The Vigil

A new role for patients' advocates

Meeting with all eligible organisations, 22 November 2017, EMA London

Presented by: Francois Houÿez - EURORDIS

Pharmacovigilance as a close watch on the medicines we take

Active monitoring of the medicines

- Reporting ADRs

Source of information

- Collecting data/views from our members (referrals, public hearings…)

Research partners

- Are the risk minimisation measures known? effective? accepted?

Information loop

- 2-way communication, awareness campaigns

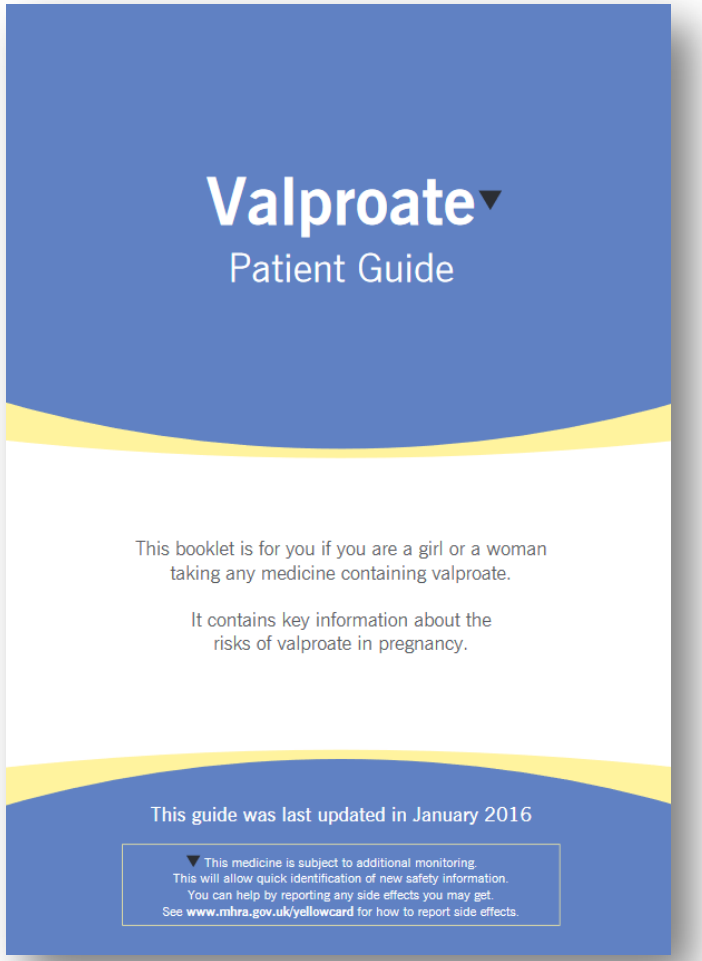
Testers

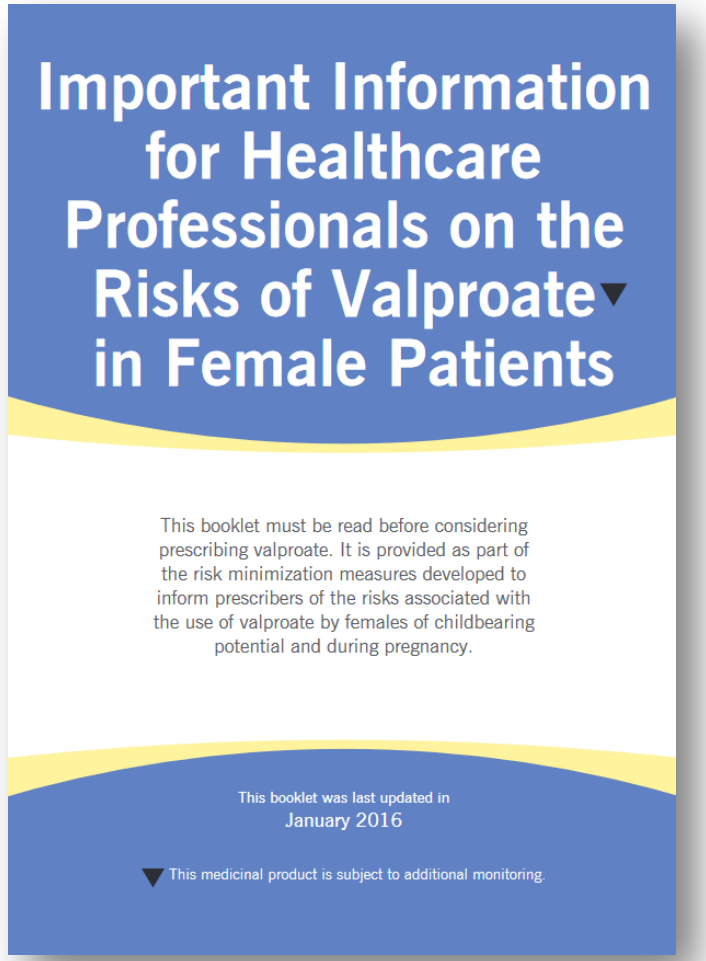
- Are the messages understood? Are benefit/risks clearly explained?

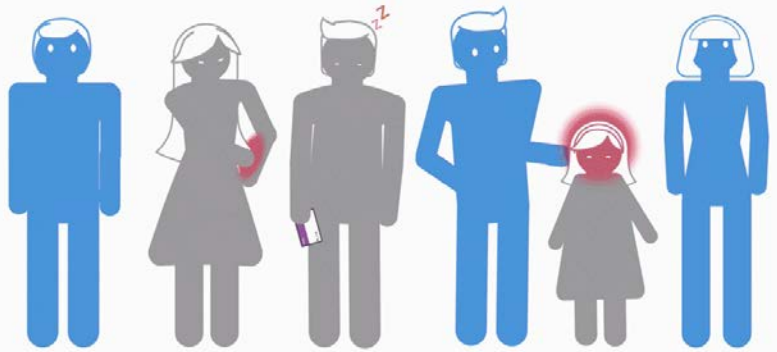
Which actions for patients and their organisations?

- National conferences on pharmacovigilance: NCA, patients' and consumers' organisations (PCO), other stakeholders
- Communication:▼, safety issues alerts, SCOPE Awareness week, Take & Tell…
- Sharing DHCP letters
- Specific calls for projects to PCOs on pharmacovigilance
- Patients as members of the national/European PRAC
- Consultation on Package leaflet, education materials
- Design of new websites/apps for spontaneous ADR reporting
- Verbal and email updates on topical issues, as appropriate
- Collect information from your member on shortages of medicines
- Could think of:
  - Award of the most informative patient ADR report of the year
  - Direct-to-patient pharmacovigilance (e.g. Pregabalin study)

e.g. contact person to disseminate







SCOPE

SCOPE

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Maladies Rares Info Services

Des experts vous écoutent et vous informent
01 56 53 81 36
Appel non surtaxé, inclus dans les forfaits

Témoigner et partager l'information sur le Forum

Nous appeler

Nous envoyer un email

Ch@tter

Découvrez Maladies Rares Info Services en vidéo

Effets indésirables liés à un médicament : vous pouvez les déclarez !

SVP EFFETS INDÉSIRABLES
Soutien à la Vigilance Pharmacologique

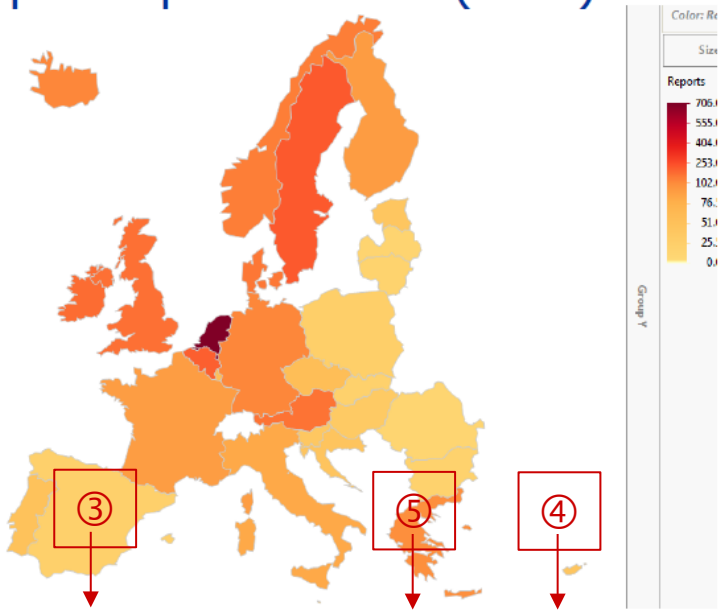
Si vous, ou un proche, avez des effets indésirables dus à un ou plusieurs médicaments pris pour une maladie rare, vous pouvez les déclarer. C'est important et utile pour renforcer la pharmacovigilance. Maladies Rares Info Services peut alors vous accompagner dans cette démarche.

Depuis la loi du 29 décembre 2011, les usagers du médicament ont la possibilité de déclarer les effets indésirables du médicament. Si vous, ou un membre de votre entourage, êtes concerné(e) par des effets indésirables liés à un ou plusieurs médicaments, vous pouvez les déclarer. Cette déclaration est effectuée à l'aide d'un simple formulaire proposé par l'Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM).

EUROPEAN MEDICINES AGENCY

Patient reporting in the EU: analysis of EV data

Patient reports per million (EEA)



Netherlands, United Kingdom, Sweden, Belgium: long-time practice
Ireland: HPRA works closely with patients' organisations

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

15 PRAC strategy on measuring the impact of Pharmacovigilance activities – *Preliminary results, do not publish.*

Patients' reporting in the EU: analysis of EudraVigilance data
Peter Arlett, Marin Banovac, David Haerry, François Houÿez. Drug Safety, 07/2017, Vol. 40, Issue 7, pp 629–645

A proposal: the Vigil

2. A contact person for pharmacovigilance in each patient organisation

The contact person for pharmacovigilance: the “Vigil”

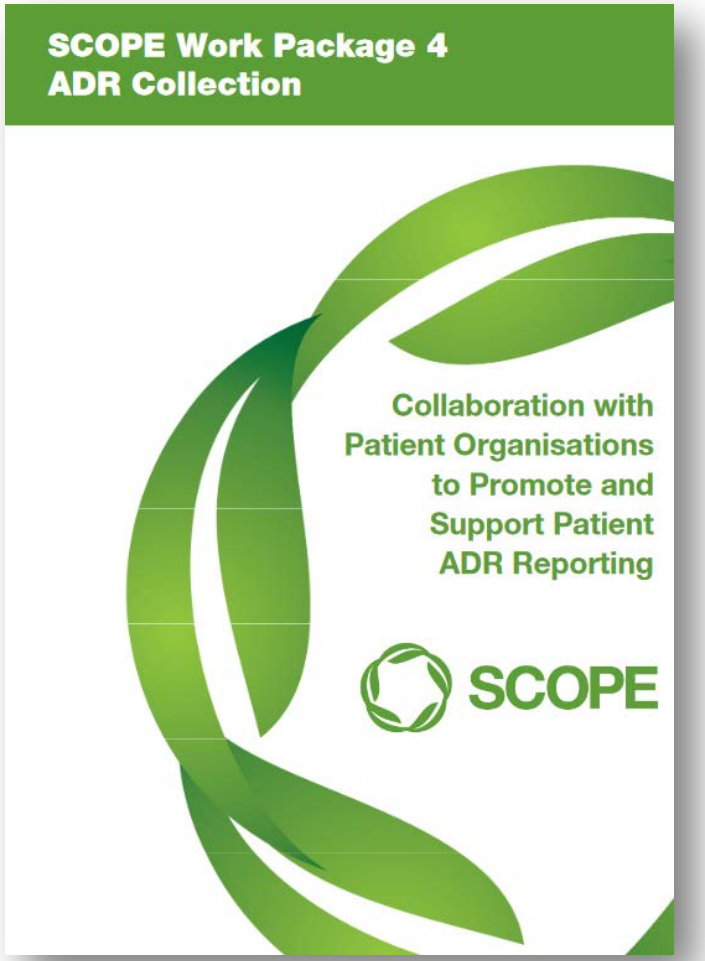
- NCA would ask patients’ organisations to appoint an official contact person for pharmacovigilance
  - The equivalent of the “QPPV”: Qualified Person for PharmacoVigilance in industry
- Who will be trained on how pharmacovigilance is organised in Europe and in Member State of interest
  - Including EudraVigilance and addreports.eu, VigiBase…
- Who will receive all safety alerts and/or DHCP and decide which ones are of interest for their members
- Who will be informed on national / international initiatives on pharmacovigilance
- Who will identify all available communication tools to increase awareness (Take & Tell, SCOPE awareness week video…)
- Who will be consulted when information needs to be prepared
- Who will receive questions from members, analyse the organisation’ social media, collect spontaneous ADRs….

Features

- Larger outreach to patients
  - France: **77** organisations in “France Assos Santé” / **7** in the “interface” committee at ANSM
  - **Yet: 2,200** patients’ groups total
  - How is it in your respective countries?
- A registry of contact persons managed by national authorities, EMA, or an international consortium (to be created)
- Training by national authorities / EMA / Patients’ Training Programmes
- Idea presented at:
  - DIA QPPV workshop 10/2016
  - DIA Washington 01/2017
  - SCOPE Flagship Event and Help Lines Training 03/2017
  - DIA Euromeeting 03/2017
  - Web-RADR final conference 09/2017
  - EMA Pharmacovigilance Stakeholder Forum 09/2017
- And very well received!

National authorities are preparing themselves

- Brainstorming and recommendations on how to engage with patients' organisations
- SCOPE Joint Action "Strengthening Collaboration for Operating Pharmacovigilance in Europe"
- here



To come

Package leaflet, education materials	• Graphic visualisation of risks, benefit/risks (post PROTECT), electronic package leaflet
Patients' social media analysis	• Web-RADR, ADR-Prism, Vigi4Med…
Public hearings	• At EU level / PRAC (and their national versions?)
Other research instruments	• Direct to patient pharmacovigilance (e.g. Pregabalin study, PROTECT (pregnancy))
Continuous b/r evaluation	• Patients' preferences elicitations / MCDA
Impact of pharmacovogilance legislation	• Input of patients and their organisations

Next steps

- 2 E-meetings in November 2017:
  - 6/11 : 9 participants present/ 10 – great contributions, strong support EMA, ISOP, MHRA, AEMPS, NDA
  - 24/11: with WHO, HPRA, Univ. Pisa, 3 other patients' representatives (e.g. PRAC)
- Creation of a working group to develop the concept further with volunteers to do the work
- Action plan
  - Informing NCAs, EMA and other patients' organisations
  - Code of Practices, legal status, job description, prioritisation of roles (Delphi), training opportunities
  - Consider flexibility for all types of patients' networks (registered org, social networks, young people groups…)
  - Start small / demonstrate utility / grow fast
- Exploration of opportunities: a new project? IMI? DG Sante? Industry be involved at second stage
- Create a sustainable structure to host the initiative. Who?
  - ISOP? CIOMS? WHO-UMC? EMA? EURORDIS? IAPO? Other PO?
- Face-to-face 2018 meeting funded by?

- How do you see this new role? Useful? Not so useful?
- Do you have examples where your organisation played an equivalent role?
- Do you think it is feasible?
- Would you like to endorse the concept? To advocate for it and join the initiative?