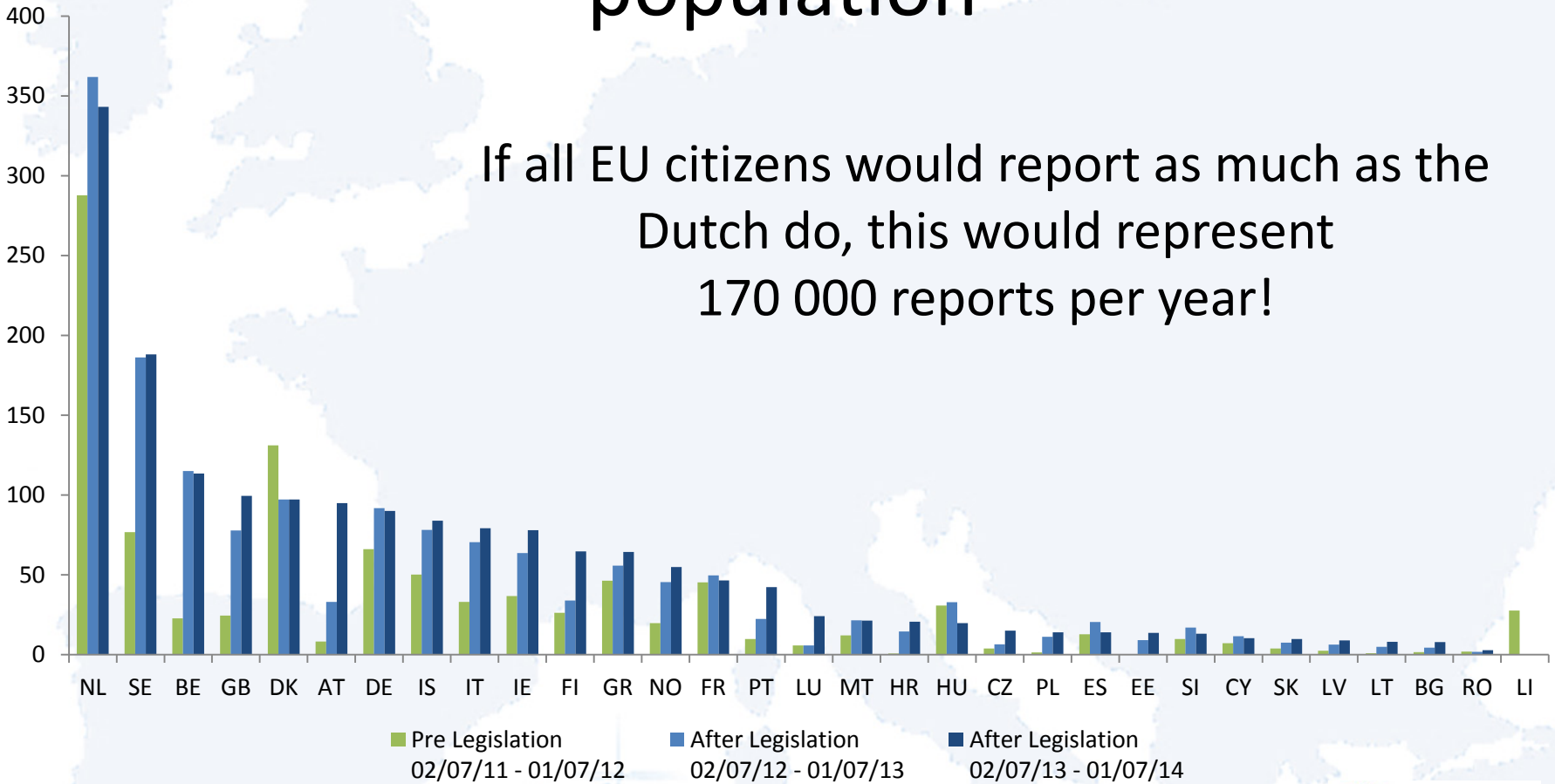
* Number of ICSRs received in EudraVigilance before de-duplication

Spontaneous reporting by patients in EEA*



* Number of ICSRs received in EudraVigilance before de-duplication

Spontaneous reporting by patients in EEA* Split by country: N° reports by 1M population

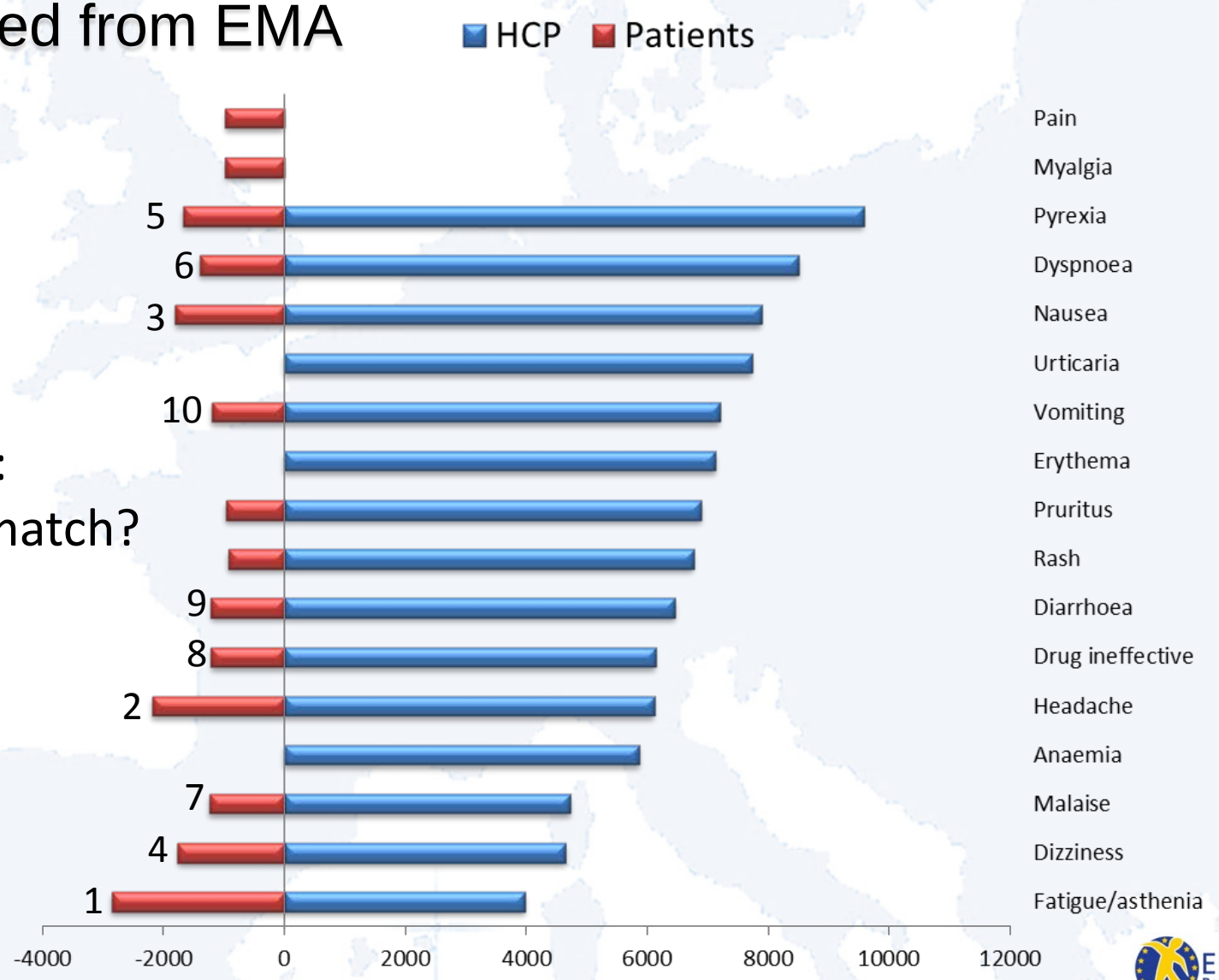


If all EU citizens would report as much as the Dutch do, this would represent 170 000 reports per year!

* Number of ICSRs received in EudraVigilance before de-duplication

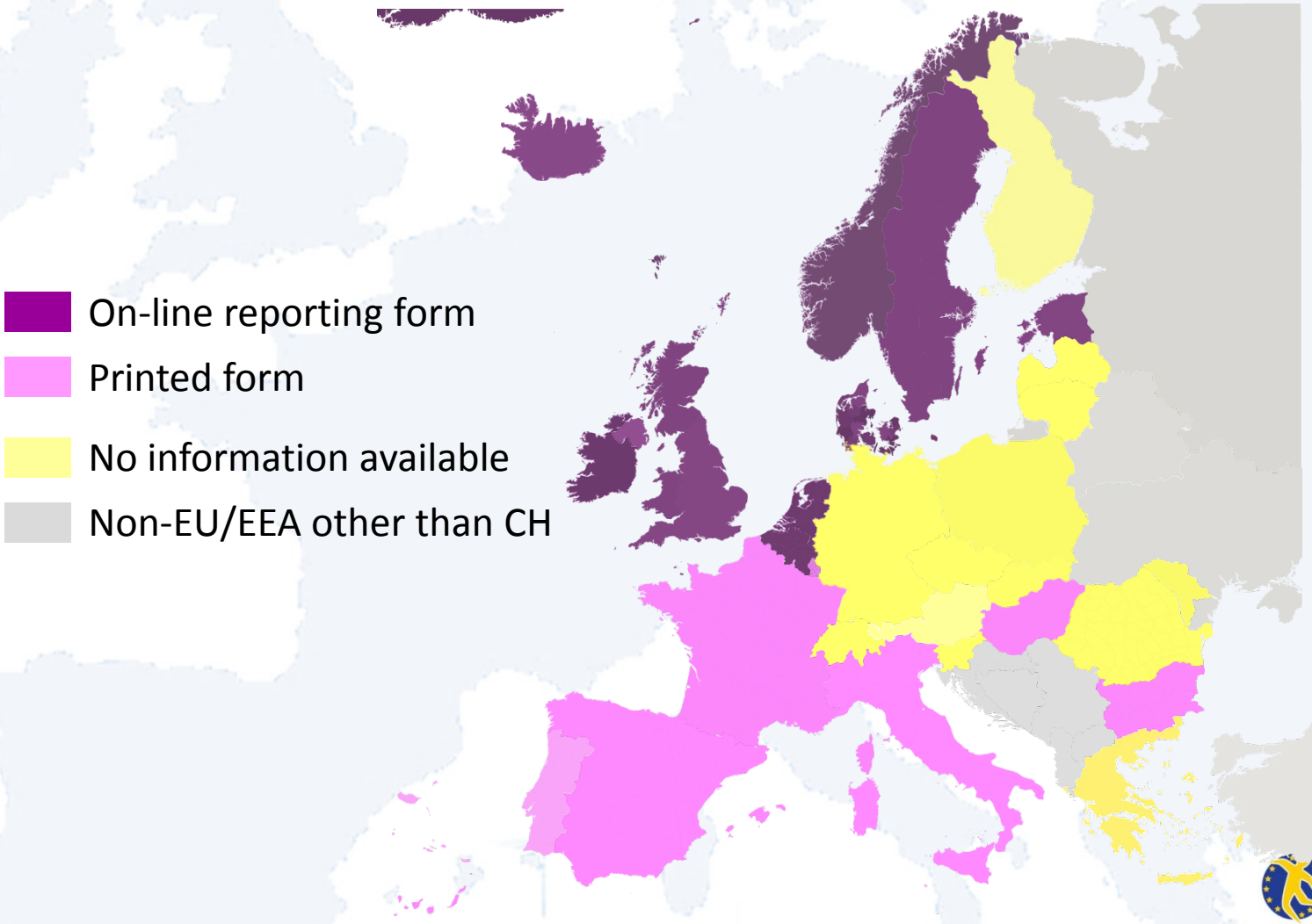
Top 15 reactions reported by HCP or non-HCP

adapted from EMA

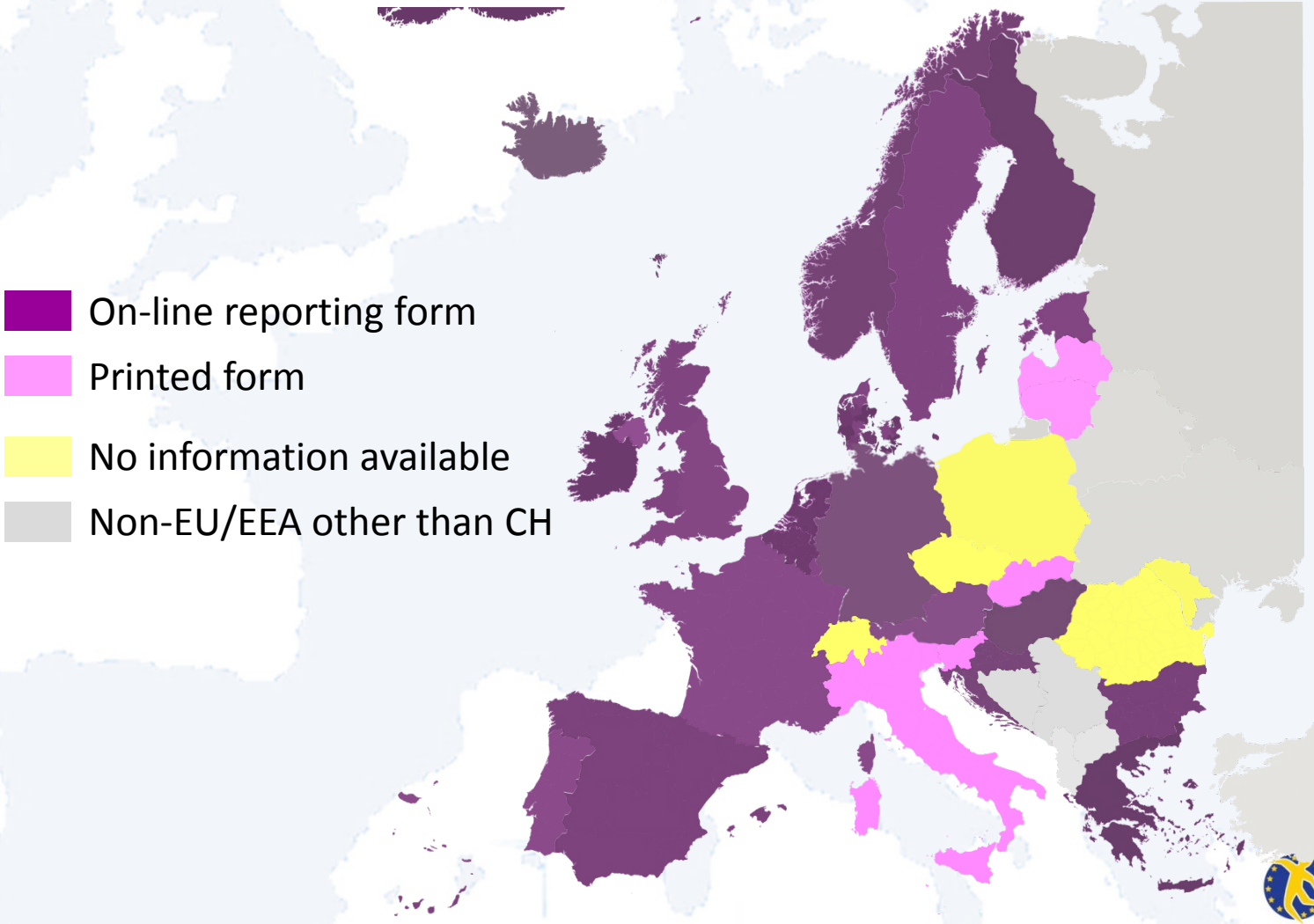


Severity:
does it match?

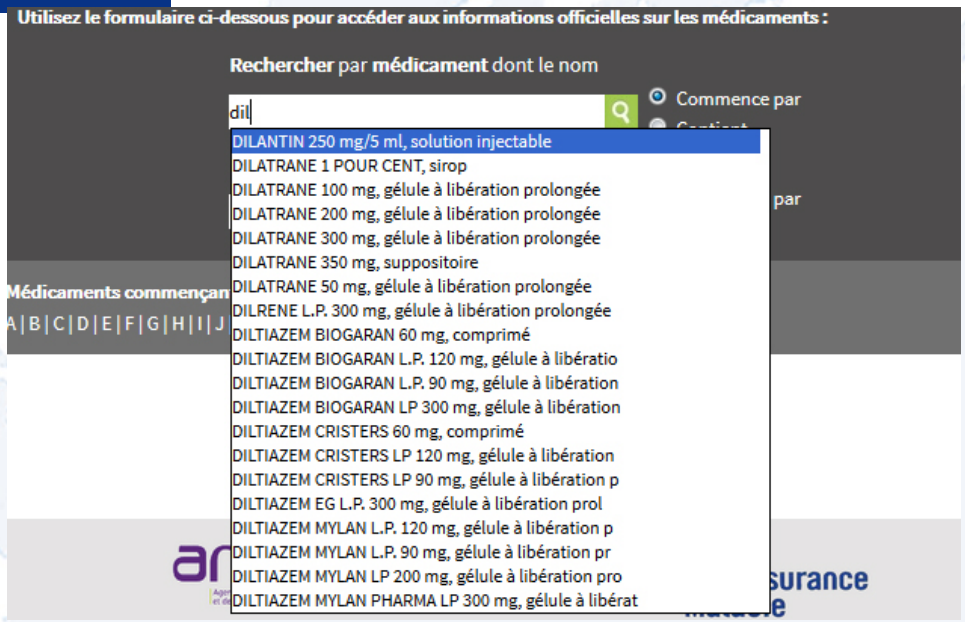
ADR reporting tools as of May 2012

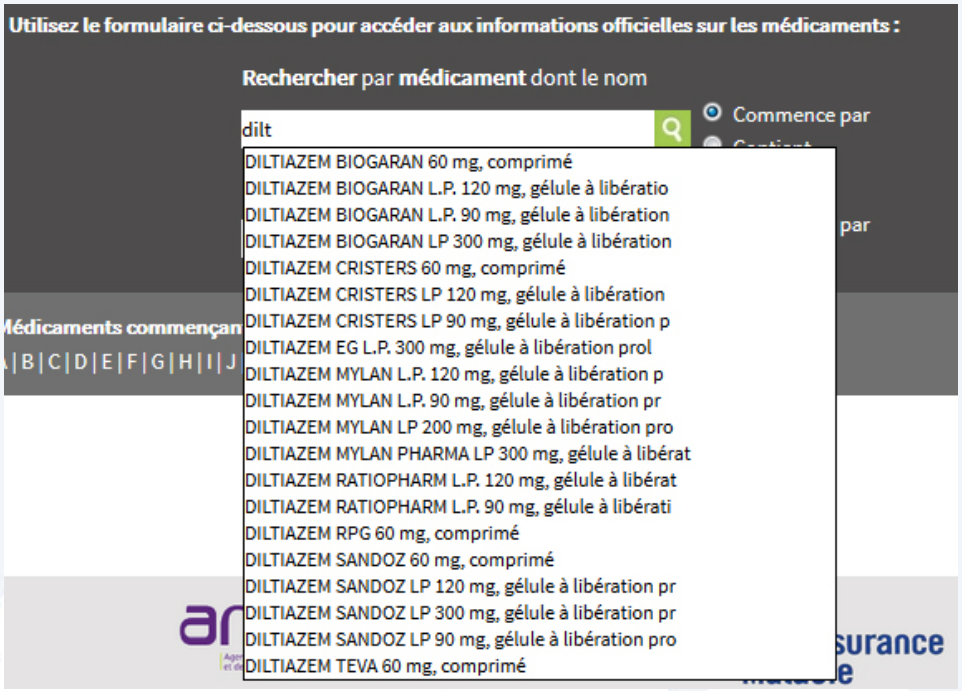


ADR reporting tools as of April 2014



HOW HELPFUL ARE THESE TOOLS?
For some: 6 clicks to find the form…


Utilisez le formulaire ci-dessous pour accéder aux informations officielles sur les médicaments :
Rechercher par médicament dont le nom
dil
Commence par
DILANTIN 250 mg/5 ml, solution injectable
DILATRANE 1 POUR CENT, sirop
DILATRANE 100 mg, gélule à libération prolongée
DILATRANE 200 mg, gélule à libération prolongée
DILATRANE 300 mg, gélule à libération prolongée
DILATRANE 350 mg, suppositoire
DILATRANE 50 mg, gélule à libération prolongée
DILRENE L.P. 300 mg, gélule à libération prolongée
DILTIAZEM BIOGARAN 60 mg, comprimé
DILTIAZEM BIOGARAN L.P. 120 mg, gélule à libératio
DILTIAZEM BIOGARAN L.P. 90 mg, gélule à libération
DILTIAZEM BIOGARAN LP 300 mg, gélule à libération
DILTIAZEM CRISTERS 60 mg, comprimé
DILTIAZEM CRISTERS LP 120 mg, gélule à libération
DILTIAZEM CRISTERS LP 90 mg, gélule à libération p
DILTIAZEM EG L.P. 300 mg, gélule à libération prol
DILTIAZEM MYLAN L.P. 120 mg, gélule à libération p
DILTIAZEM MYLAN L.P. 90 mg, gélule à libération pr
DILTIAZEM MYLAN LP 200 mg, gélule à libération pro
DILTIAZEM MYLAN PHARMA LP 300 mg, gélule à libérat
par
Médicaments commençan
A|B|C|D|E|F|G|H|I|J


Utilisez le formulaire ci-dessous pour accéder aux informations officielles sur les médicaments :
Rechercher par médicament dont le nom
dilt
Commence par
DILTIAZEM BIOGARAN 60 mg, comprimé
DILTIAZEM BIOGARAN L.P. 120 mg, gélule à libératio
DILTIAZEM BIOGARAN L.P. 90 mg, gélule à libération
DILTIAZEM BIOGARAN LP 300 mg, gélule à libération
DILTIAZEM CRISTERS 60 mg, comprimé
DILTIAZEM CRISTERS LP 120 mg, gélule à libération
DILTIAZEM CRISTERS LP 90 mg, gélule à libération p
DILTIAZEM EG L.P. 300 mg, gélule à libération prol
DILTIAZEM MYLAN L.P. 120 mg, gélule à libération p
DILTIAZEM MYLAN L.P. 90 mg, gélule à libération pr
DILTIAZEM MYLAN LP 200 mg, gélule à libération pro
DILTIAZEM MYLAN PHARMA LP 300 mg, gélule à libérat
DILTIAZEM RATIOPHARM L.P. 120 mg, gélule à libérat
DILTIAZEM RATIOPHARM L.P. 90 mg, gélule à libérati
DILTIAZEM RPG 60 mg, comprimé
DILTIAZEM SANDOZ 60 mg, comprimé
DILTIAZEM SANDOZ LP 120 mg, gélule à libération pr
DILTIAZEM SANDOZ LP 300 mg, gélule à libération pr
DILTIAZEM SANDOZ LP 90 mg, gélule à libération pro
DILTIAZEM TEVA 60 mg, comprimé
par
Médicaments commençan
A|B|C|D|E|F|G|H|I|J

15 choices

As proposed 24 June 2010

(after release of Google Goggle)

Med App checks moles for irregularities in size, shape, colour and border

Puzzling

Batch number. What's this?

Does everyone know what subcutaneous means as opposed to intradermal?

?

63 characters

	Médicament	N° Lot	Mode d'utilisation (orale, cutanée, nasale, ...)	Dose/jour utilisée	Début d'utilisation du médicament	Fin d'utilisation du médicament	Motif de l'utilisation du médicament
1							
2							
3							
4							
5							
6							

auriculaire
cutanée
sous-cutanée
intraveineuse
intramusculaire
intradermique
ophtalmique
nasale
orale
rectale

Si vous utilisez d'autres médicaments, vous pouvez continuer la liste sur une autre feuille annexe

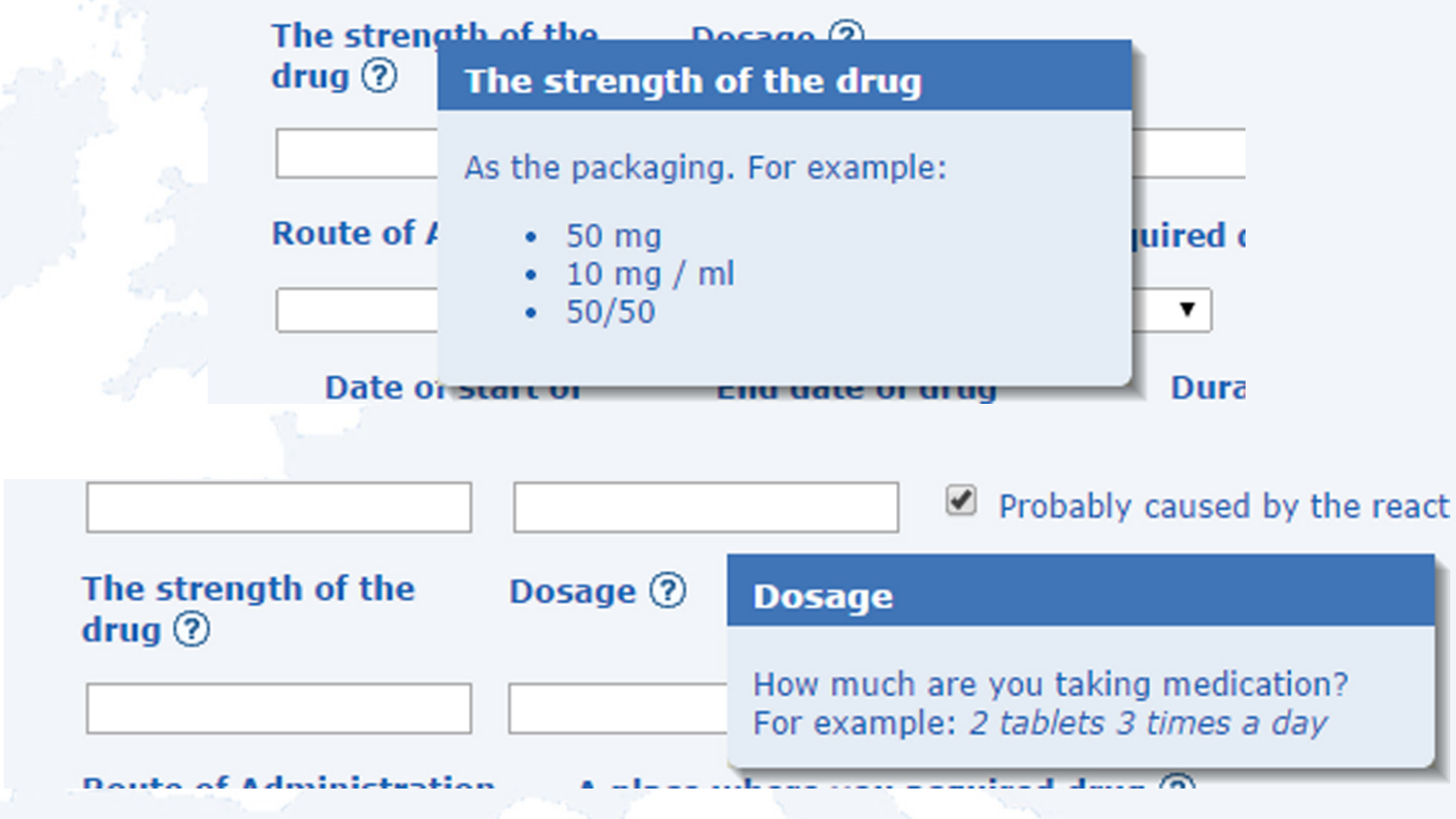
6, but in the elderly: average 10 medicines.

Humm… How do I add a sheet to a pdf?

What if ADR occurs after 6 months of treatment during which the patient alternatively took the originator product or a generic or a second generic? e.g. loose tools and ricin oil as excipient in the generic

EURORDIS Rare Diseases Europe

Croatia – dose



Publicising self-reporting

As a patient, you have the right to report unwanted side effects of medicines directly to the authorities. You can also report a side effect on behalf of someone in your care, such as a child or relative.

Remember to speak to your doctor or pharmacist if you are worried about any suspected side effects.

Why report a side effect?

We are always learning more about medicines.

Although they are tested extensively in clinical trials before they are authorised, not everything can be known about their side effects until they have been used by many people over time.

By reporting side effects, you can help to provide more information about medicines, which will ultimately help to make them safer.

How do I report a side effect?

If you think a medicine has caused a side effect, please check the package leaflet that comes with the medicine for information on how to report it.

You can usually report side effects by filling in a form online or from your doctor or local pharmacy.

For more details, and to report online, please check the website of your national authority (use these links to ensure you are reporting to the appropriate website).

What information should I report?

If possible, you should provide the following information when making your report:

- information on the person who has had the side effect (such as age and sex);
- the description of the side effect;
- the dose and the name of the medicine suspected to have caused the side effect (brand name as well as active ingredient);
- the batch number of the medicine (found on the packaging);
- any other medicines being taken around the same time (including non-prescription medicines, herbal remedies and contraceptives);
- any other health conditions that the person who experienced the side effect may have.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Frequently asked questions

How do I know I've experienced a side effect?

A side effect (also called an adverse reaction) is an unwanted symptom or effect caused by a medicine. You cannot always be certain that what you are experiencing is caused by the medicine, but by reporting suspected side affects you can help the authorities in their investigations, which will lead to safer medicines.

What happens to my report after I've sent it?

Your report, along with other reports on the medicine, will be reviewed by medicines safety experts to see if there is any new information (known as a 'safety signal'). After evaluating the safety signal and all other relevant data, medicines authorities may issue new warnings or advice on how the medicine should be used, and can even stop its use.

Can I get help with reporting a side effect?

Yes. Your doctor or pharmacist can help you complete your report, and you can also request that they send the report on your behalf. Patients' organisations in your country may also be able to help.

The medicine has a black triangle symbol in its package leaflet. What does this mean?

The inverted black triangle symbol '▼' serves as a reminder to report any suspected side effects, either because the medicine is new or because there is a particular need to find out more about its long-term safety. The symbol does not mean that your medicine is unsafe.

Are my personal data protected?

All personal information related to the reporting of a side effect is processed in accordance with EU data protection legislation. Your report is used solely for the scientific evaluation of the medicine.

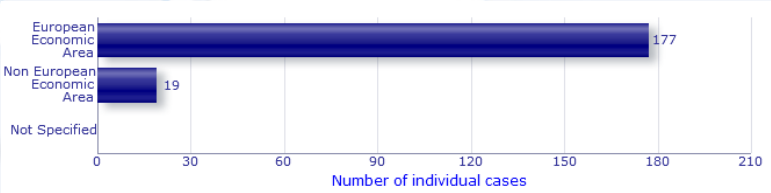
Where can I find information on side effects that have already been reported with the medicine?

You can check the package leaflet that comes with the medicine. You can also check the publicly available European database (www.adrreports.eu) or contact your national medicines authority for further information.

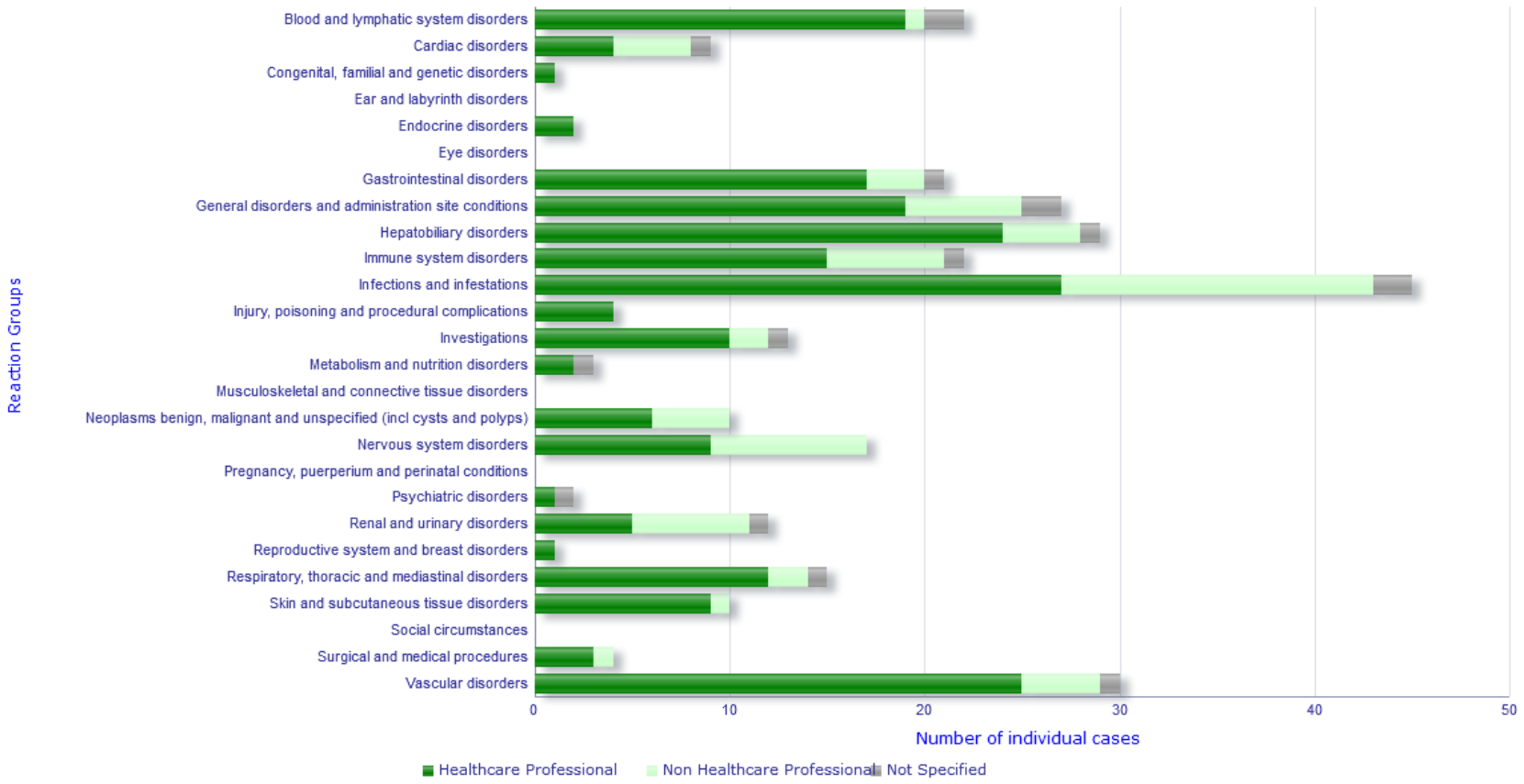
If you are worried about any suspected side effects from your medicine, please speak to your doctor or pharmacist for advice. You should contact them immediately if you have a side effect that you think is serious or that is listed as serious in the package leaflet that comes with your medicine.

EURORDIS Rare Diseases Europe

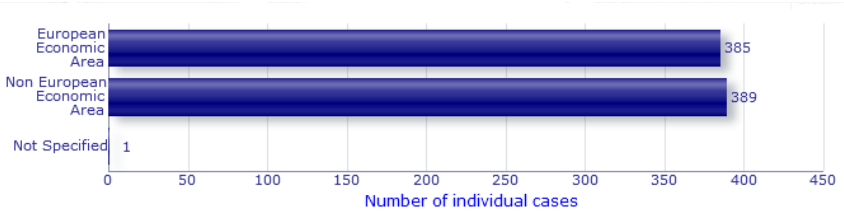
2003 Stem cell transp. (expired)

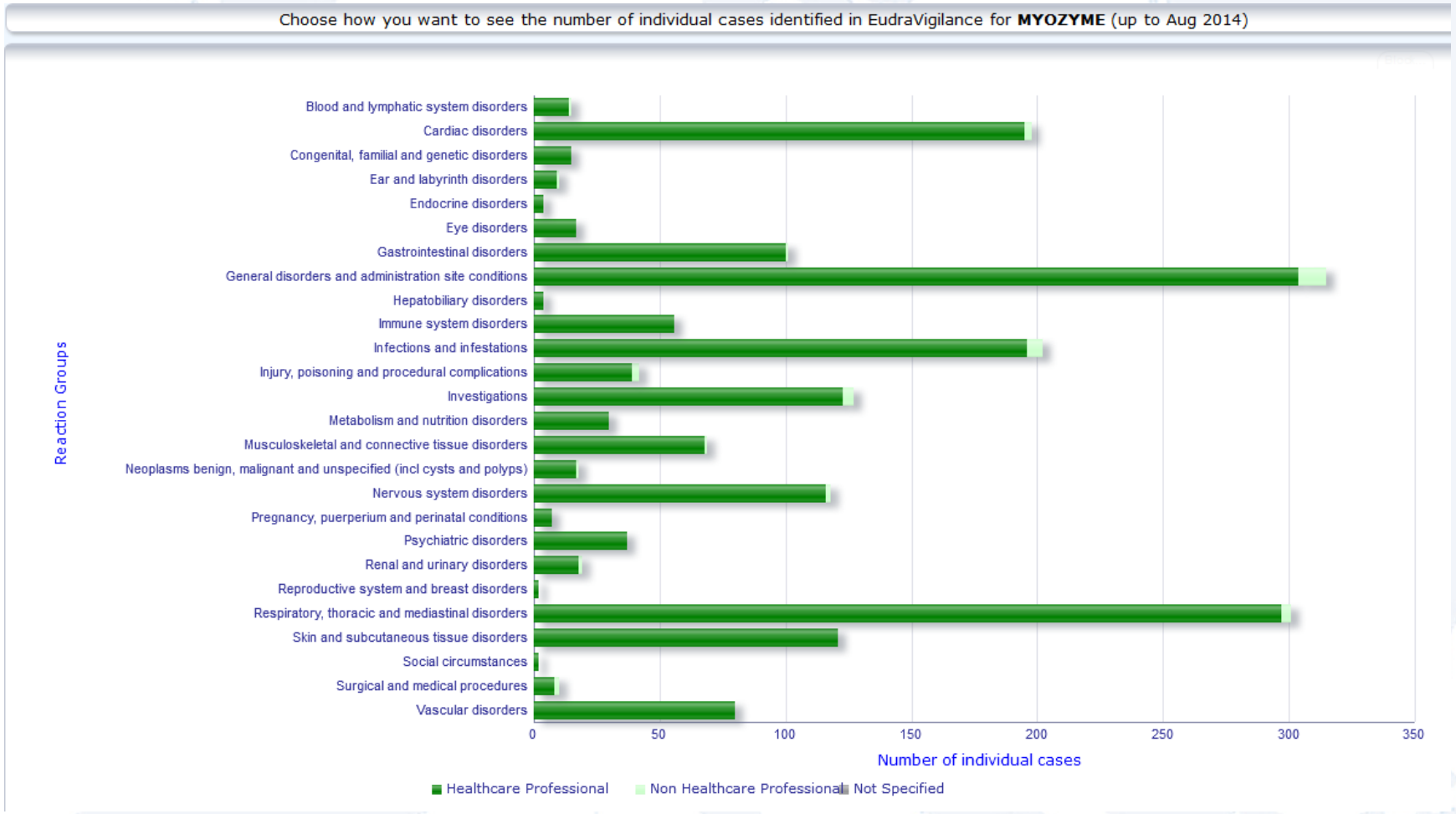


Choose how you want to see the number of individual cases identified in EudraVigilance for **BUSILVEX** (up to Aug 2014)

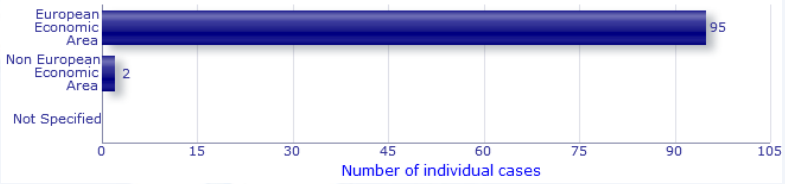


2006 Pompe's

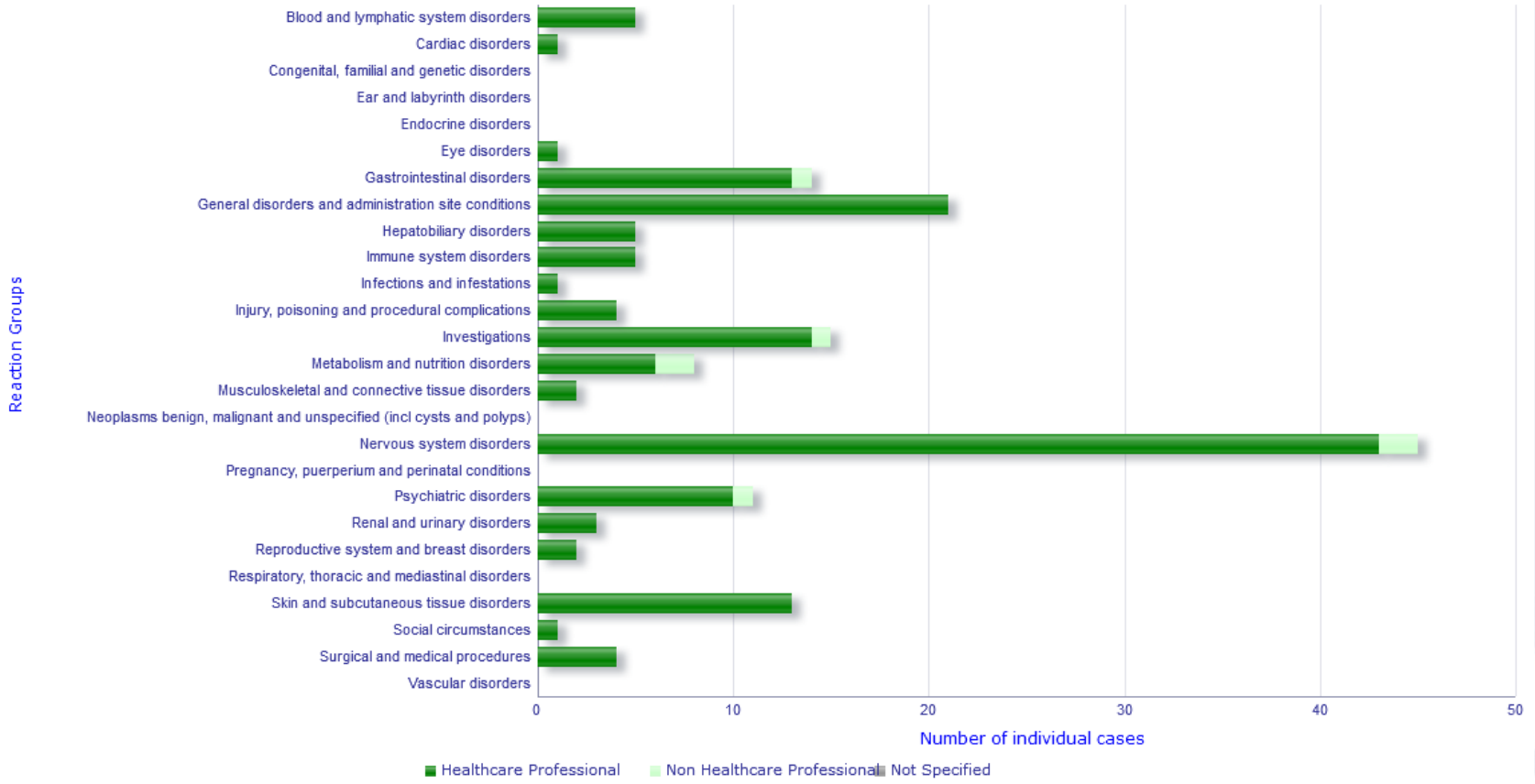

European Economic Area
385
Non European Economic Area
389
Not Specified
1
0
50
100
150
200
250
300
350
400
450
Number of individual cases


Choose how you want to see the number of individual cases identified in EudraVigilance for **MYOZYME** (up to Aug 2014)
Reaction Groups
Blood and lymphatic system disorders
Cardiac disorders
Congenital, familial and genetic disorders
Ear and labyrinth disorders
Endocrine disorders
Eye disorders
Gastrointestinal disorders
General disorders and administration site conditions
Hepatobiliary disorders
Immune system disorders
Infections and infestations
Injury, poisoning and procedural complications
Investigations
Metabolism and nutrition disorders
Musculoskeletal and connective tissue disorders
Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Nervous system disorders
Pregnancy, puerperium and perinatal conditions
Psychiatric disorders
Renal and urinary disorders
Reproductive system and breast disorders
Respiratory, thoracic and mediastinal disorders
Skin and subcutaneous tissue disorders
Social circumstances
Surgical and medical procedures
Vascular disorders
0
50
100
150
200
250
300
350
Number of individual cases
Healthcare Professional
Non Healthcare Professional
Not Specified

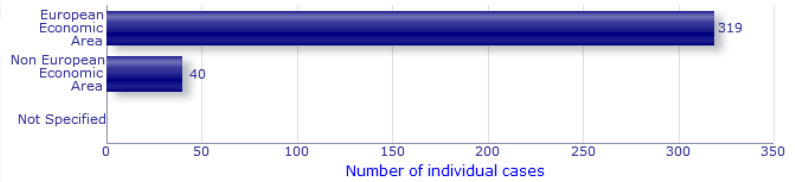
2007 Epilepsy



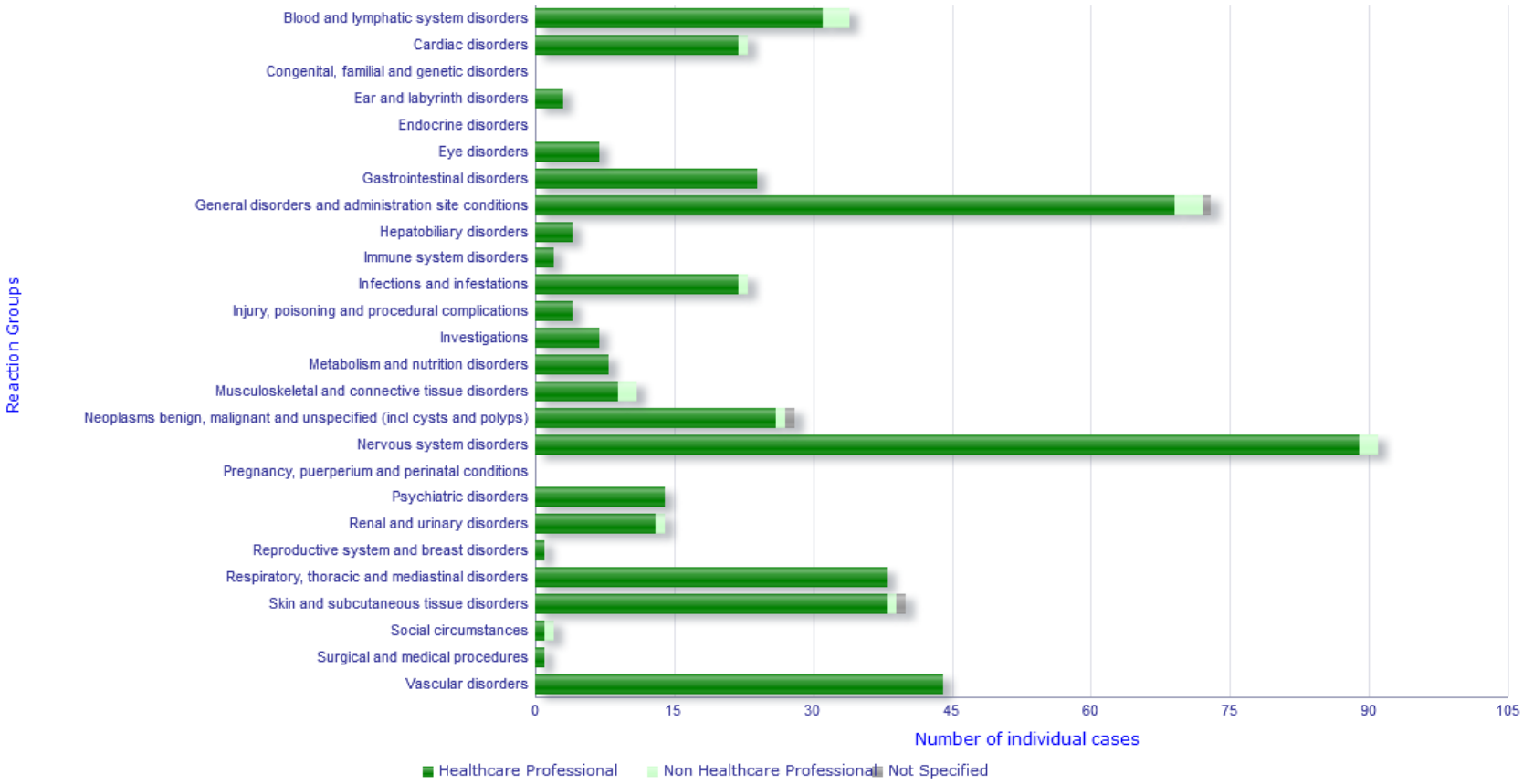
Choose how you want to see the number of individual cases identified in EudraVigilance for **INOVELON** (up to Aug 2014)



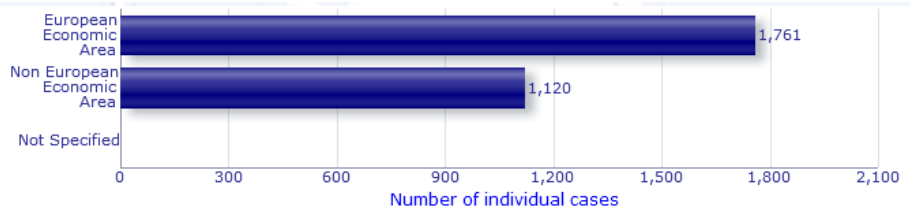
2008 Multiple myeloma



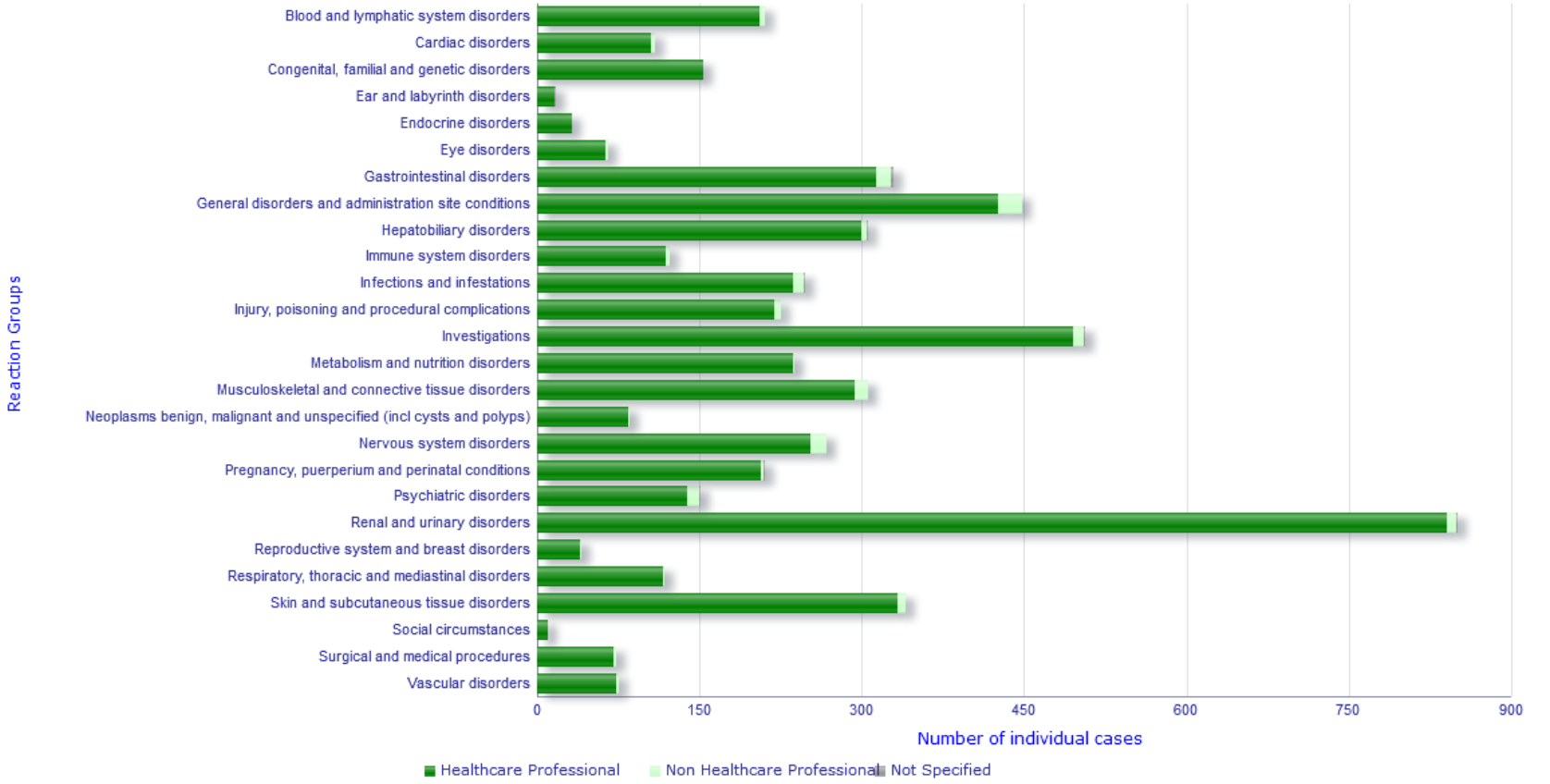
Choose how you want to see the number of individual cases identified in EudraVigilance for **THALIDOMIDE CELGENE** (up to Aug 2014)



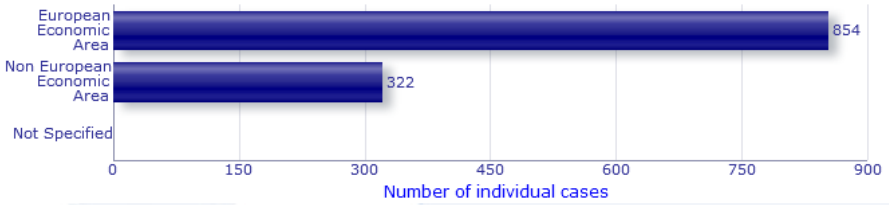
2005 HIV



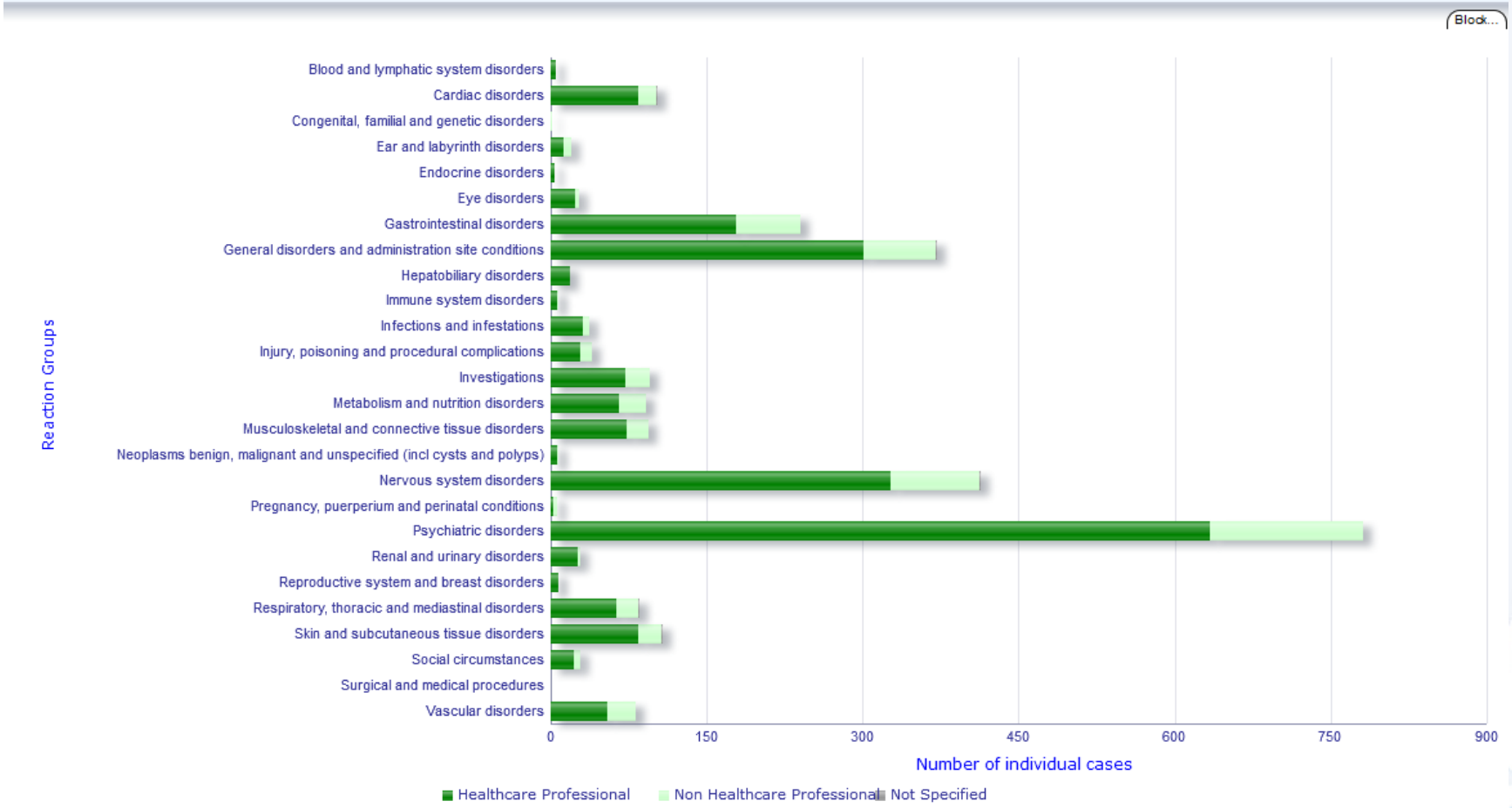
Choose how you want to see the number of individual cases identified in EudraVigilance for **TRUVADA** (up to Aug 2014)



Withdrawn obesity



Choose how you want to see the number of individual cases identified in EudraVigilance for **ACOMPLIA** (up to Aug 2014)



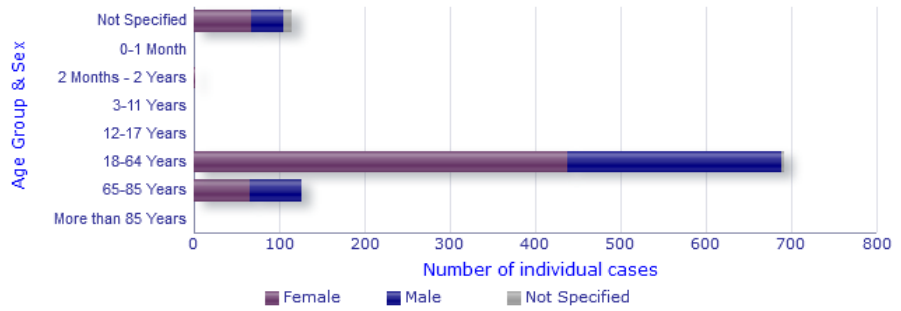
Corroborates PhWP recommendation

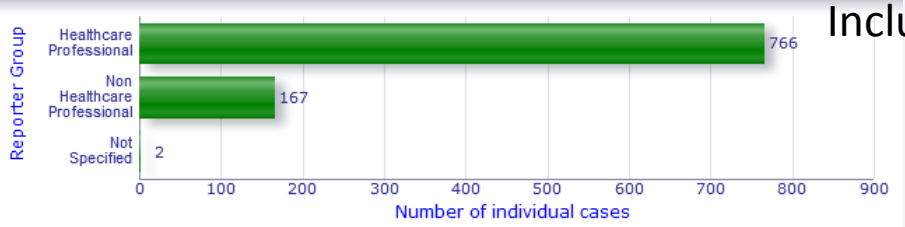
Choose a Reaction Group to see the number of individual cases identified in EudraVigilance for **ACOMPLIA** (up to Aug 2014)

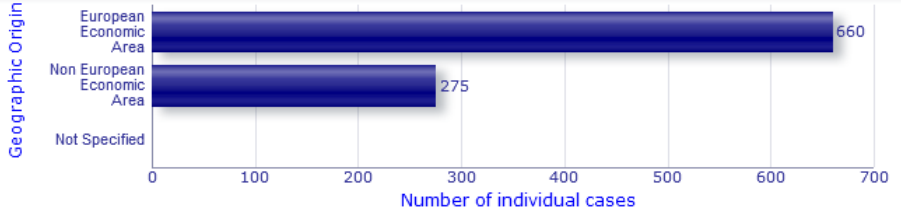
Reaction Groups

- [ ] Blood and lymphatic system disorders
- [ ] Cardiac disorders
- [ ] Congenital, familial and genetic disorders
- [ ] Ear and labyrinth disorders
- [ ] Endocrine disorders
- [ ] Eye disorders
- [ ] Gastrointestinal disorders
- [ ] General disorders and administration site conditions
- [ ] Hepatobiliary disorders
- [ ] Immune system disorders
- [ ] Infections and infestations
- [ ] Injury, poisoning and procedural complications
- [ ] Investigations
- [ ] Metabolism and nutrition disorders
- [ ] Musculoskeletal and connective tissue disorders
- [ ] Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- [x] Nervous system disorders
- [ ] Pregnancy, puerperium and perinatal conditions
- [x] Psychiatric disorders
- [ ] Renal and urinary disorders
- [ ] Reproductive system and breast disorders
- [ ] Respiratory, thoracic and mediastinal disorders
- [ ] Skin and subcutaneous tissue disorders
- [ ] Social circumstances
- [ ] Vascular disorders

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



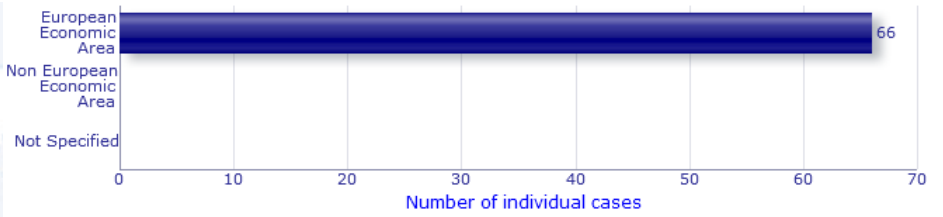




Including 6 CS Signal

PRAC

Patient safety



Choose a Reaction Group and then a Reported Suspected Reaction to see the number of individual cases identified in EudraVigilance for **HELIXATE NEXGEN** (up to Aug 2014)

Reaction Groups & Reported Suspected Reaction

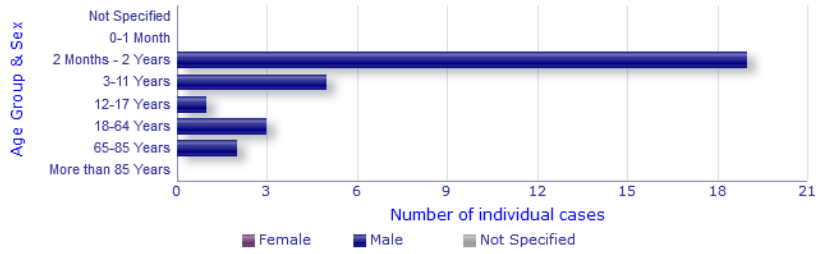
Reaction Groups

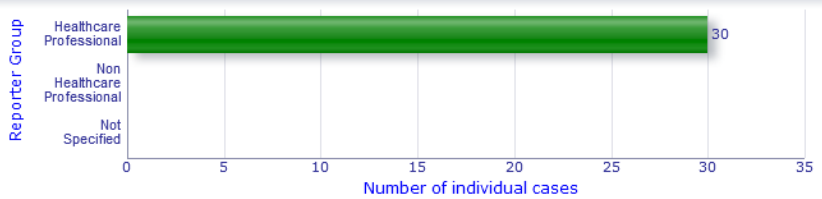
Blood and lymphatic system disorders

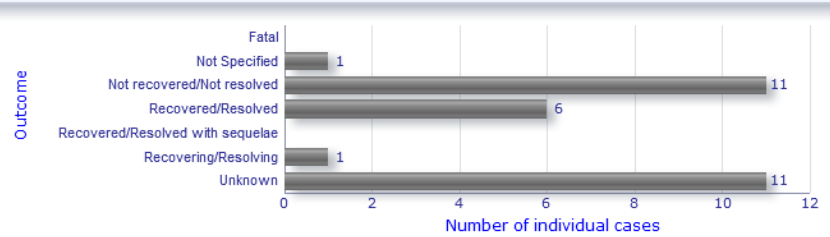
Reported Suspected Reaction

Factor VIII inhibition
Haemorrhagic diathesis
Leukocytosis
Monocytosis

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



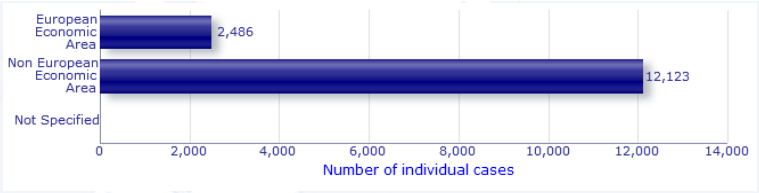




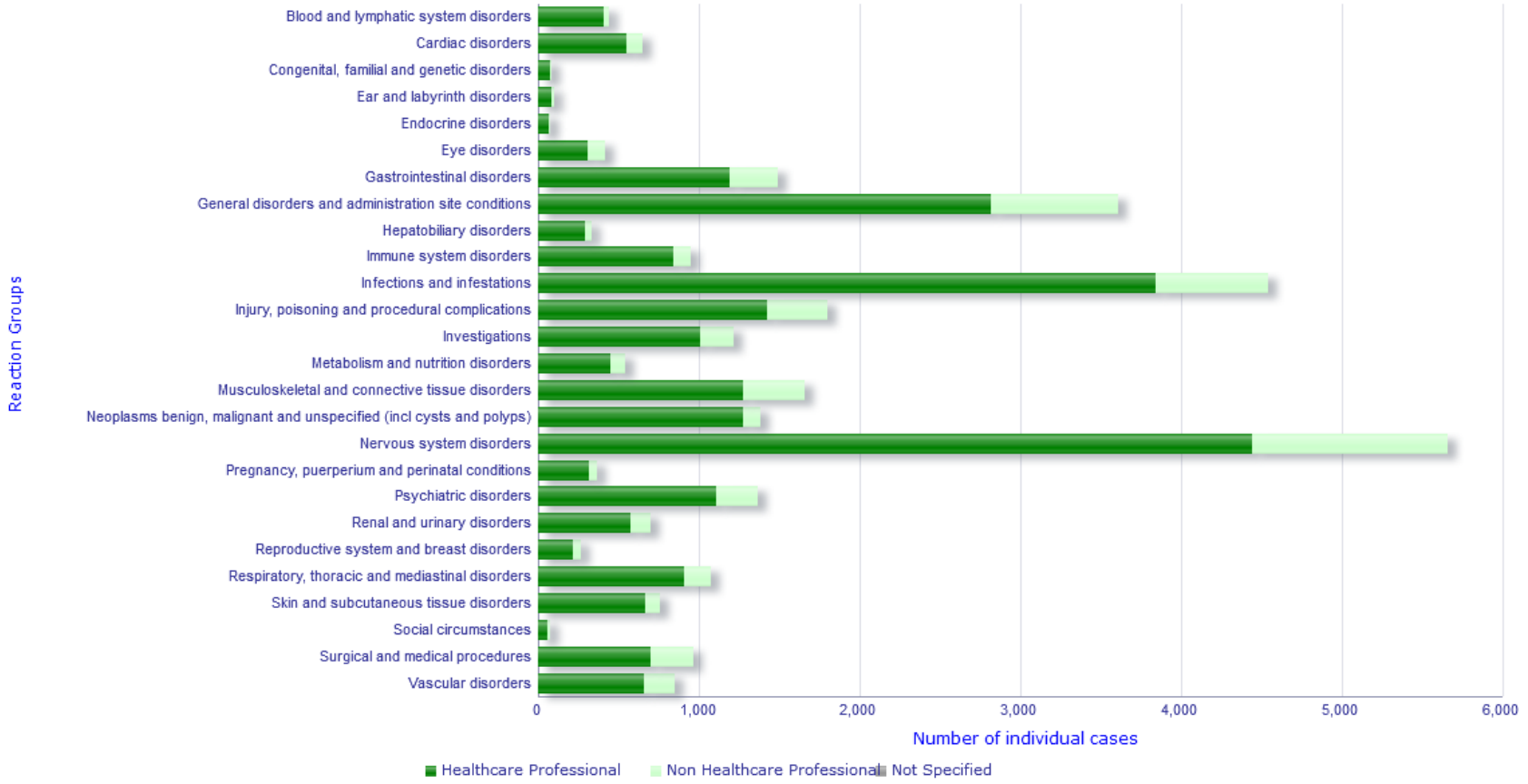
Rodin/PedNet study corroborated by ADR reports

EURORDIS Rare Diseases Europe

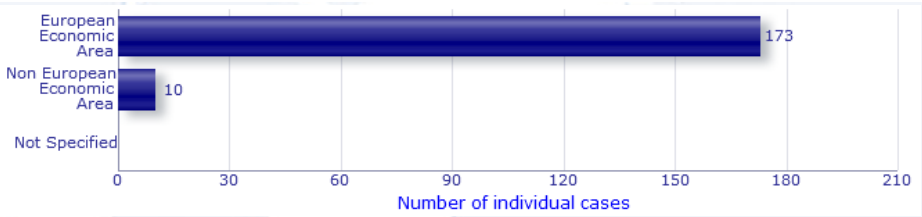
▼ 2006 MS



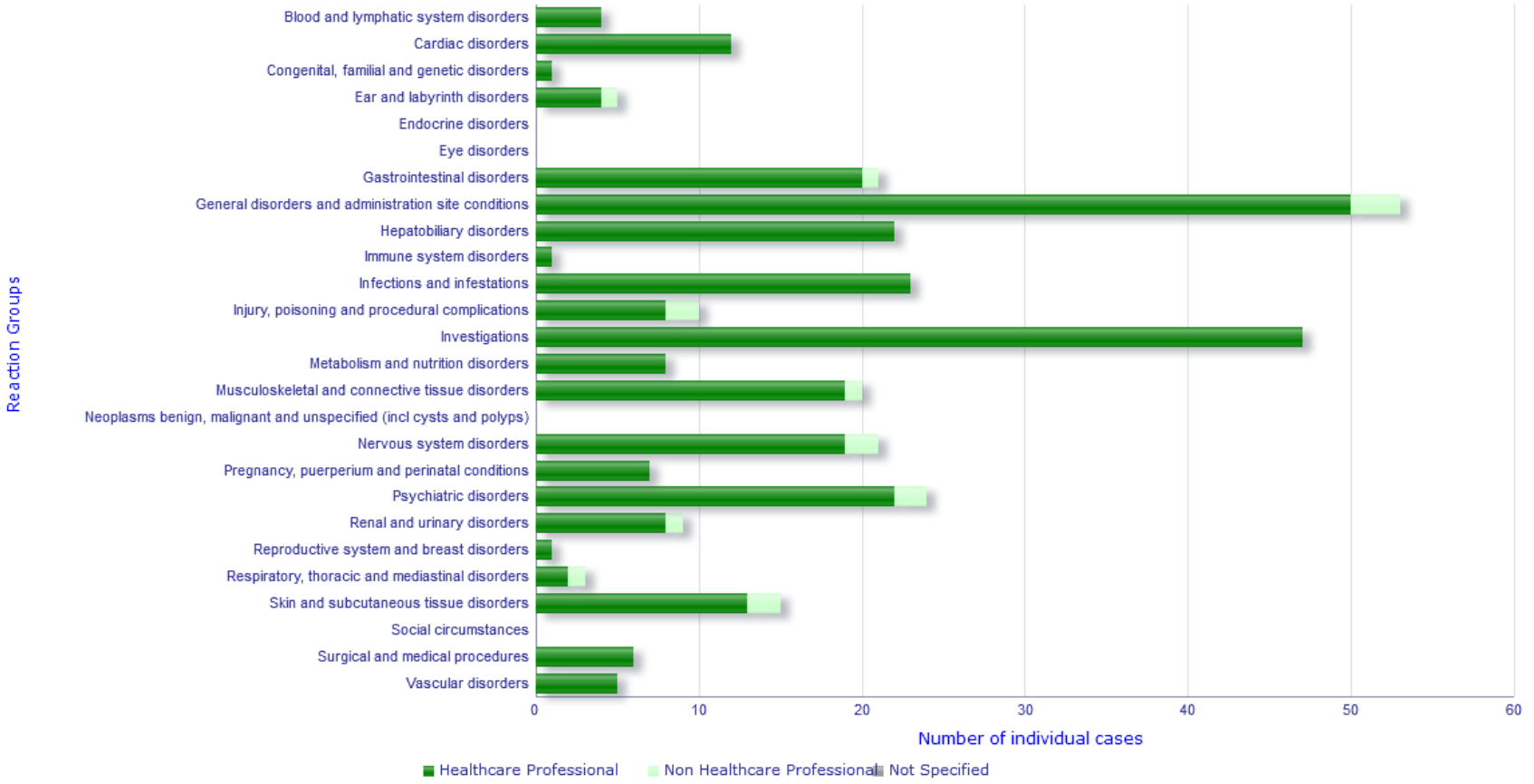
Choose how you want to see the number of individual cases identified in EudraVigilance for **TYSABRI** (up to Aug 2014)



2011 HIV

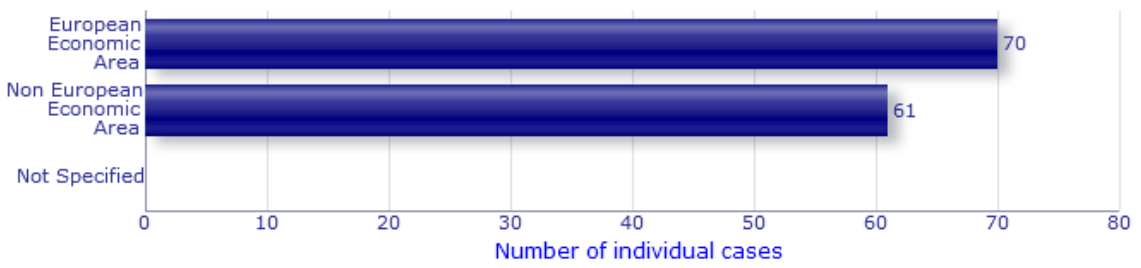


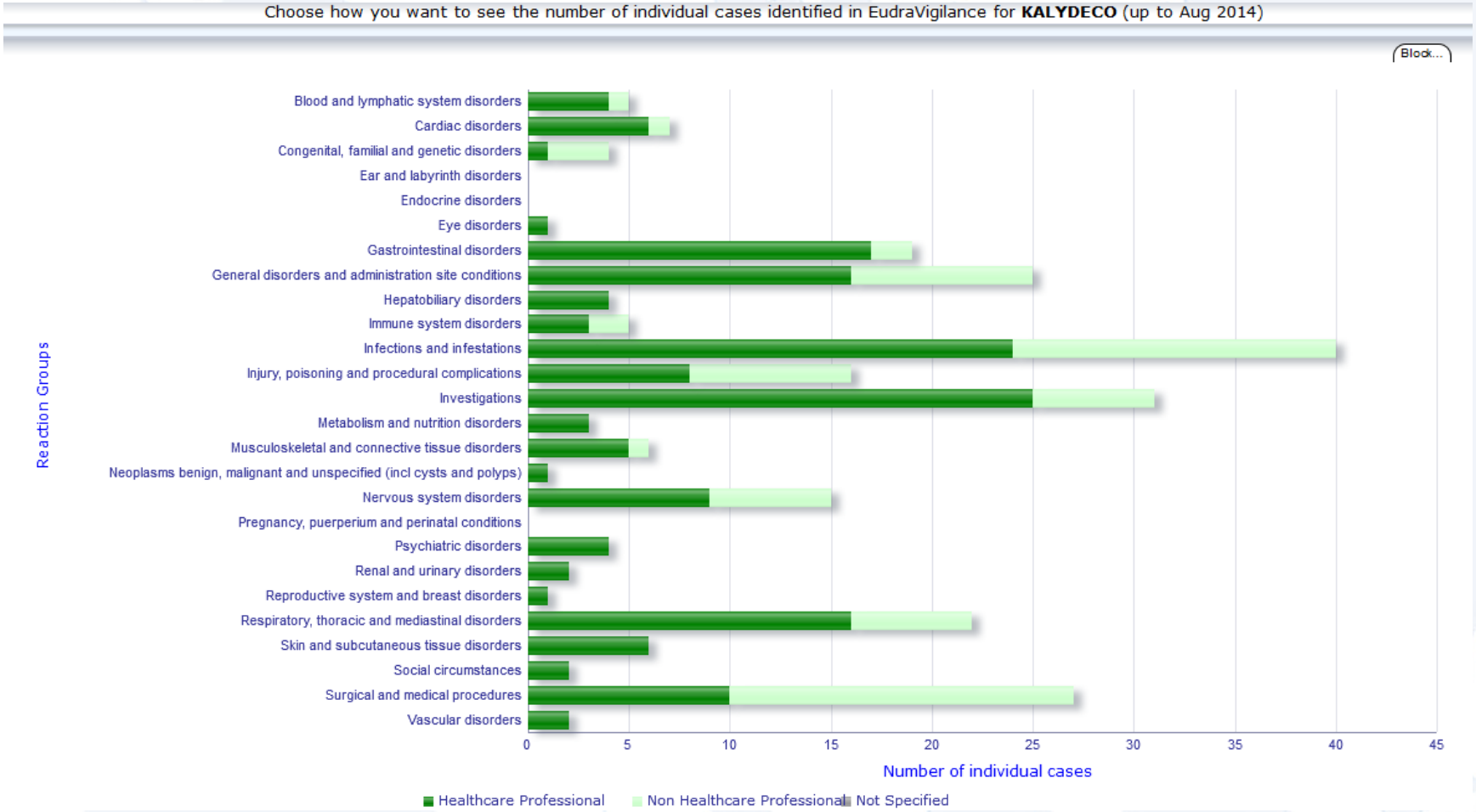
Choose how you want to see the number of individual cases identified in EudraVigilance for **EVIPLERA** (up to Aug 2014)



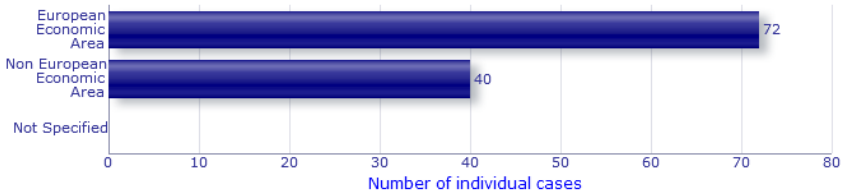
EURORDIS Rare Diseases Europe

2012 cystic fib.

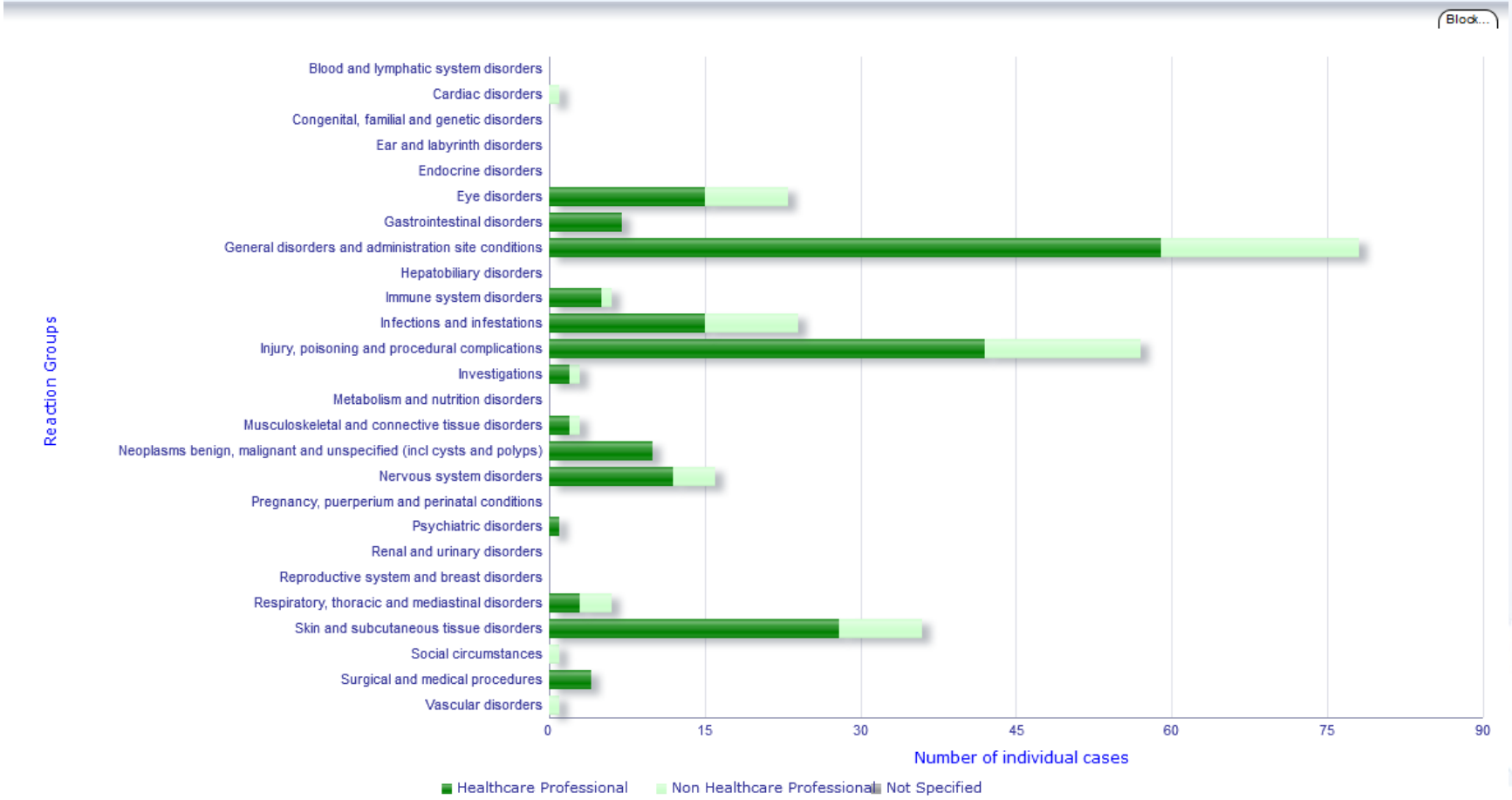




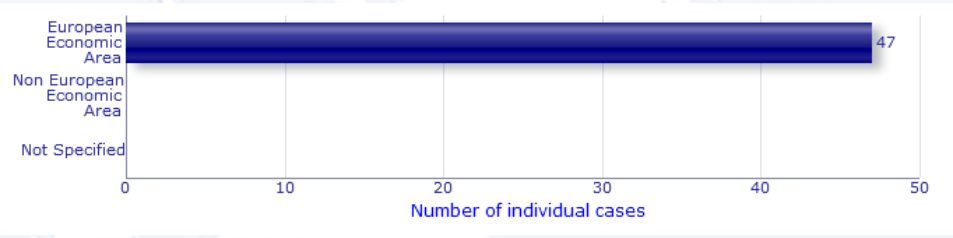
2012 Keratosis



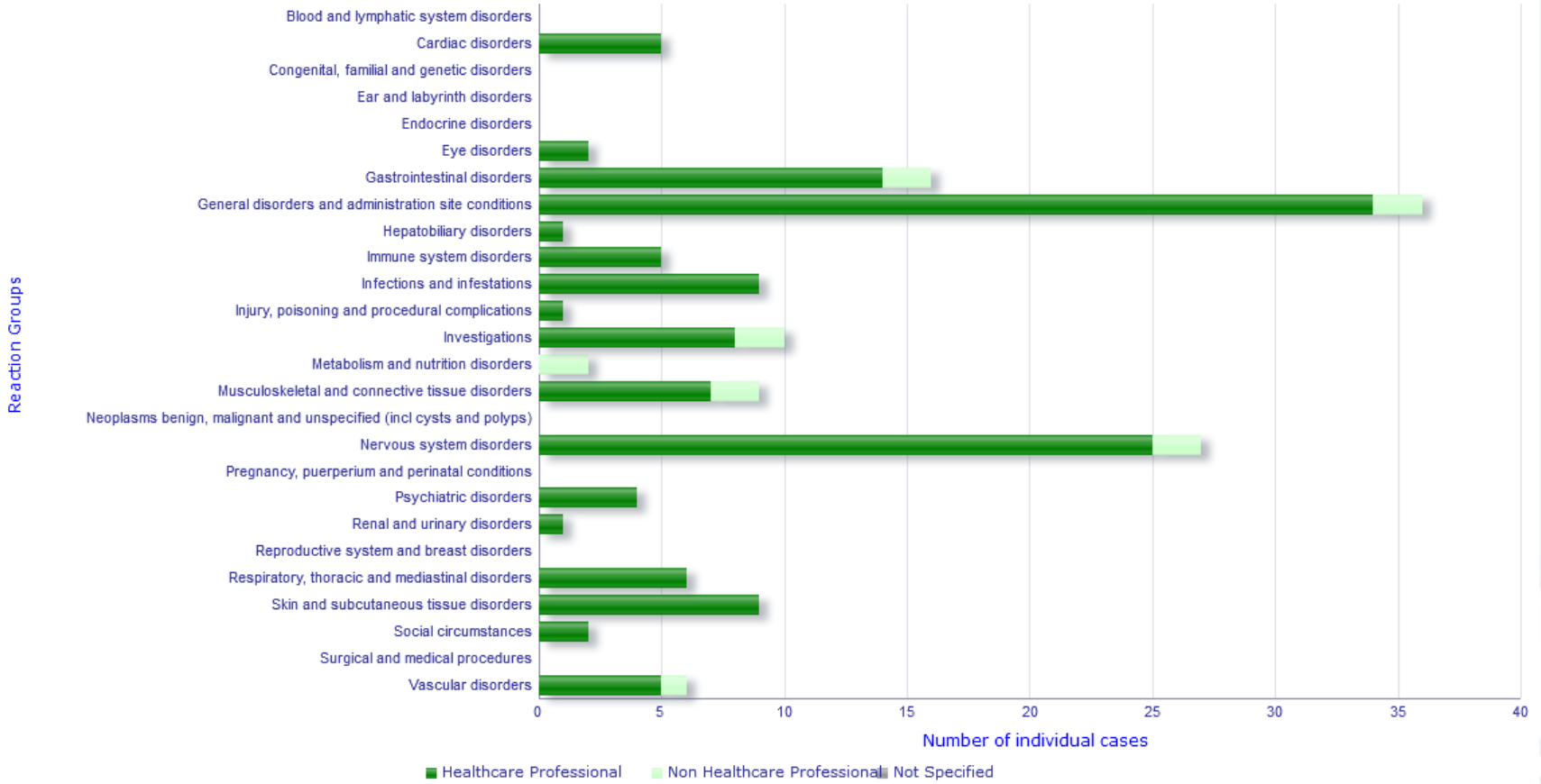
Choose how you want to see the number of individual cases identified in EudraVigilance for **PICATO** (up to Aug 2014)



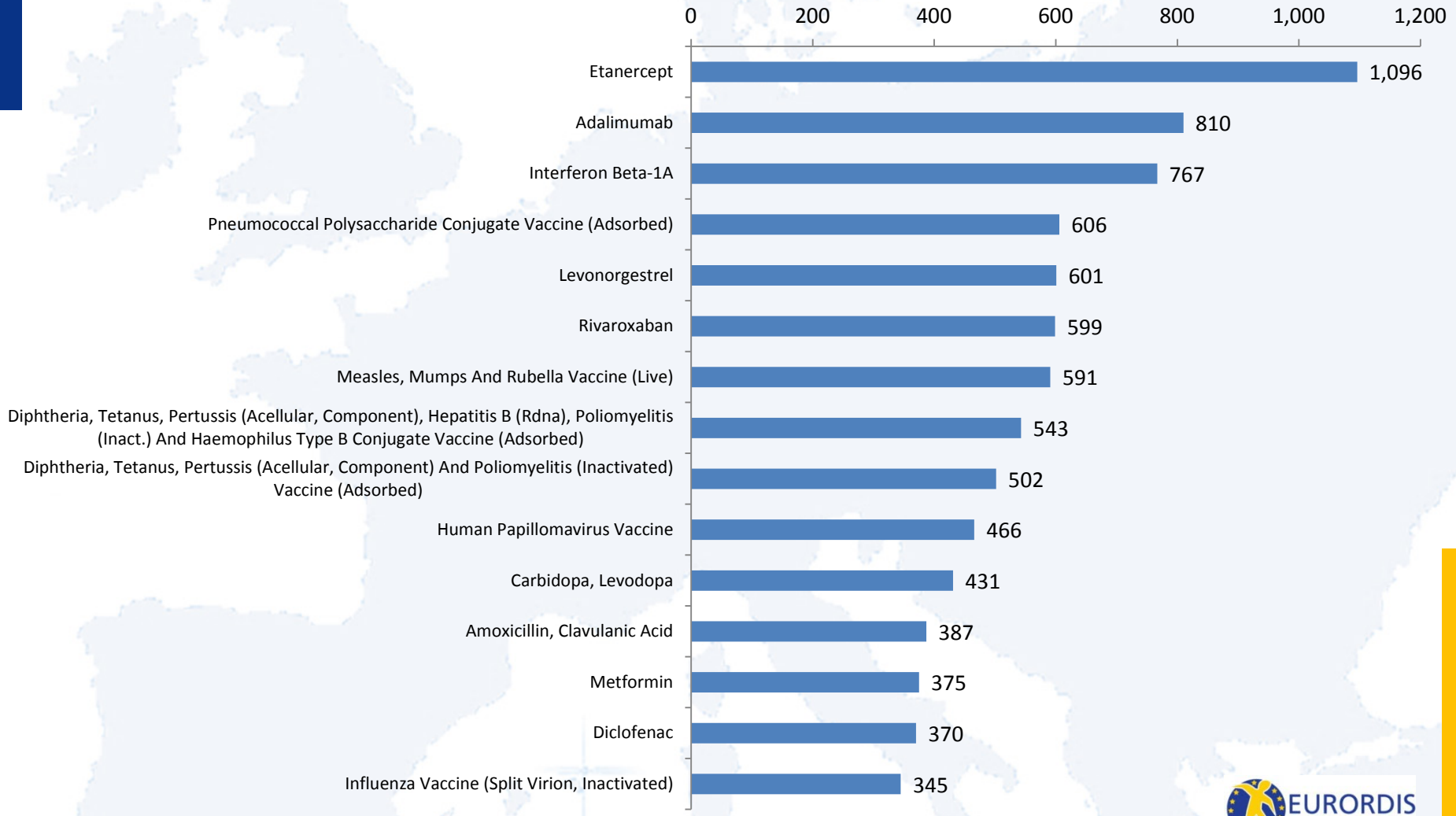
2012 Meningitis meningoc.



Choose how you want to see the number of individual cases identified in EudraVigilance for **NIMENRIX** (up to Aug 2014)



Spontaneous reporting by patients in EEA* Top 15 Substances



* Number of ICSRs received in EudraVigilance before de-duplication – Period: 02/07/13 - 01/07/14

Conclusions

- Eudravigilance = a live database, not a cemetery of data
- Patient reporting and active involvement of patients in pharmacovigilance: a reality
- www.adrreports.eu informs on where more efforts can be invested:
  - Understanding the drivers of patient reporting
    - Specific research by disease area, by MS, ▼ or not, orphan or not, drug authorised ante/post 2012, delays MA- first reports…
  - May help targeting the communication on reporting tools
  - May help in defining appropriate measures as defined in article 102 Pharmacovigilance Directive
  - Be curious: look for the drugs in your own disease area!