‘INVOLVING PATIENTS IN PHARMACOVIGILANCE’ EPF TOOLKIT

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EPF About us

- Independent, non-governmental umbrella organisation set up in 2003
- **VISION:** High-quality, patient-centred, equitable healthcare for all patients in the EU
- **MISSION:** To provide a strong and united patients' voice –> Putting patients at the centre of EU health policy

54 member organisations – **150** million patients with chronic conditions across the EU

WHY the EPF toolkit

- EPF very active in providing a patients' perspective on the 2008 EC Pharmacovigilance proposals:
- Working closely with EU institutions
- And other health stakeholders (e.g. PGEU)

- Final legislation promising: principles of patient involvement and empowerment embedded in the text, key measures to improve patient safety…

- But implementation by Member States + the way they will engage with patient organisations is essential to deliver on this promise

=> Need for involvement of the patient community at national level

The EPF Guidance for Patient organisations

Available here

GUIDANCE content

Guidance designed for patient organisations:

- Gives an helicopter view of Pharmacovigilance: what it is, actors involved & their role, importance for patients and the safety and quality of medicines…
- Presents all the key changes brought by the 2010 EU legislation, in particular for patients & their organisations
- Identifies opportunities and areas for involvement at national and EU level
- Provides list of key dates for the implementation of the adopted EU legislation, a glossary, links to further information

WHAT IS Pharmacovigilance ?

"The science and activities relating to the detection, assessment, understanding and prevention of adverse drug effects or any other drug related problem" (WHO, 2002)

- A system used to monitor safety of medicines after they are authorised for public use – actions to reduce risks and increase benefits
- **Adverse reactions: 5th most common cause of deaths in hospital – BUT only 10–25% are reported**
- Reporting is key to increasing vital knowledge for the safe use of medicines, early detection of safety issues

=> Patients play a key role in pharmacovigilance

NEW EU legislation

Directive 2010/84 and Regulation 1235/2010

- Amending Directive 2001/83/EC (nationally authorised products, common provisions) and Regulation (EC) No. 726/2004 (centrally authorised products, European Medicines Agency)

European Medicines Agency: new legislation will have a "bigger impact than any other" since its creation

- Publication – 31 December 2010
- Rules will apply from – 2/12 July 2012
- EC report on shortcoming of package leaflet and summary of product information – January 2013
- Member States audit of their systems – September 2013

Some key issues for patients

1. Direct patient reporting across the EU
2. More transparency of the system for patients and the public
3. Patient involvement at national level
4. Information, awareness, capacity-building
5. Potential implications for role of patients, patient-health professional relationship

1. Direct Patient Reporting

- A key tool for better medicines safety
- Expression of + tool for patient empowerment:
  - Patients know best (their body, their mind, their daily life…)
  - Experiential knowledge complements scientific knowledge
  - Health professionals under-report
  - Sometimes patients prefer not to report to their doctor
- ADRs can be detected earlier, different ADRs reported by patients, better understanding of impact of ADRs
- EU MS will provide standardised Web form + one other way of reporting

Patient reporting is equal quality and adds value

1. Direct Patient Reporting (2)

Implementation is crucial: National reporting systems should ***capture the richness*** of patient experience

- Richness of detail, description, quality of life
- Capture & qualitative analysis
- Inclusion of mis-use, medication errors – possibly other useful information
- Feedback and follow-up is important

Patients should be involved in the creation of the reporting system to make sure it is user-friendly and captures relevant information

1. Direct Patient Reporting (3)

Information to patients includes improvements to medicines packaging and the patient leaflet:

- Standardised text + explanation of options for reporting + contact details
- Products under additional monitoring: black symbol + explanation
- Ongoing work at European Medicines Agency with patients/consumers to improve PL
- EC review of the shortcomings of the patient leaflet and summary of product characteristics –> proposals to make them more user-friendly -> 2013

2. Transparency

New law increases transparency of the EU pharmacovigilance system – and access to information for patients and public:

- Eudravigilance database will be accessible to patients and public
- National medicines web-portals
- European medicines web portal
- Public hearings at European Medicines Agency (urgent procedure/serious safety concerns)

EPF has worked EMA in finalising and user-testing the new website for public access to safety data:

www.adrreports.eu

3. Patient involvement

At national level: Opportunities to develop an optimal system

- Public information campaigns;
- Setting up the national reporting systems;
- Setting up national medicines web portals;
- Liaising with regulators on effective safety communications
- Building awareness and educating patient communities

Maybe you are already doing something that adds value!

Does your ministry / regulatory body know you exist?

4. Information and capacity

- For full benefit of the rules & patient reporting it is vital that patients are informed about:
  - what Pharmacovigilance is
  - why it is important to report suspected adverse reactions
  - what opportunities will be available to do it.
- National authorities and EC should organise information and awareness campaigns
- ***Patient groups*** can effectively support awareness in the longer term with “grass-roots” patient communities

4. Information and capacity (2)

- Patient organisations are interested in getting involved – but many feel they lack knowledge
- Patient groups often lack working relationships with national authorities
- **EMA** could support at EU level by organising capacity-building workshops for patient groups from national level + information materials
- **EMA/EC** could facilitate contacts with patient organisations and national regulators – e.g. joint stakeholder conference
- International & EU-level **patient organisations** can inform and support their members

5. Patients' role

- Direct patient reporting contributes to development of **health literacy and empowerment** → patient involvement
- "Health literate" patient needs the "patient literate" health professional
- Education needs of health professionals → concordance, meaningful patient involvement

Patients' and health professionals' organisations to enter into dialogue on how to promote patient empowerment and patient-centred healthcare

The EPF recommendations

Available here

+ a “ready for use” version sent to EPF Members

RECOMMENDATIONS

- Recommendations on all of the key issues, based on EPF's previous positions developed with our members.
- For authorities and bodies in EU Member States tasked with the implementation of Directive 2010/84/EU
- to ensure that this Directive, as intended, will lead to a strong, open and transparent pharmacovigilance system that represents a step forward for safety, high quality, and patient-centred healthcare.
- We encourage patient organisations to use these recommendations in their exchanges with national ministries of health or other bodies in charge of pharmaceutical products + to share with any interested parties

CONCLUSIONS

The new legislation provides ***both a need and an opportunity*** to increase patients' involvement at national level

Need → ensure that the law is implemented in a way that is patient-centred and meets patients' needs

Opportunity → foster patient involvement and patient-health professional collaboration → a ***cultural shift*** towards more patient-centred health systems

Your involvement in Pharmacovigilance is crucial to build a 'patient safety culture' in which patients are considered equal partner, and which encourages openness and transparency to prevent and address adverse events.

THANK YOU FOR YOUR ATTENTION!

More information:

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"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"

europeanpatients'forum