EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Patient reporting in EudraVigilance – a measure of patient engagement?

Workshop on measuring the impact of pharmacovigilance activities
05-06 Dec 2016

Presented by Marin Banovac 06 December 2016

Patient reporting in the EU: Analysis of EudraVigilance data. Banovac M, Candore G, Slattery J, Arlett P, Houÿez F, Haerry D, Genov G.

Patient reporting in the EU: analysis of EV data

Aims of the study

- In collaboration with patient representatives (special thanks to **David Haerry** and **François Houÿez**) to complement previous research and further profile the patient reporting *before* and *after* the implementation of new PhV legislation at EU level as well as to compare patients' with HCP's reports
- Use the potentially identified gaps in reporting to
  - inform the provision of information and training to patients;
  - support better collaboration with patient associations;
  - support better communication campaigns on the awareness of reporting suspected ADRs;
  - inform improved approaches to the analysis of reports for future safety signal detection and evaluation;

Patient reporting in the EU: analysis of EV data

Reporter categories (Primary Sources) and naming convention

1. Only Patient = reports where only **patient** was listed as the reporter
2. Only HCP = reports where only **HCP** was listed as the reporter
3. All Patient = reports where **patient** was listed as the reporter (**including** where **HCP** is a co-reporter)
4. Legal = reports where **lawyer** was listed as the reporter

Patient reporting in the EU: analysis of EV data

Spontaneous reports per year (July 2009- July 2015)

	02Jul09 - 01Jul10	02Jul10 - 01Jul11	02Jul11 - 01Jul12	02Jul12 - 01Jul13	02Jul13 - 01Jul14	02Jul14 - 01Jul15
Only Patient	14,425	17,125	21,580	32,722	35,474	45,175
Only HCP	190,132	185,529	194,905	220,623	243,235	241,393
All Patient	35,121	33,420	35,140	50,560	49,561	59,220
Legal	323	552	1,919	953	1,448	1,433
Not reported	11,702	563	1	3	1	0
Total EEA Spontaneous	237,278	220,064	231,965	272,139	294,245	302,046

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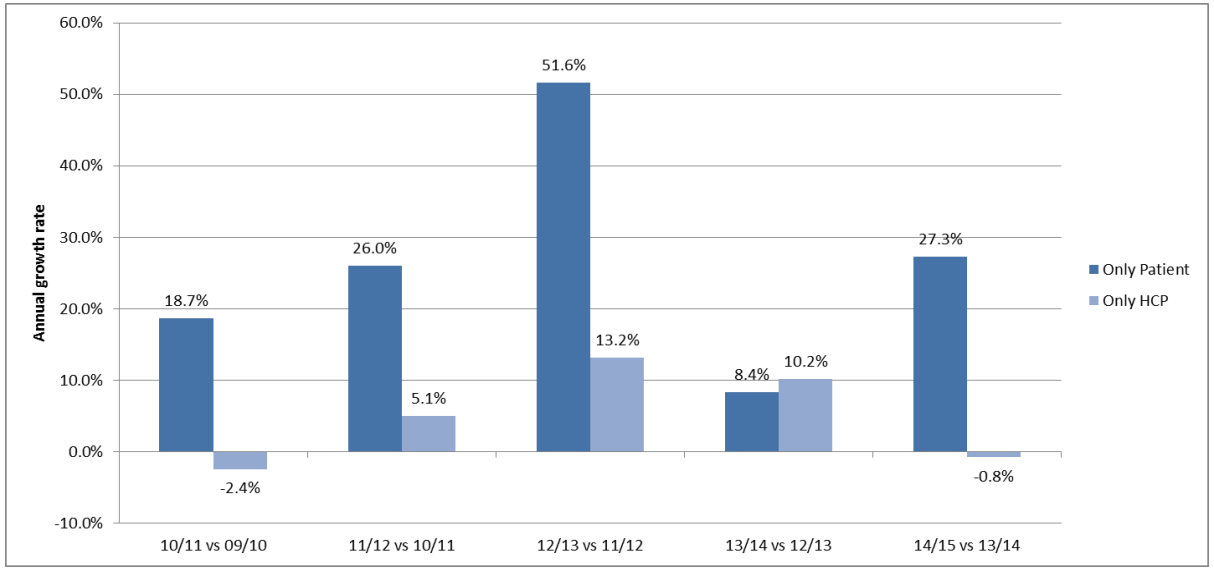
Annual growth rates



Before vs after the implementation of the new legislation:

- 53,130 vs 113,371 patient reports (Only Patient group)
- proportion of patient reports in EV increased from 9% to 15% (Only Patient group)

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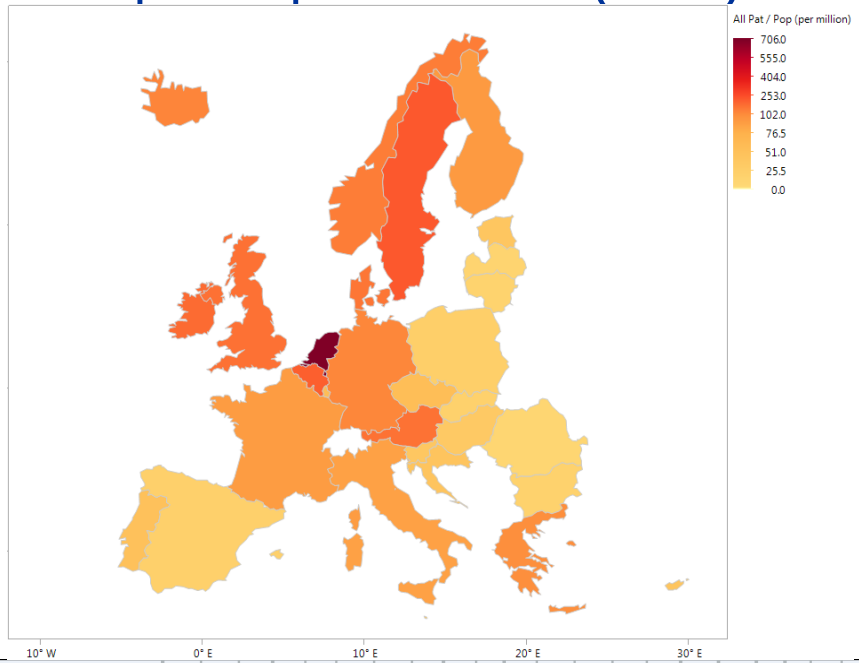
Patient reports per million (EEA)



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

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

- The Netherlands stand out with 706 patient reports/million

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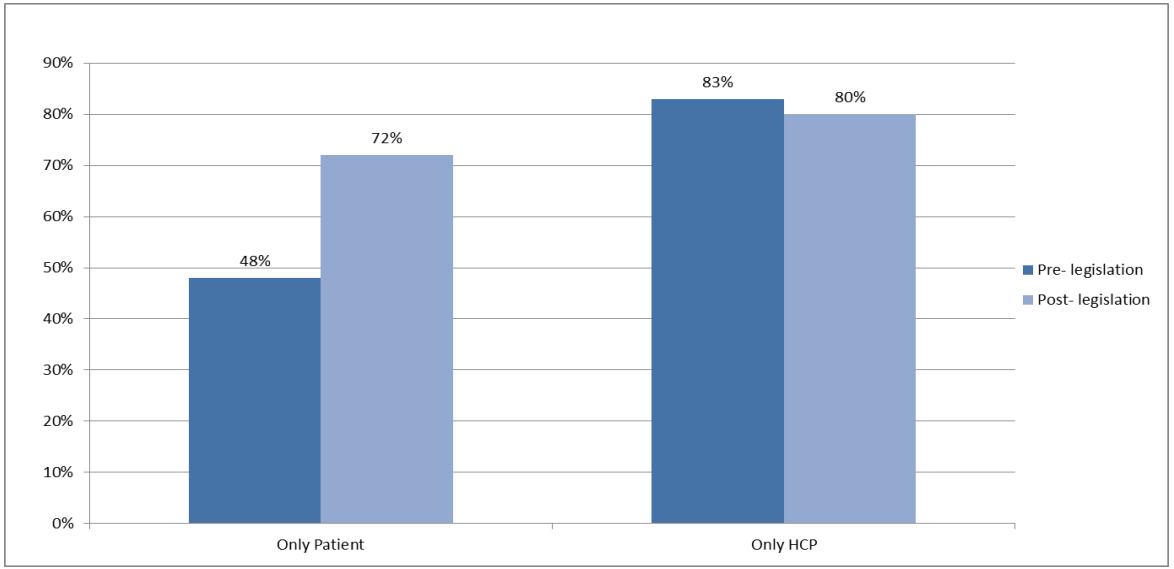
Seriousness



	02Jul2009 - 01Jul2010	02Jul2010 - 01Jul2011	02Jul2011 - 01Jul2012	02Jul2012 - 01Jul2013	02Jul2013 - 01Jul2014	02Jul2014 - 01Jul2015
Only Patient	42%	54%	49%	76%	75%	67%
Only HCP	78%	88%	84%	85%	80%	77%

After the new PV legislation was implemented a transitional period was put in place to enable all the stakeholders to adapt to the change in EV business rules.

After the transitional period ends all non-serious reports will have to be sent to EV by NCAs and MAHs.

Hence, the results on seriousness should be interpreted with caution.

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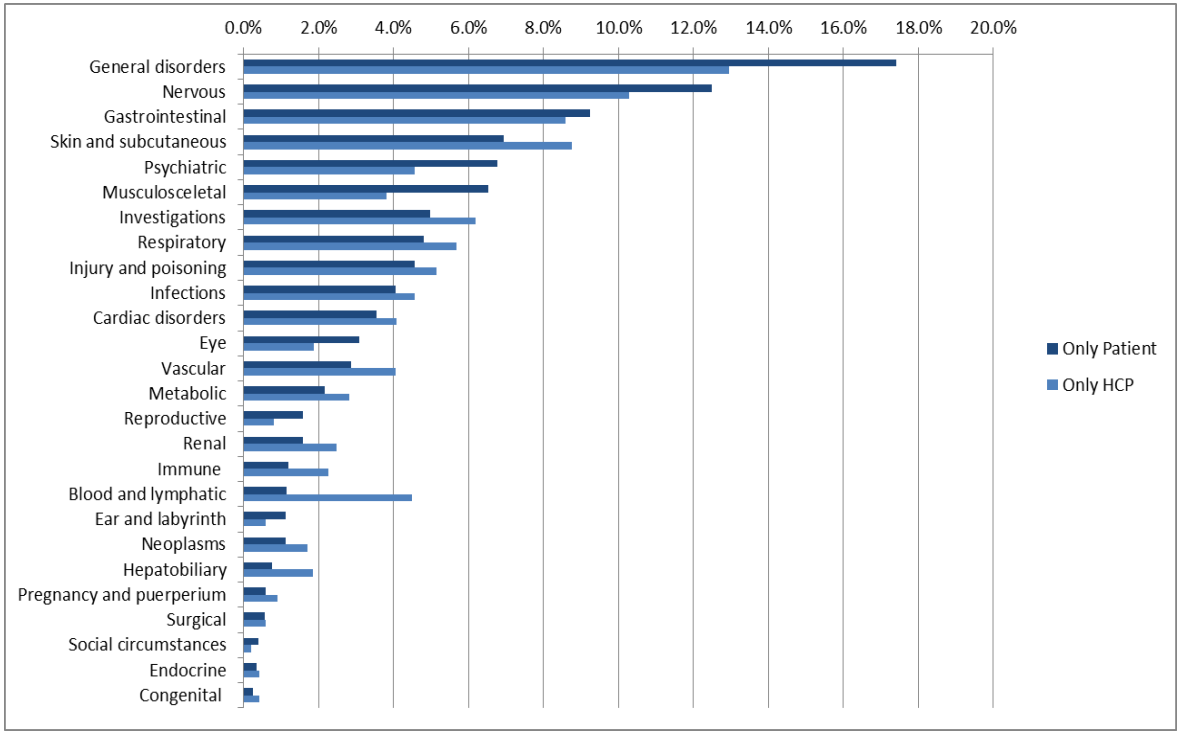
System Organ Classes



At the level of System Organ Classes, patients do not report very differently from HCPs, however…

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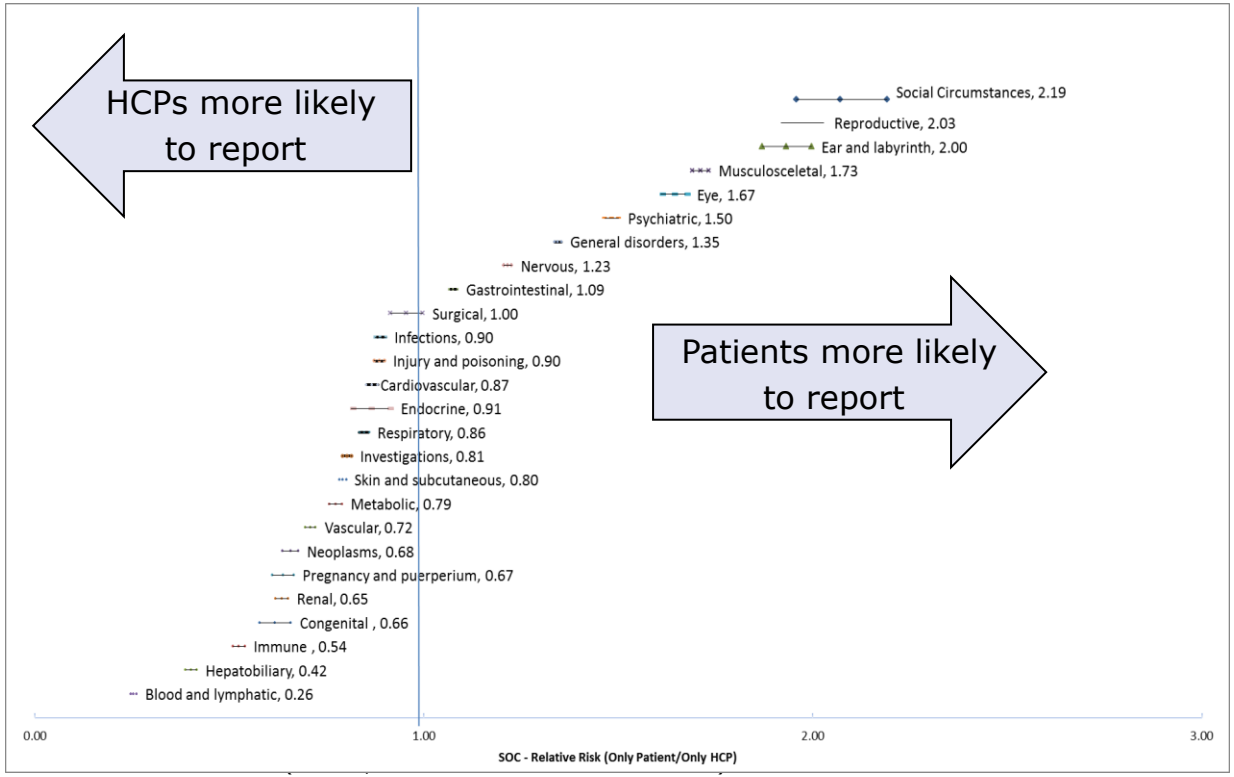
System Organ Classes – likelihood of reporting (Relative Risks)



…when compared by RRs, there seem to be differences in the likelihood to report by SOCs between patients and HCPs

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Top reactions by PT

Reaction (MedDRA Preferred Term)	Only Patient		Only HCP	
	Rank	N ICSRs	Rank	N ICSRs
Headache	1	12,074	9	29,982
Fatigue	2	11,681	16	22,153
Nausea	3	10,030	2	43,336
Dizziness	4	9,217	12	25,308
Pyrexia	5	9,066	1	55,114
Dyspnoea	6	6,629	3	42,912
Diarrhoea	7	6,465	6	33,120
Drug ineffective	8	6,366	11	26,761
Vomiting	9	5,982	4	39,853
Malaise	10	5,843	13	25,211
Myalgia	11	5,834	28	15,389
Palpitations	12	4,815	74	7,488
Pruritus	13	4,640	7	33,095
Arthralgia	14	4,608	37	13,170
Pain in extremity	15	4,046	45	11,375
Rash	16	3,973	5	33,678
Pain	17	3,921	34	13,461
Insomnia	18	3,875	99	6,446
Hyperhidrosis	19	3,755	48	11,014
Asthenia	20	3,614	18	19,923

Most frequently reported PTs by the Only Patient group in the July 2009- July 2015 period

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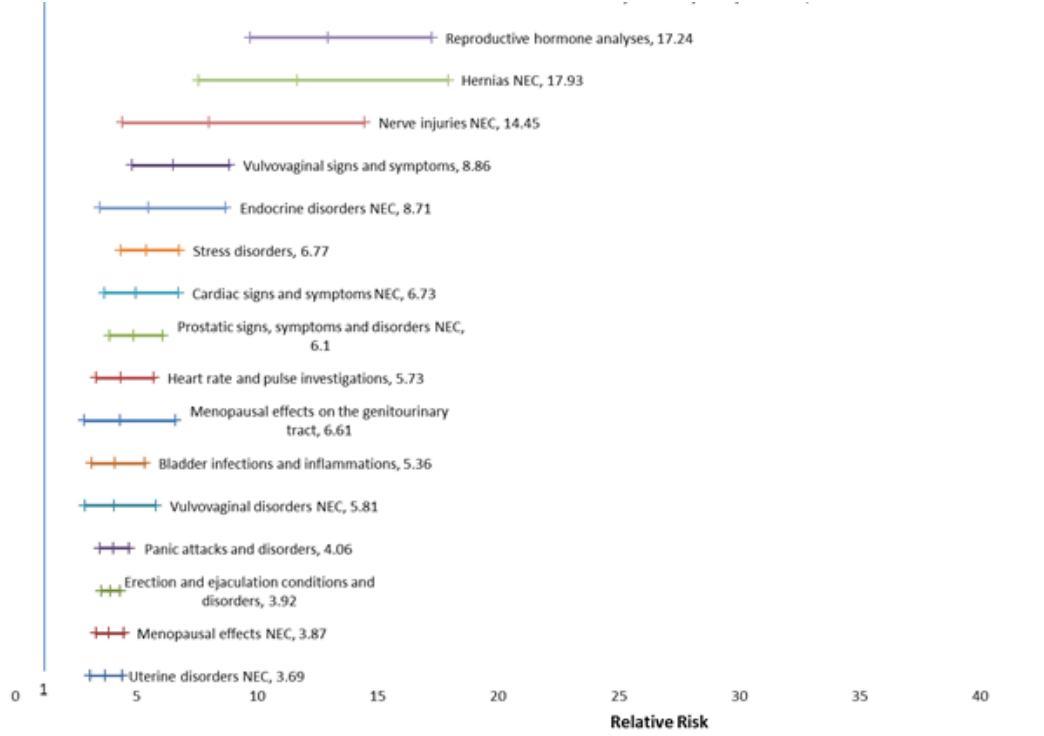
Indications by MedDRA High Level Term – HLT (Relative Risks)



9 of the top 16 indications were related to reproductive and genitourinary systems.

ADRs related to the use of medicines in psychiatric indications such as panic attacks and stress disorders are also more likely to be reported by patients than by HCPs

*top 4 indications by RRs belong to Thyroid related conditions likely due to a product quality issue. Considered outliers and not presented for readability purposes.

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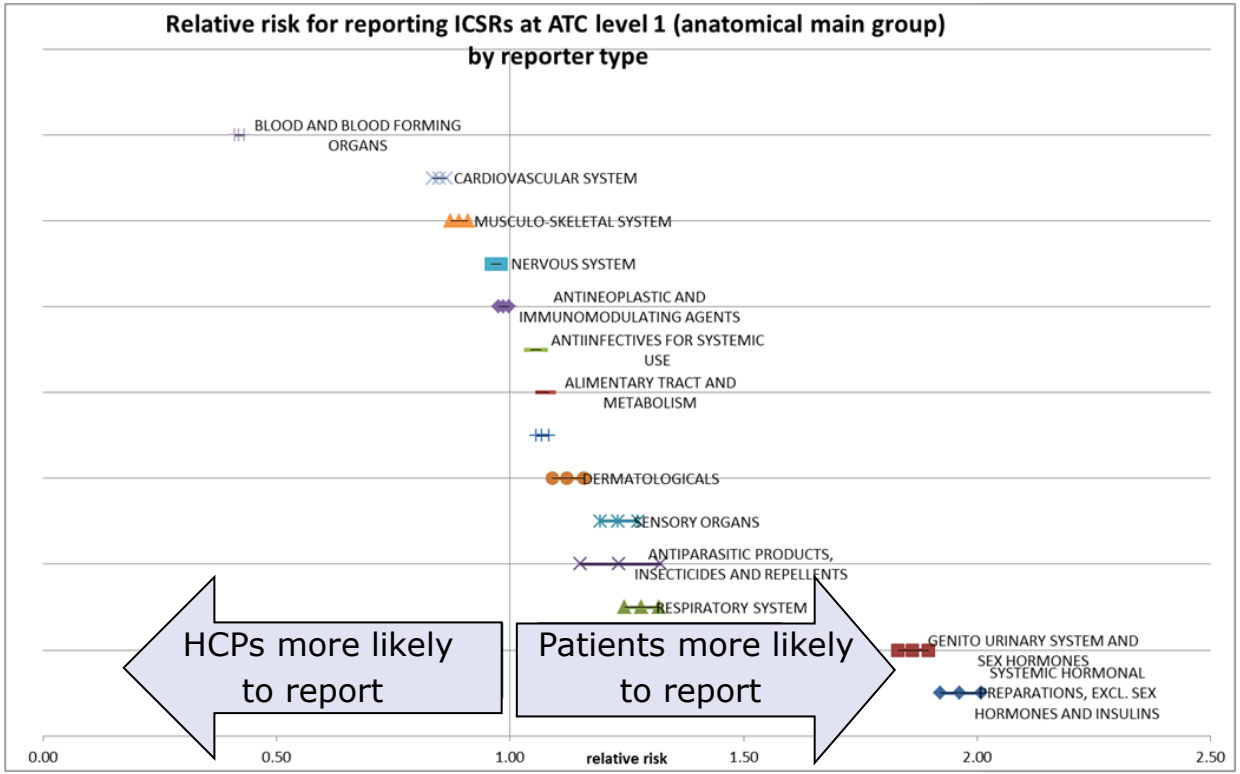
Substances by ATC 1

- Patients are more likely to report ADRs for substances for genitourinary system and systemic hormonal preparations than HCPs – aligned with the results for Indications



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Time to report an ADR

	All period	Pre legislation	Post legislation
	Median	Median	Median
Only Patient	26	18	32
Only HCP	34	37	31
Legal	607	610	606

- Before the new legislation Only Patient group reported ADRs with a median of 18 days, whereas the median after the new legislation exceeds one month (32 days).

- At the same time, in the Only HCP group the median time to report was reduced by almost 1 week (from 36 days before, to 31 days after the new legislation)

Patient reporting in the EU: analysis of EV data

Summary

- Overall increased patient reporting after the implementation of the new PhV legislation
- 13/20 most frequently reported PTs by patients and HCPs are identical
- Patients more likely to report in genitourinary, hormonal and reproductive indications than HCPs (2009 - 2015 period)
- Reporting more symptoms and less laboratory results in the patient reports is in line with previous studies

Thank you for your attention

Further information

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Discussion

- How do we actually define patient engagement in pharmacovigilance?
- Is the quantity of ADR reports a measure of patient engagement and what can we conclude from crude numbers?
- Patient empowerment vs Patient engagement – has legislation driven empowerment translated into engagement?
- One Member State is receiving more patient reports than HCP reports and a few others are showing a similar trend. Is there a shift in the ADR reporting paradigm? If so, are we prepared for this impact **on** pharmacovigilance?