A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE

"Guidance to patients and consumers on medication-error reporting"

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Who are we?

- 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 –> patients at the centre of EU health policy & programmes
- Varied membership of 54 national & EU-level organisations
- Cross-cutting non-disease-specific issues

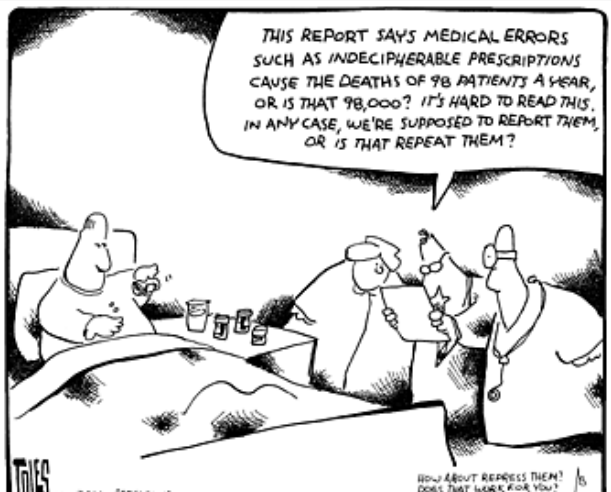
ME In context

Errors can happen in many contexts:

A) in prescribing – by physician
B) in dispensing – by pharmacist
C) in administering – by healthcare professional
D) in self administering – by patient

PHARMACOVIGILANCE:

- Reporting of ME addressed in the context of reporting ADR
- Collection of <u>all</u> ADRs – incl. off-label use, misuse, and errors
- Objectives are:
  - to prevent harm
  - to promote safe and effective use of drugs
  - Incl. provision of information to patients / public



Patients play a key role in PhV generally

Benefits of patient reporting

Patient reporting is of good quality and adds value:

- Patients know their body, mind, daily life…
- Experiential knowledge = complement to 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 on people's lives

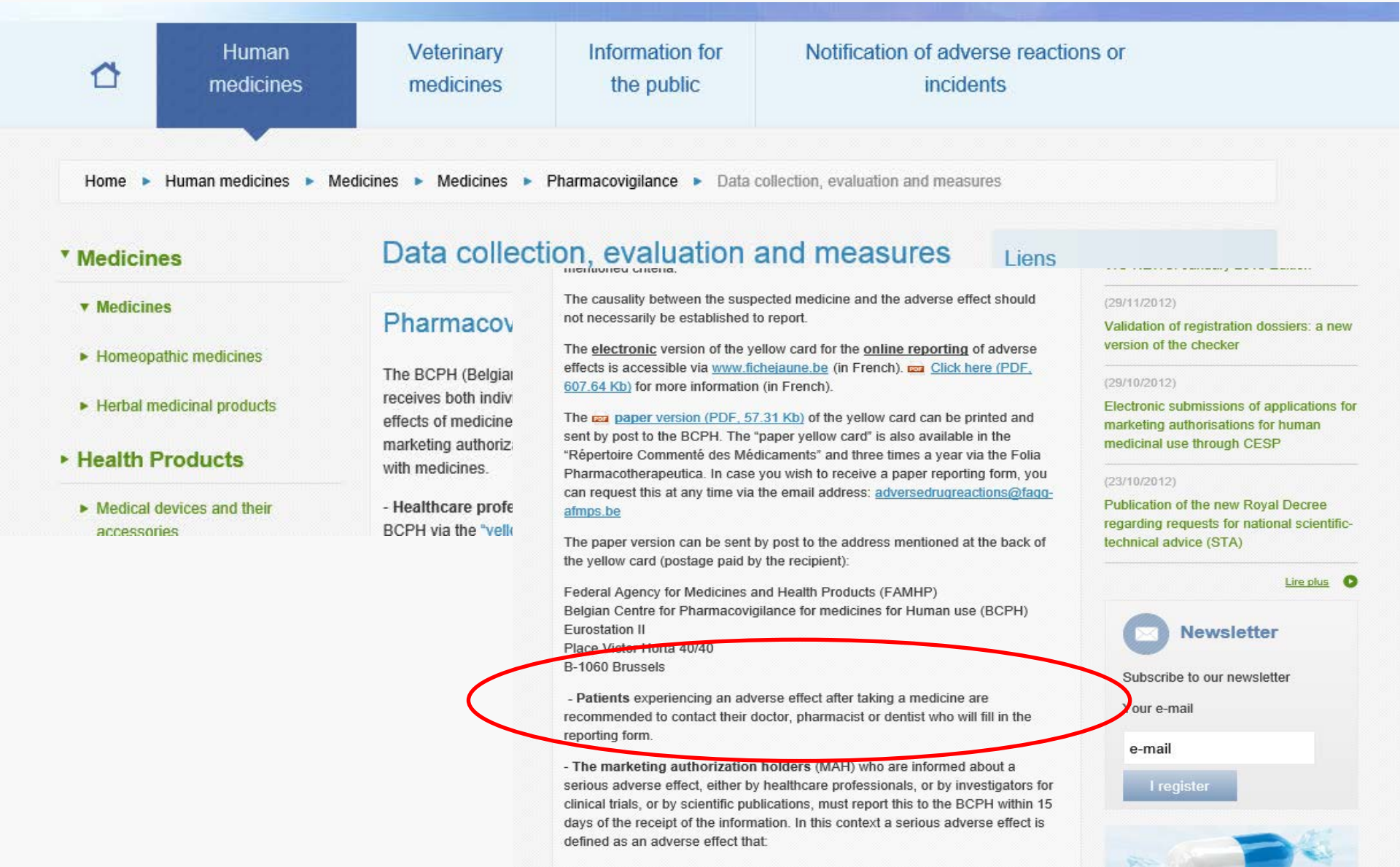
Expression of + tool for patient empowerment:

- Patient engagement in own health
- take on a role of equal partner with health professionals
- awareness and knowledge about medicines use → adherence to treatment.

Challenges

- Varied knowledge concerning pharmacovigilance
- EPF 2012 toolkit on pharmacovigilance: guidance and recommendations
- Feedback indicates: not much patient engagement, and low awareness
- Particular challenges in countries where patient involvement in health policy is not recognised
- EPF 2013 follow-up activity: survey to assess extent of awareness, degree of patient involvement and degree to which medication safety is considered a priority by POs.

Where we are now… one example



Human medicines | Veterinary medicines | Information for the public | Notification of adverse reactions or incidents

Home ▸ Human medicines ▸ Medicines ▸ Medicines ▸ Pharmacovigilance ▸ Data collection, evaluation and measures

▾ Medicines

▾ Medicines

▸ Homeopathic medicines

▸ Herbal medicinal products

▸ Health Products

▸ Medical devices and their accessories

Data collection, evaluation and measures

Pharmacov

The BCPH (Belgia
receives both indiv
effects of medicine
marketing authoriz
with medicines.

- Healthcare profe
BCPH via the "vell

The causality between the suspected medicine and the adverse effect should not necessarily be established to report.

The **electronic** version of the yellow card for the **online reporting** of adverse effects is accessible via www.fichejaune.be (in French). Click here (PDF, 607.64 Kb) for more information (in French).

The paper version (PDF, 57.31 Kb) of the yellow card can be printed and sent by post to the BCPH. The "paper yellow card" is also available in the "Répertoire Commenté des Médicaments" and three times a year via the Folia Pharmacotherapeutica. In case you wish to receive a paper reporting form, you can request this at any time via the email address: adversedrugreactions@fagg-afmps.be

The paper version can be sent by post to the address mentioned at the back of the yellow card (postage paid by the recipient):

Federal Agency for Medicines and Health Products (FAMHP)
Belgian Centre for Pharmacovigilance for medicines for Human use (BCPH)
Eurostation II
Place Victor Horta 40/40
B-1060 Brussels

- **Patients** experiencing an adverse effect after taking a medicine are recommended to contact their doctor, pharmacist or dentist who will fill in the reporting form.

- **The marketing authorization holders** (MAH) who are informed about a serious adverse effect, either by healthcare professionals, or by investigators for clinical trials, or by scientific publications, must report this to the BCPH within 15 days of the receipt of the information. In this context a serious adverse effect is defined as an adverse effect that:

Liens

(29/11/2012)
Validation of registration dossiers: a new version of the checker

(29/10/2012)
Electronic submissions of applications for marketing authorisations for human medicinal use through CESP

(23/10/2012)
Publication of the new Royal Decree regarding requests for national scientific-technical advice (STA)

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How to stimulate patient reporting?

Some critical success factors

Clarity about what, where, how

- Basics: What medication errors are, and in what kind of context they can occur.
- What the reporting system is for
- Reassurance:
  - medication errors /misuse by health professionals
  - medication error by patient themselves
- Where and to whom patients can turn to concerning adverse events of any type, or if they have questions.
- Information about medicines should be informative but not alarming – PO role

Accessibility

- Reporting options
  - Forms available at health centres
  - in pharmacy…
  - Telephone help line
  - Reporting to a patient organisation?
- Hard to reach groups, e.g. older people, people with disabilities, linguistic/ethnic minorities, socially disadvantaged groups

Engagement & feedback

- Feedback = major motivator –
  - general purpose and benefits of patient report,
  - How the information will be used
  - provide patients with further information or indicate to them where it is available (e.g. through the publicly accessible part of the EudraVigilance database)
  - Individual feedback

Awareness & Trust

- Awareness of the importance of reporting
  - Role of Media, pros and cons
  - Role of community health professionals
  - Role of patient organisations
- Basic awareness about medicines safety and pharmacovigilance
- Trust in the system – whose voice is listened to?
- Public info campaigns: engage stakeholders

Information

- Access to information at the time when I need it
- Consider different levels of health literacy
- National medicines web-portals (Art. 106) presented in understandable way, relevant to patients' concerns
- Patient organisations can support awareness in the longer term & respond to patient queries

Patient organisations

- Patient organisations see as their role the promotion of safety, addressing queries
  - EPF toolkit on PhV legislation (English only)
  - IAPO patient safety toolkit & FAQs, practical checklists targeted at patients
  - Social media networks
- PO need support in this task
- NCA meetings with patient organisations (directive 84, article 102) – is this happening?
- Communication strategies
- Risk communications (DHCP) to Patient organisations

Patient – health professional

- Patients who report adverse reactions directly to competent authorities say they did it themselves "because the doctor did not seem interested"
- Patients want more information than they receive; health professionals overestimate the amount of information they supply
- Empowered patients can drive change – requires attitudinal changes, new skills from health professionals.
- From monologue to dialogue → better safety & better health outcomes

Recommendations

- MS: engage Patient groups in awareness campaigns, developing of key messages
- Guidelines for follow-up of reports
- User testing of tools, open channel for feedback
- Engage with patient organisations to evaluate reporting system & improve it
- Support and capacity-building for patients organisations – EU level & in MS
  - MS – training sessions on pharmacovigilance for patient groups at national level to equip them to engage with national authorities. EC to coordinate?

Recommendations (ii)

- Reporting and learning systems, based on a no blame philosophy, and with an effective channel to elicit feedback from patients – for any observations which could help improve the system
- EU wide study of the implementation of patient reporting, including experiences of patients in different countries and extent of public awareness

europeanpatients'forum

Thank you!

For more information visit

www.eu-patient.eu

or email

info@eu-patient.eu