

EPF MEMBER SURVEY ON PHARMACOVIGILANCE

First results & tentative conclusions

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EMA London

“ A STRONG PATIENTS’ VOICE TO
DRIVE BETTER HEALTH IN EUROPE ”

EPF involvement in PhV legislation – several member consultations, information about the results of the legislative process at every stage

Joint event with PGEU in 2011

2012: “Toolkit” (guidance to Pos, recommendations)

PhV featured in EPF’s member communications – website, e-newsletter

European Parliament Event on Direct Patient Reporting

On 15 September the European Patients’ Forum (EPF), together with the Pharmaceutical Group of the European Union (PGEU), organised a lunch seminar entitled “Adverse Drug Reactions: Moving Forward Together on Patient Safety” that took a critical look at the Direct Patient Reporting, part of the Pharmacovigilance legislation. The seminar was hosted by Linda McAvan, Member of the European Parliament and Rapporteur on the draft directive on Pharmacovigilance within the European Parliament.

A wide range of stakeholders were invited to hear the views of pharmacists’ and patients’ representatives,




Short online survey disseminated to EPF members

13 August – 20 September 2013

Answers received: 29

Countries : 12

- 
- Belgium (6)
 - Bulgaria (2)
 - Denmark (1)
 - Greece (1)
 - Hungary (2)
 - Ireland (3)
 - Italy (2)
 - Portugal (2)
 - Romania (4)
 - Spain (1)
 - Sweden (1)
 - United Kingdom (4)

As far as you know, what channels exist in your country for patients to report suspected adverse events (side effects, reactions...) related to medicines? (Multiple options available)

Doctor:	11 (65%)
Pharmacies:	6 (35%)
Patient organisations:	2 (12%)
Website:	4 (24%)
All of the above:	4 (24%)
No options:	0
Don't know:	0

Patient reporting (ii)



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Safety information ▾ [Home](#) > [Safety information](#) > [Reporting safety problems](#) > [Adverse](#)

Safety warnings, alerts and recalls

General safety information and advice

How we monitor the safety of products

Reporting safety problems

Adverse drug reactions

Defective medicines

Adverse drug reactions

You can report a suspected adverse drug reaction (ADR) or a side effect from a vaccine using the Yellow Card Scheme by clicking on the Yellow Card button. This will take you to the online reporting site. Anybody from the United Kingdom can

YellowCard

Helping to make medicines safer

[Go to the Yellow](#)

The Yellow Card Scheme is run by the MHRA and the Commission on Human Medicines (CHM), and is used to collect information from both health professionals and the general public on

Healthcare pro



MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

¡ BIENVENIDO AL SEFV-H !

Bienvenido al formulario electrónico para notificar sospechas de reacciones adversas a medicamentos del Sistema Español de Farmacovigilancia de Medicamentos de uso Humano (SEFV-H)



Directorate General of National Institute of Pharmacy



GYEMSZI

National Institute for Quality- and Organizational Development in Healthcare and Medicines



Is there a standard form for reporting?

Yes: 9 (53%)

No: 1 (6%)

Do not know: 7 (42%)

“ A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE ”

Is patient-friendly information on medicines safety (side-effects, reporting options...) available in your country?

Yes:	6 (35%)
No:	2 (12%)
Don't know:	9 (53%)

3 websites referred to, 2 of which were the same as the website for reporting (UK MHRA, BG)

Has your patient organisation received any information from the government/body responsible for pharmacovigilance, about the new EU rules?

Yes:	4 (24%)
No:	13 (76%)
Don't know:	9 (53%)

Involvement of Pos (ii)

Has your patient organisation been involved in some way in the implementation of the EU rules?

Yes, in developing information:	1 (6%)
Yes, in some other way:	1 (6%)
No, but we know other PO(s) that have:	4 (24%)
No:	11 (65%)

Have you read the EPF toolkit on pharmacovigilance ?

Yes: 5 (29%)

No: 12 (71%)

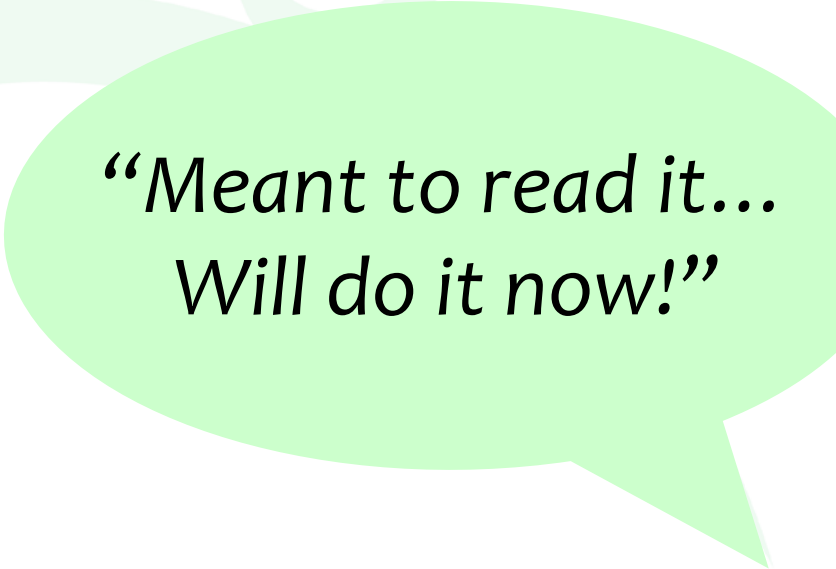
If not, why not?

Did not know it existed: 10 (83%)

Not interested: 0

Too complicated: 0

Other: 2 (17%)



*“Meant to read it...
Will do it now!”*

Some suggestions received from respondents

What do you think the EMA or the European Commission should do to support the implementation of the EU pharmacovigilance legislation in your country?

“Easy access to information on existing medicines”

“Plain English information for professionals and especially for patients”

"monitoring implementation of the pharmacovigilance rules “

“information campaigns on social media”

Also several responses received suggesting that more information is needed on basics:

- Role of EMA and MS (access!)
- Generics (safety and quality, substitution etc.)

Awareness of PhV is fairly low

Interest? (response rate) – but some PO advocates very interested

Low level of PO engagement in Member States

Need for simple information about “basics”, such as

- Role of EMA vs MS authorities (access)
- Generics (safety & quality, substitution etc.)

Challenge: how to “feed down” information from EU-level to national & local patient communities

EU guidance on patient reporting can help – with effective info campaign by EMA (PO will support)

Opportunity to raise awareness about medicines safety & patient safety generally

THANK YOU FOR YOUR ATTENTION!

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More information

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