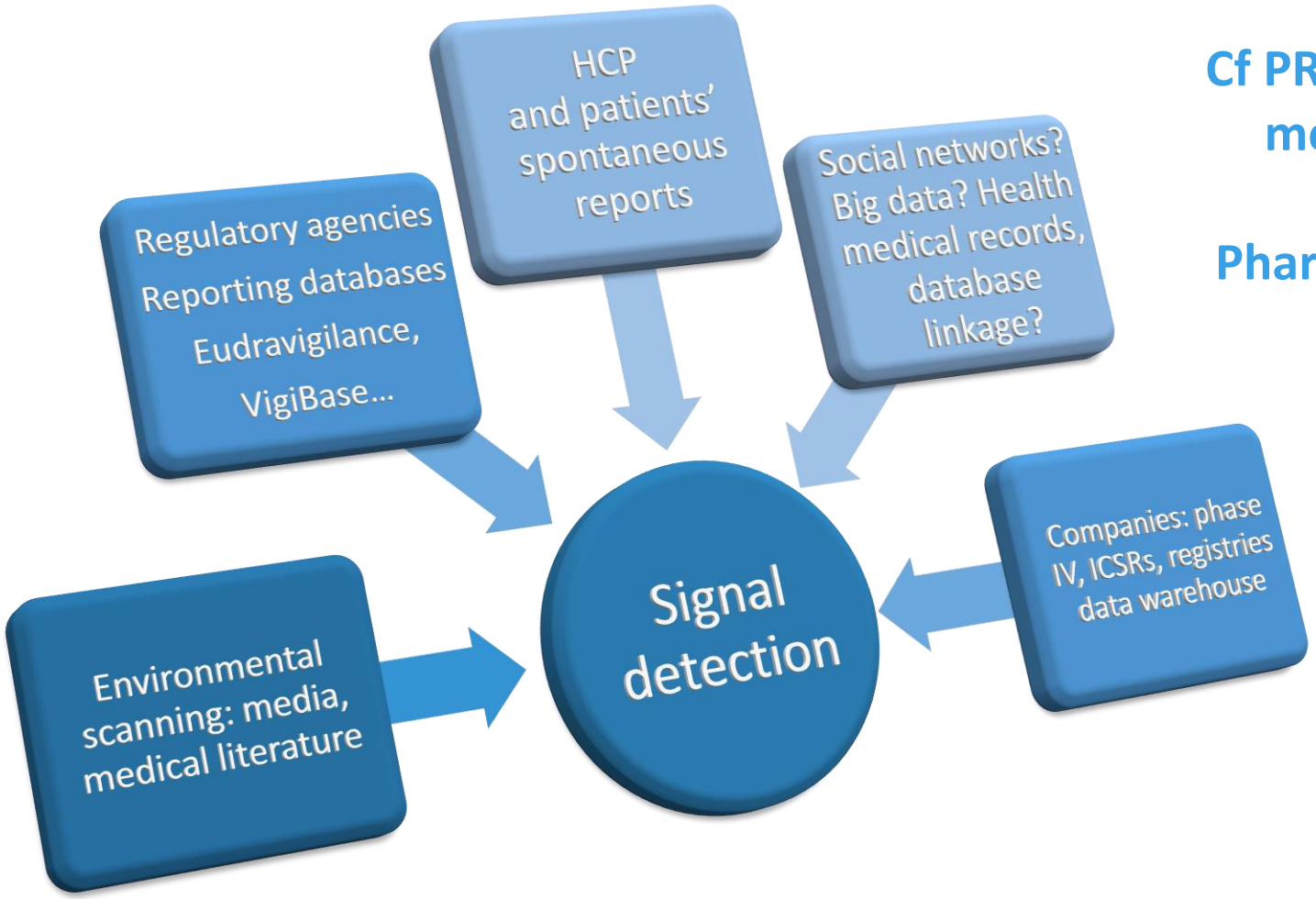
SCOPE Joint Action
Stakeholder Event

Collaboration to promote and support ADR reporting and feedback to patients

François Houÿez, European Organisation for Rare Diseases (EURORDIS)

20 - 21 March 2017
London

Where can signals come from? Which sources are more (cost)-effective? Do we need them all?



Cf PRAC strategy on measuring the impact of Pharmacovigilance activities

Are we there?

1981: no internet. USA: 300 million citizens

5 pneumonias in L.A. (pneumocystis carinii)→ CDC alert, AIDS epidemic started

2017: Web 2.0 and ICT. EU: 510 million citizens

Are 2-5 reports enough to trigger regulatory alert?

When experiencing side effects, patients have two main questions:

Is it caused by one of my medicines? Which one?

Will reporting the side effect respond these questions? No. So?

Is there anything I can do to alleviate the reaction?

Gambling? Sex addiction? Caused by a medicine?

SCOPE

Abilify® for bipolar disorder, schizophrenia, depression

- Top-selling drug in the U.S. in 2013 with sales of over $6.4 billion

Anecdotic reports triggered regulatory action

- 2013: Gaboriau et al. examined several people who checked into a clinic because of their compulsive gambling behaviors
- Study looked at 8 who took Abilify® as part of ongoing treatment
  - Abilify® caused 7/8 patients to lose control of their gambling habits
  - Abilify® over-stimulates dopamine reward brain receptors (dopamine 3 (D3) receptors) and triggers compulsive behavior
- Package leaflet and SmPC subsequently updated

Your report can be the one that triggers action!

And patients do report (www.adrreports.eu)

Choose a Reaction Group and then a Reported Suspected Reaction to see the number of individual cases identified in EudraVigilance for **ABILIFY** (up to Feb 2017)

Reaction Groups & Reported Suspected Reaction

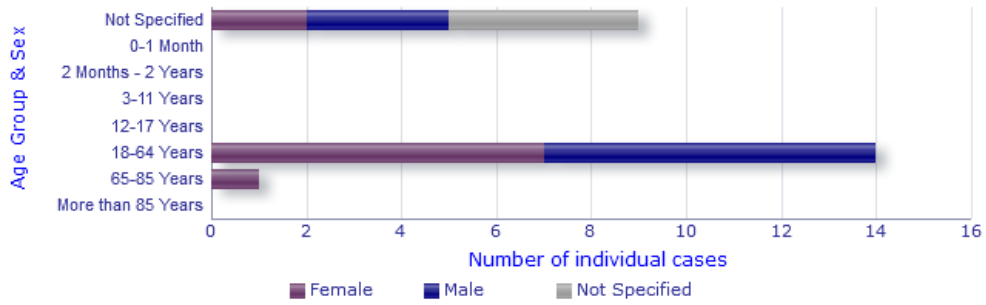
Reaction Groups

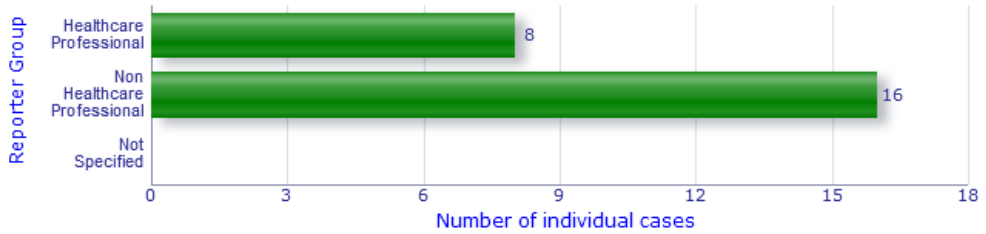
Social circumstances

Reported Suspected Reaction

Aborted pregnancy
Activities of daily living impaired
Alcohol use
Bedridden
Breast feeding
Corrective lens user
Crime
Disability
Drug abuser
Drug diversion
Economic problem
Educational problem
Gambling
Hearing disability
High risk sexual behaviour
Homicide
Immobile
Impaired driving ability
Impaired quality of life
Impaired work ability
Imprisonment
Inability to afford medication
Menopause
Mental disability
Patient uncooperative
Physical assault
Physical disability
Poor personal hygiene
Pregnancy of partner
Refusal of treatment by patient
Sexual abuse
Sexual activity increased

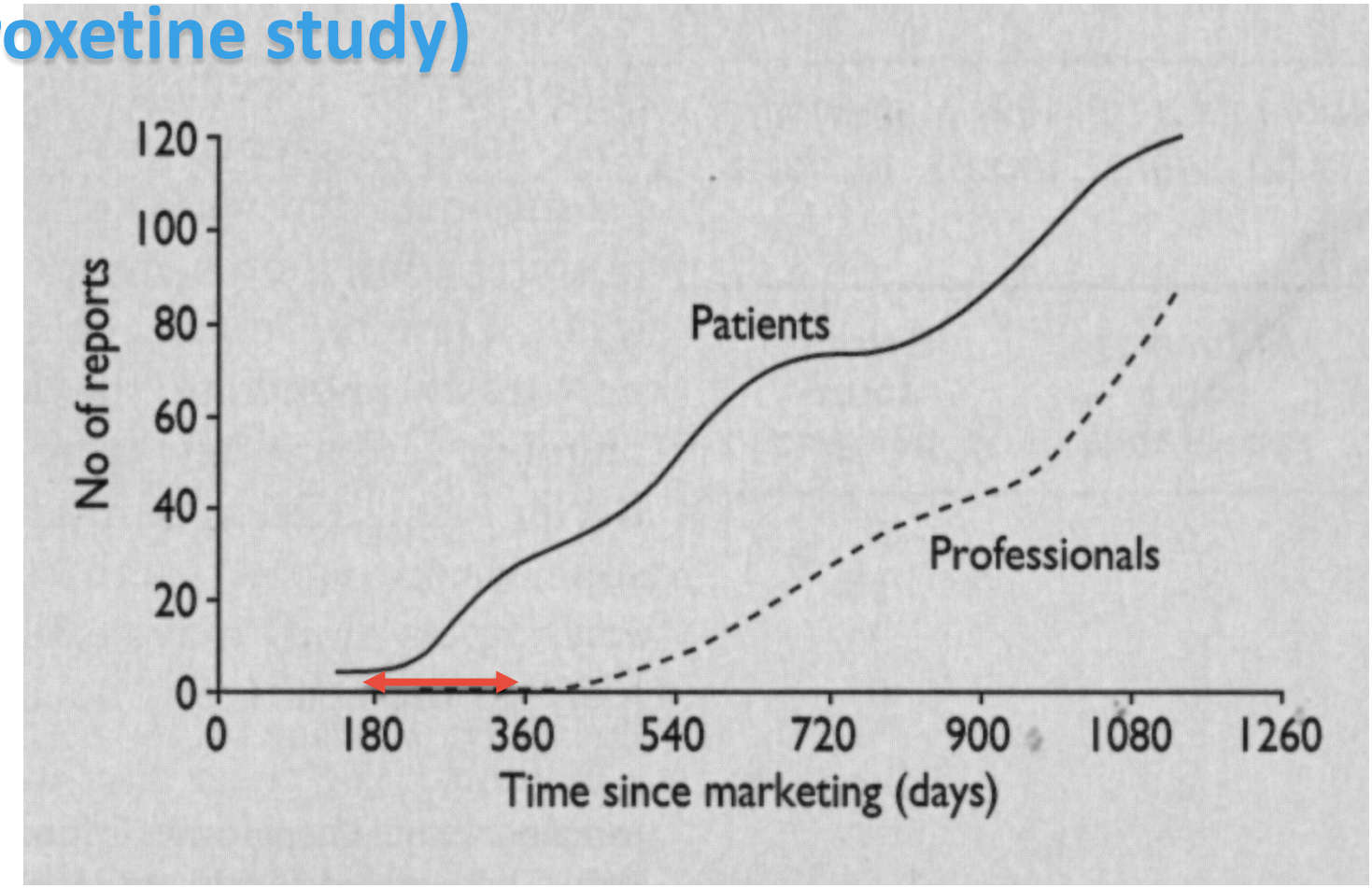
Number of individual cases by Age Group & Sex, Reporter Group and Outcome





Total: 24 reports of gambling in 2017
(78 in Vigibase, http://www.vigiaccess.org/)

Self reporting by patients: faster reporting behaviours compared to HCP? (Paroxetine study)



BMJ 1996;313:530-531

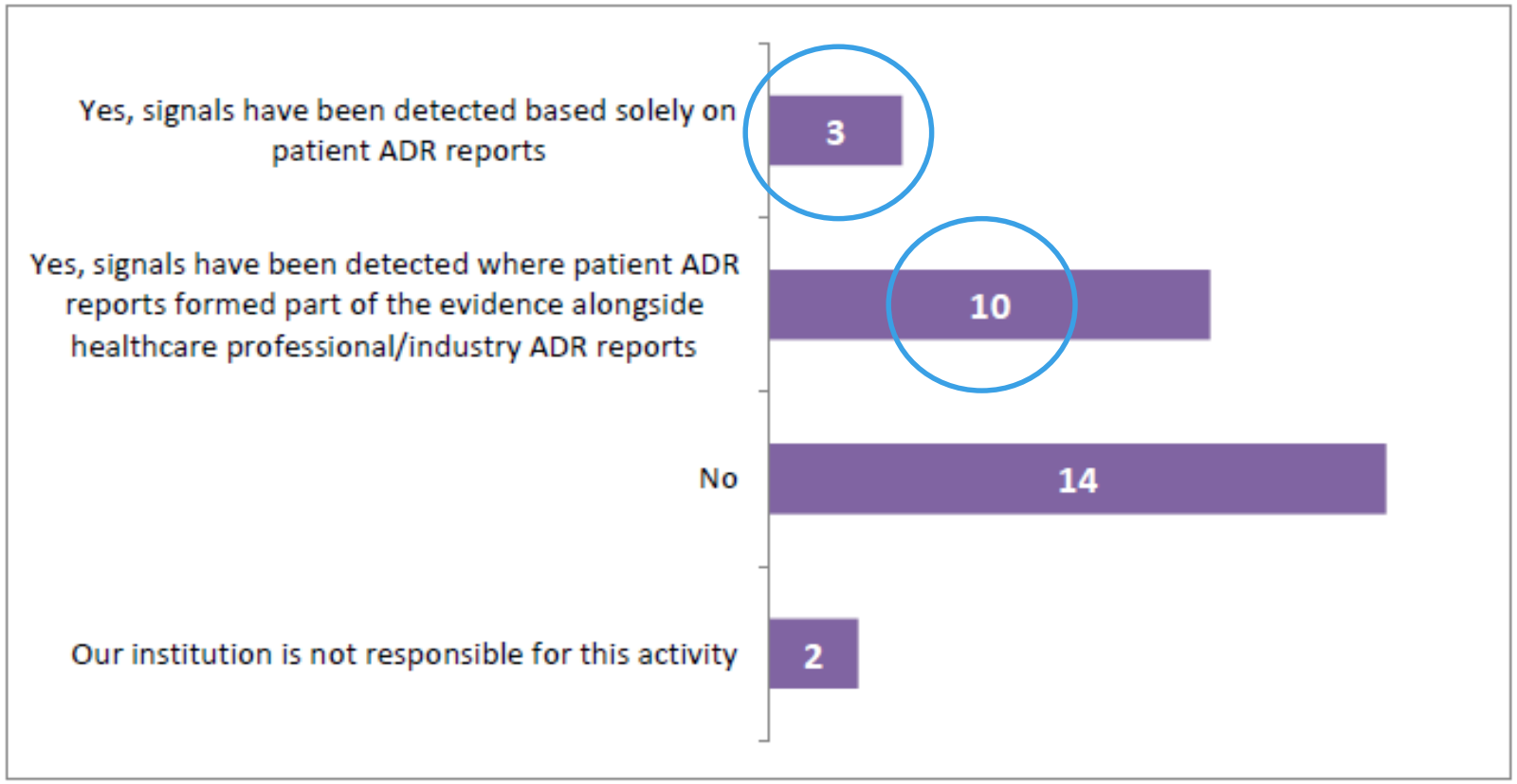
Known for long, but not always so.
What can explain these differences?

Regarding utility of patient reporting, what did we learn from the

SCOPE WORK PACKAGE 4 SURVEY REPORT

Yes, patients' reports can include signals, confirmed or not.

But this experience is not yet shared by all MS: a PR campaign would be welcome!



From SCOPE Work Package 4 Survey Report

Quality of patient reports

- Often very good and overall judged as beyond expectations
- 75% of the reports were deemed valuable for further assessment (French pilot)
- Netherlands: patients provided more details than HCP on outcome e.g. non-recovery (Lareb)
  - significant difference between patient reports and reports from HCP in the proportion of reports that included mention of the outcome of the ADR (87% vs 68%; $p < 0.01$)

Report from the CHMP Pharmacovigilance Working Party (PhVWP) on Direct Reporting of Adverse Reactions by Patients, EMA

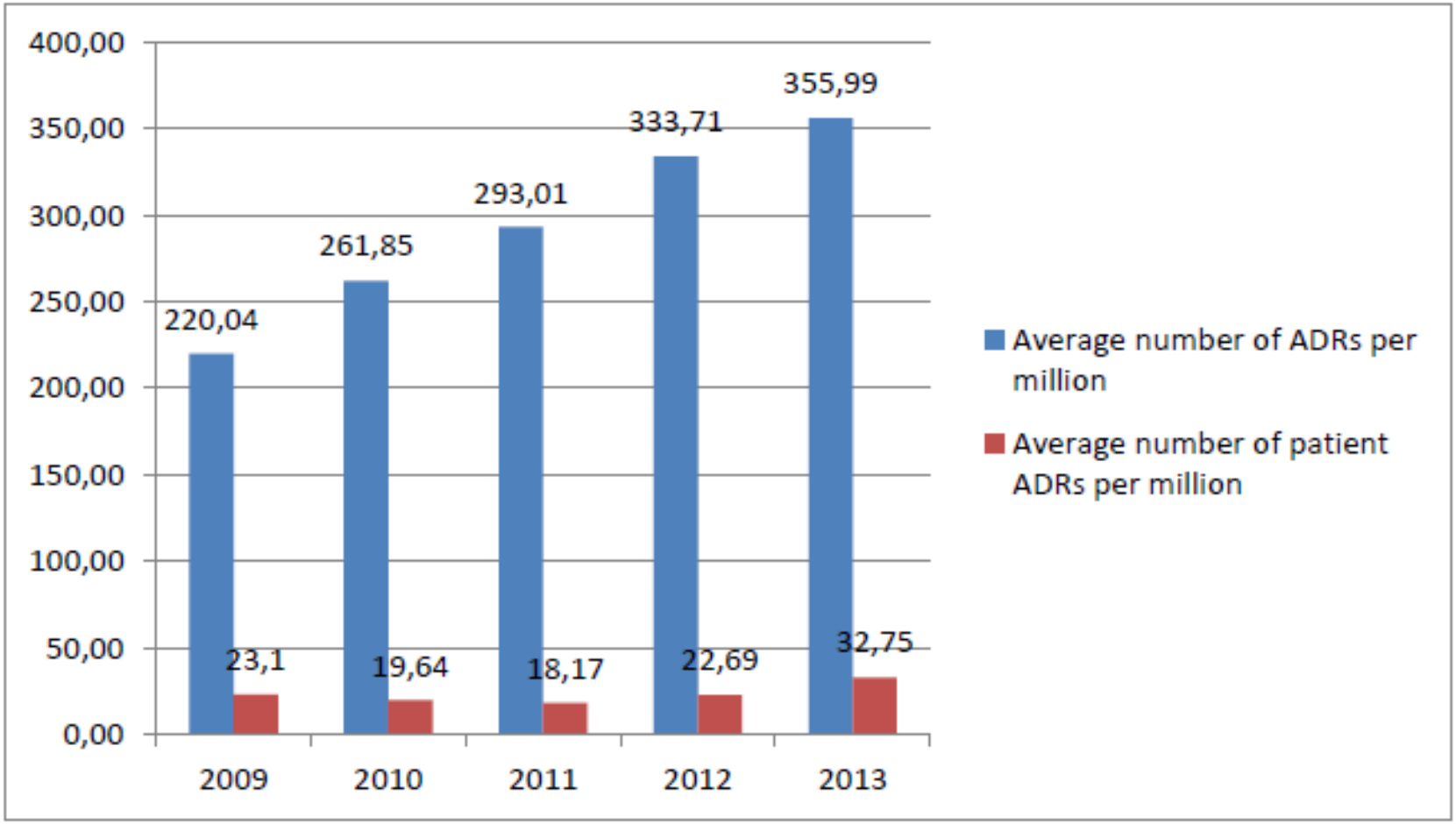
Not all subjects are easily discussed with healthcare professionals

- Effects on sexual activity, loss of libido…
- Unexpected but not severe ADRs:
  - E.g. change of flavour of some aliments
  - when this happens, you want to know if it's something you should worry about
- Life style:
  - Use of NATC products, alcohol, diet, herbal product, over-the-counter products, illicit/recreational products...
- Products used to treat the ADR
  - E.g. absorbent carbon for bloating

Patient ADR reporting

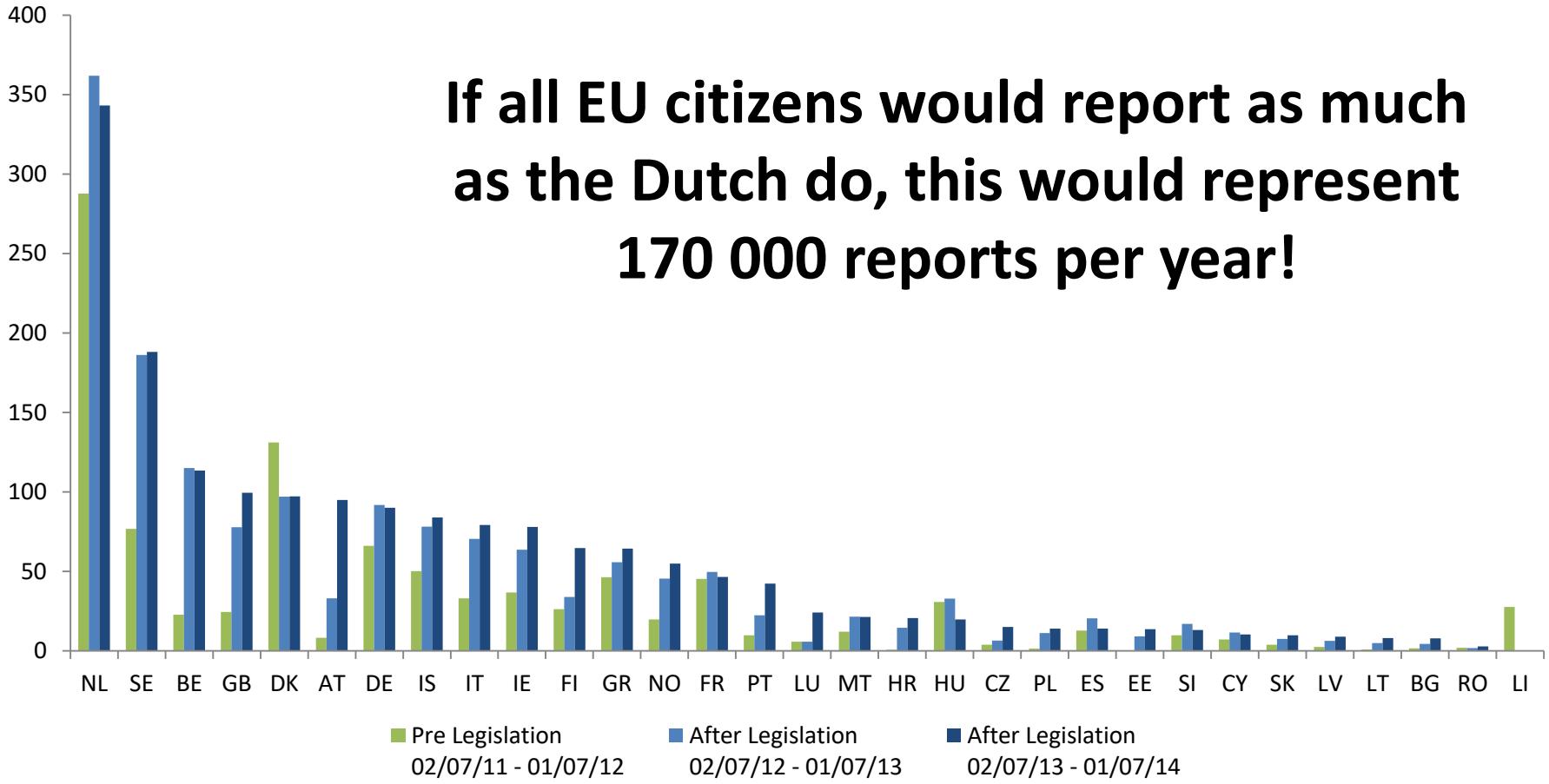
HOW TO MAKE IT EVEN MORE USEFUL?

Expressed as numbers of reports per million pop



From SCOPE Work Package 4 Survey Report

Spontaneous reporting by patients in EEA* by country (reports by Mio pop.)



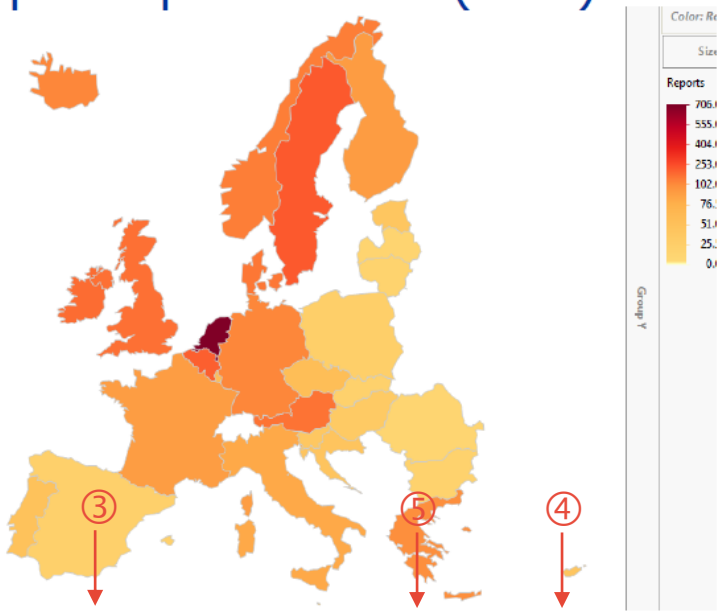
If all EU citizens would report as much as the Dutch do, this would represent 170 000 reports per year!

* Number of ICSRs received in EudraVigilance before de-duplication

EUROPEAN MEDICINES AGENCY

Patient reporting in the EU: analysis of EV data

Patient reports per million (EEA)



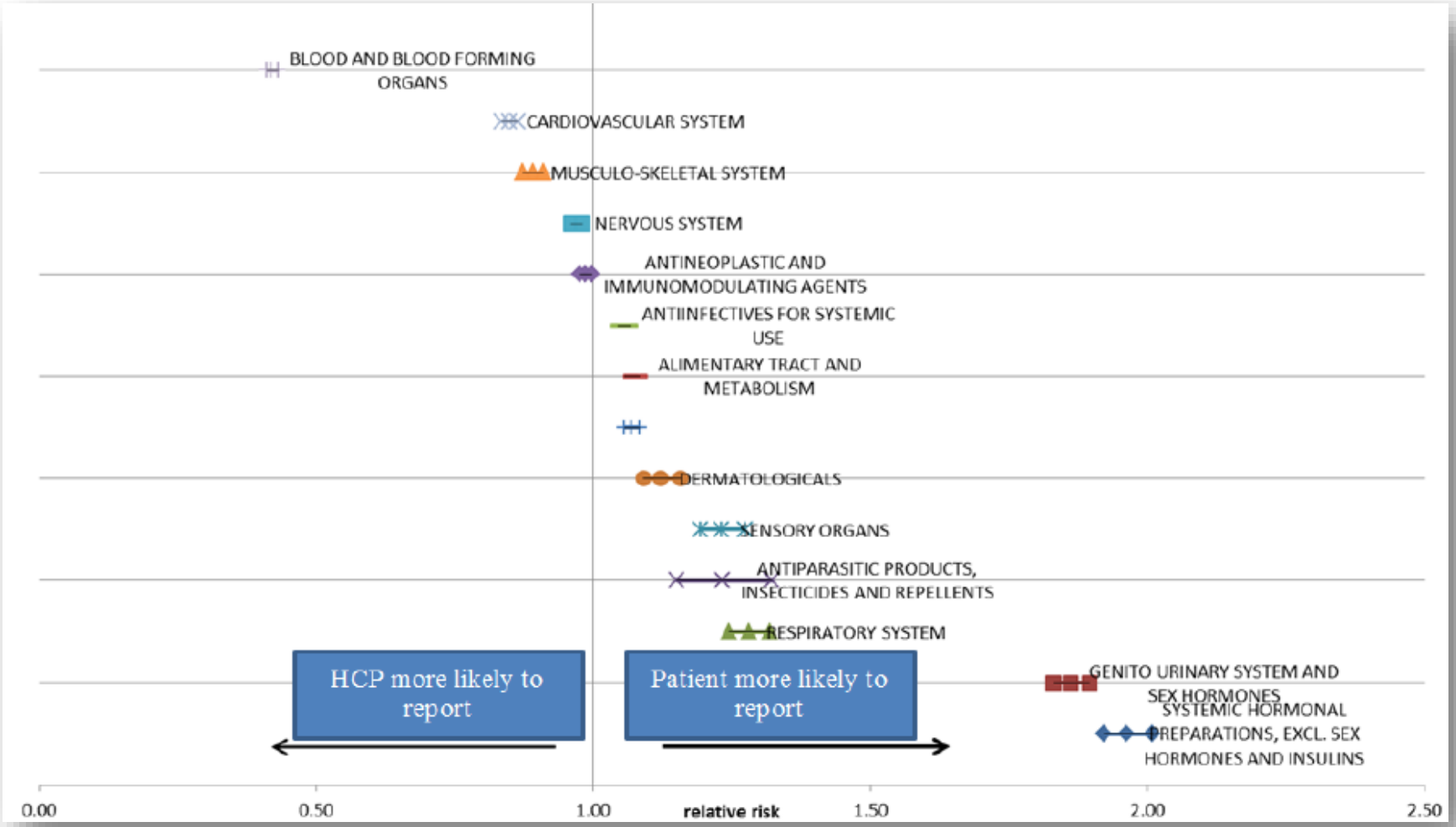
Patient reports per million inhabitants in EEA between July 2014 and June 2015 expressed as Only Patient+ category

- The Netherlands stand out with 706 patient reports/million

Member State	AT	BE	BU	CY	CZ	DE	DK	EE	ES	FI	FR	GB	GR	HR	HU	IE	IS	IT	LI	LT	LU	LV	MT	NE	NO	PL	PT	RO	SE	SI	SK
Patient reports per million inhabitants	171	217	19	45	58	121	160	42	24	93	92	176	101	46	36	187	122	84	0	18	59	14	40	706	144	26	51	12	231	41	21

Patients' reporting in the EU: analysis of EudraVigilance data
Peter Arlett, Marin Banovac, David Haerry, François Houÿez, Drug Saf. 2017 Apr 17

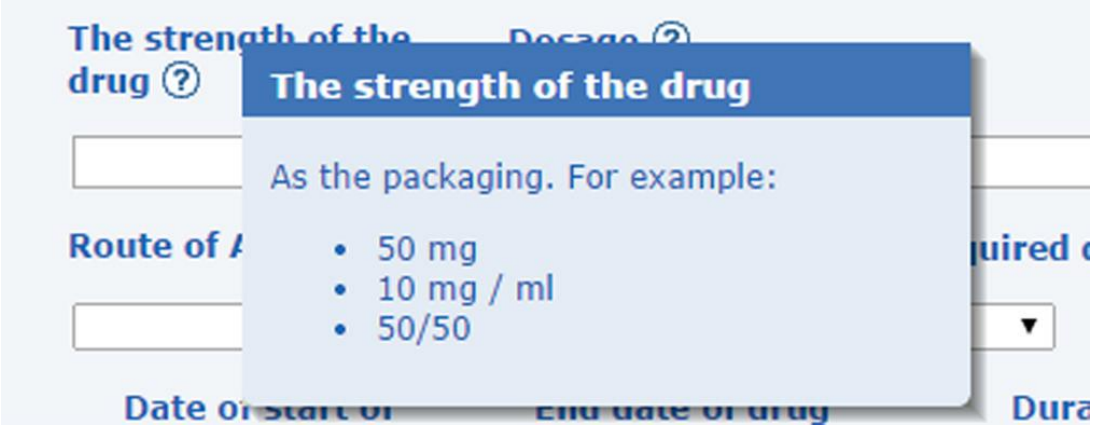
Relative risk of reporting, by therapeutic class. Patients versus professionals

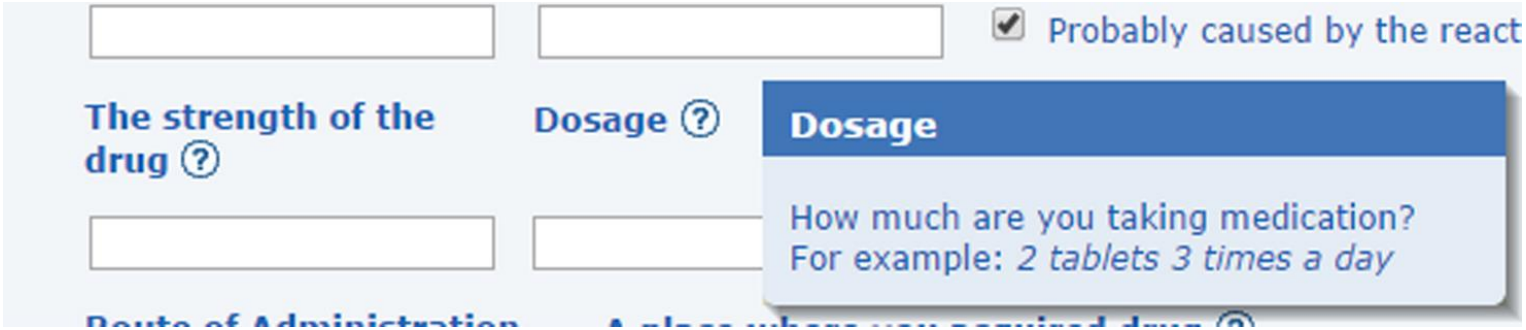


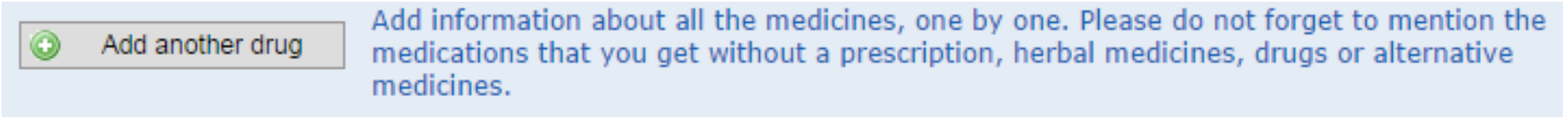
Reporting

DO WE HAVE THE REPORTING TOOLS WE NEED?

Croatia with VigiFlow.
SCOPE: e-form







Collaboration between regulators and patients' organisations to promote reporting. Can we think of other actions?

12 MS work with patient' organisations to promote or support ADR reporting: methods	Number of MS
Reporting via URL link posted on patient organisations' web sites	8
Reporting via URL link posted on patient forums	3
Patient organisations collecting ADR reports from patients	4
Other	6

Diseases	Number of MS
Cancer	4
Diabetes mellitus	3
Multiple Sclerosis	3
Blood diseases	3

To improve the quality of reporting

- Engage with your authorities to review the reporting forms and how easy to find they are
- Promote the tools developed by European cooperation (SCOPE e-web form, Web-RADR)
- Train your members to report, act as a pharmacovigilance liaison
- Review excellent reports with your authorities, or MAH
- Any other idea?

After we report

WHAT HAPPENS?

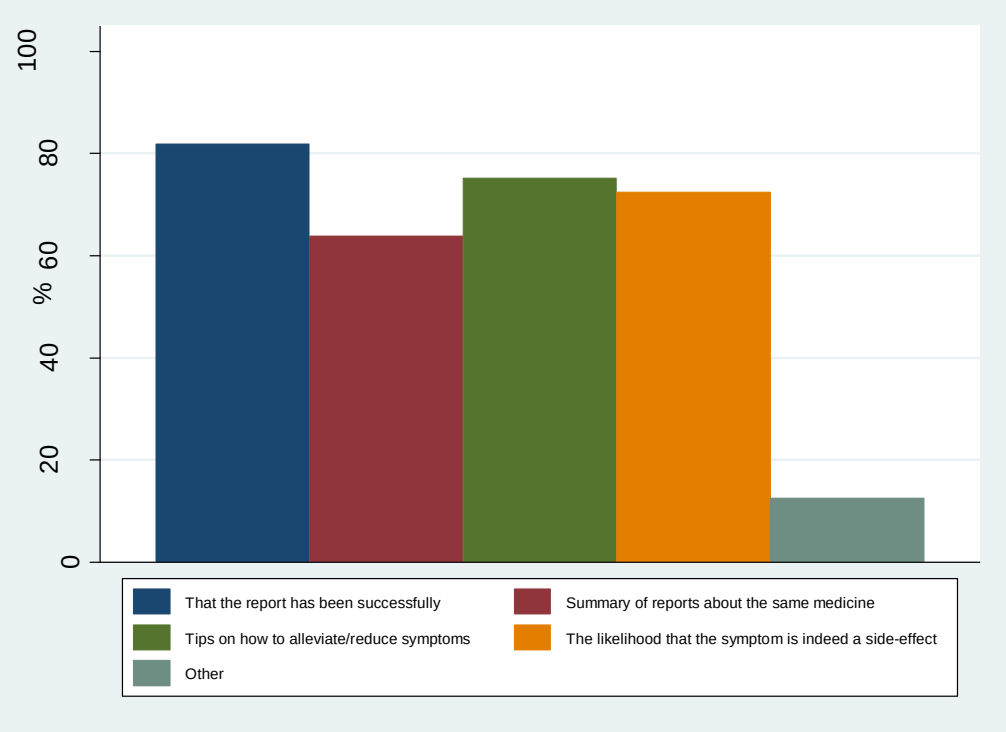
Type of feedback after reporting ADR - Patients

Web-RADR project Peter Mol and colleagues

What type of feedback would you like to receive after submitting an ADR?

- 24 MSs provide feedback to patients
  - 18 send acknowledgments
  - 15 provide individual case feedback
  - 4 respond with individual case feedback

From SCOPE Work Package 4 Survey Report



WEB-RADR

SCOPE Deliverable

Collaboration with Patient Organisations to Promote and Support Patient ADR Reporting

SCOPE

- General considerations
- Targeting/identifying patient organisations
- Eligibility of patient organisations
- Types of patient organisations
- Establishing a collaboration
- Scope of collaboration/
- Types of performed activities
- Impact of collaboration
- Presentation of results and transparency

http://www.scopejointaction.eu/_assets/files/WP4-DEL5-Collaboration-with-Patient-Organisations.pdf

Questions?

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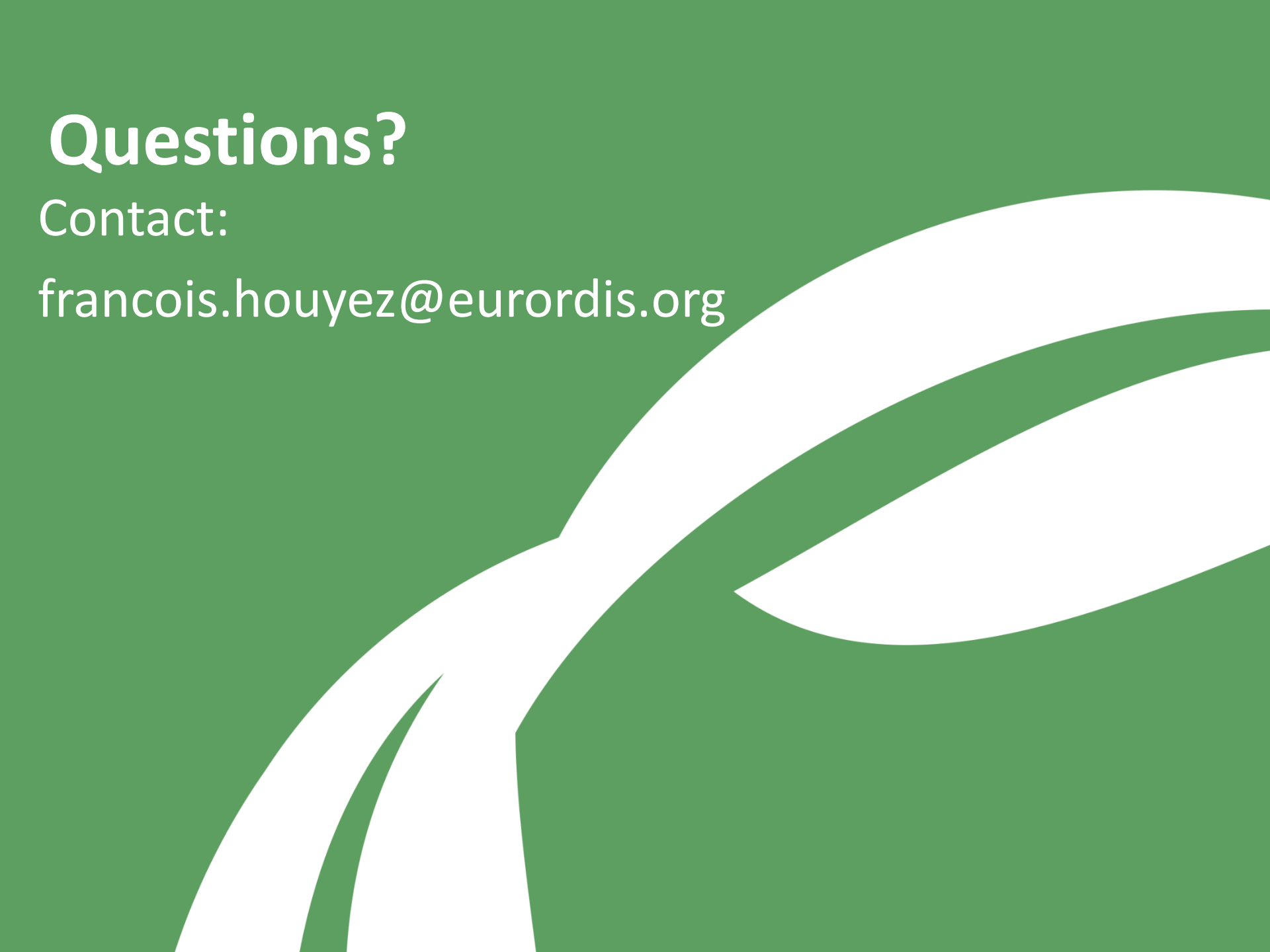
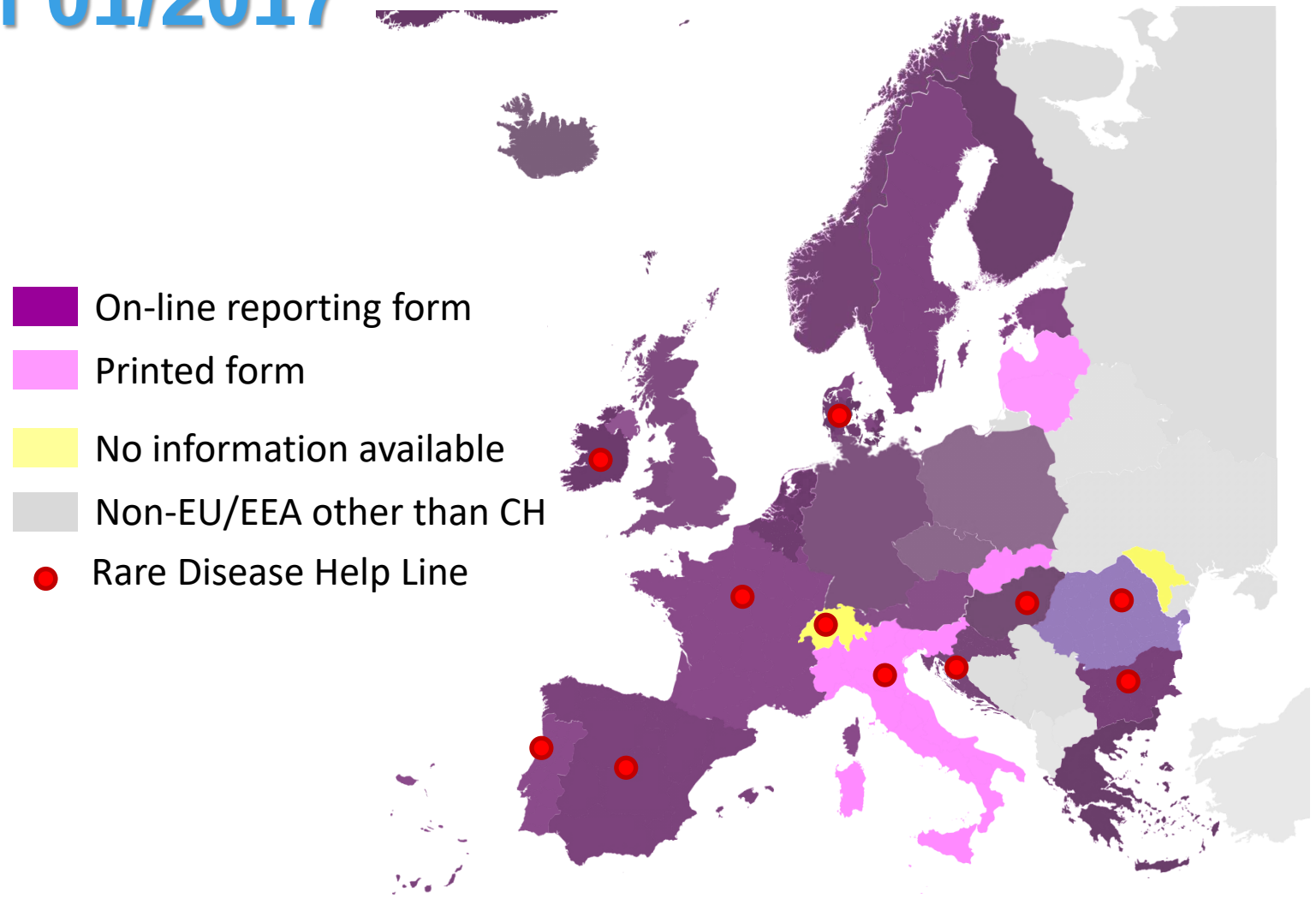


Engaging patients in pharmacovigilance!

SCOPE

ADR reporting tools as of 01/2017



www.eurordis.org/pharmacovigilance