SCOPE Joint Action
Stakeholder Event

Patient and Consumer Organisation Consultation

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20 - 21 March 2017
London

Overview

- Background to the consultation
- Feedback received
- Conclusions

Background

- Patients and Consumers - key stakeholders
- Risk communication topics identified where patient and consumer feedback of particular interest
  - Topics presented in an *'aide memoire'* document designed to stimulate discussion within Patient & Consumer Organisations & allow descriptive responses
- Disseminated in collaboration with

- EUPATI (European Patients' Academy on Therapeutic Innovation) patient advocacy programme
- BEUC (The European Consumer Organisation)
- EURORDIS (The European Organisation for Rare Diseases)

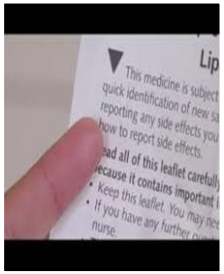
Topics for discussion

SCOPE

Information about medicines

- Trust - whose information about medicines are patients & consumers most likely to rely on?
- Access - preferred channels for receipt of information

National Regulatory Authority awareness

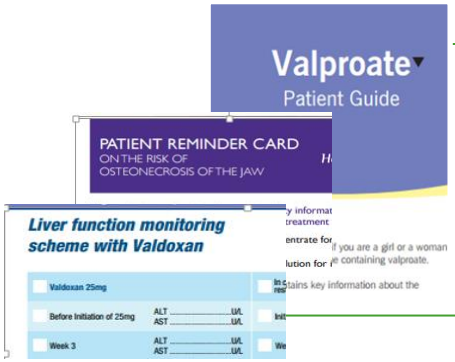


ADR reporting

- Familiarity with direct patient reporting and black triangle symbol

Communications about specific safety reviews

- Attitudes and preferences



Educational materials

- Familiarity with the concept, role of national regulatory authoririties, preferred tools and format

Respondents

- Eleven (11) patient/consumer organisations from 7 countries;
  - Belgium, Spain, Portugal, Ireland, Italy Lithuania and Macedonia
  - Included large patient/consumer groups and smaller organisations representing rare diseases
    - Responses broadly similar regardless of organisation type

* Total numbers contributing within the organisations unknown
  - One consumer organisation supported their views with results from a survey they previously carried out to which 4,832 replied
* Participants likely to be more informed
  - May not be representative of the general patient population

Feedback – trusted sources of medicines information

- Doctors, followed by pharmacists and other Health Care Professionals, considered most reliable sources by respondents

- Patient Organisations (depending on disease area & country), fellow patients

- Face-to-face discussion with the HCP is the preferred channel
  - Range of communication channels should be used
  - Hardcopy version of the Package Leaflet and Patient Organisation websites frequently used as per the respondents. NCA websites and social media patient community discussion forums also mentioned
  - Some organisations had carried out their own research, estimates of patients who read the package leaflet varied from 30% to 80%

Feedback – ADR reporting

- Familiarity of direct patient ADR reporting considered to be low
- Awareness of the additional monitoring scheme symbol also considered to be poor
- Respondents felt most patients were not aware of the NCA and do not use NCA websites as a source of information
- Collaboration between Patient/Consumer Organisations including EUPATI National Platforms could benefit patients and regulators in helping to raise awareness of the NCA and ADR reporting

Feedback – communications about specific safety reviews

- Preference for information to be communicated at the start of the review
- Transparency is important to patients and consumers and will enhance trust
- Target communications to those for whom they are most relevant
  - Potential for collaboration with Patient Organisations highlighted

Educational materials

- Aim to promote the safe and effective use of the medicinal product, supplement ingthe SmPC & Package Leaflet where required
- Focus on specific risk(s) related to the medicine and describe what actions are required to prevent and minimise such risks
- Target audiences can include HCPs (e.g. specialists, general practitioners, pharmacists) and/or patients/carers
- Produced and distributed by the Marketing Authorisation Holder (MAH) of the medicine once reviewed by the national regulatory authority. Separate from promotional material and activities
- Often hard-copy materials distributed by post to HCPs and given to patients by their HCP. Electronic versions available in some countries for HCPs/patients to download or print etc.

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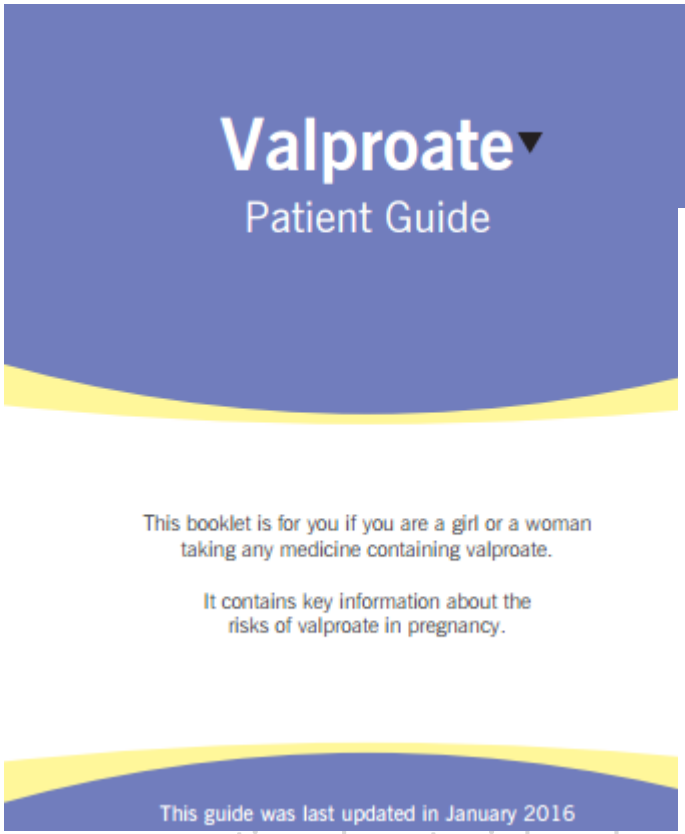
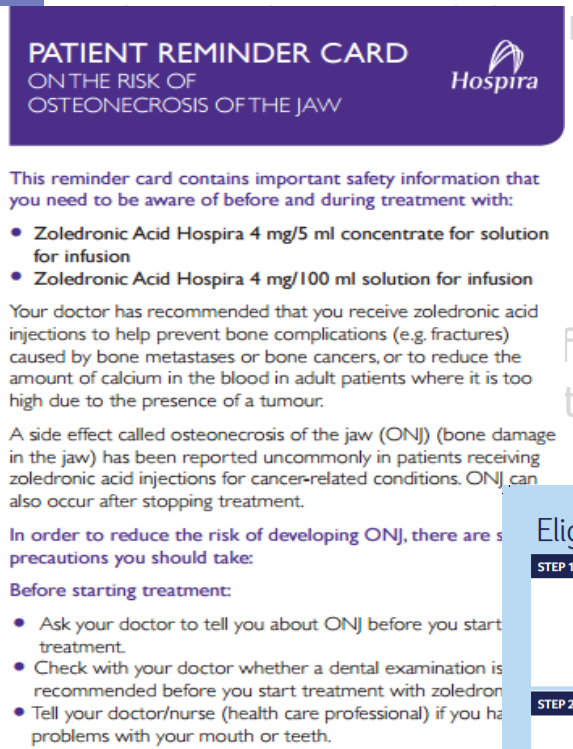
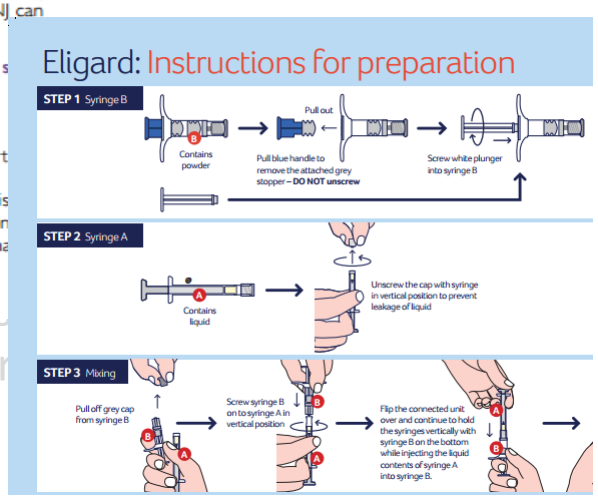






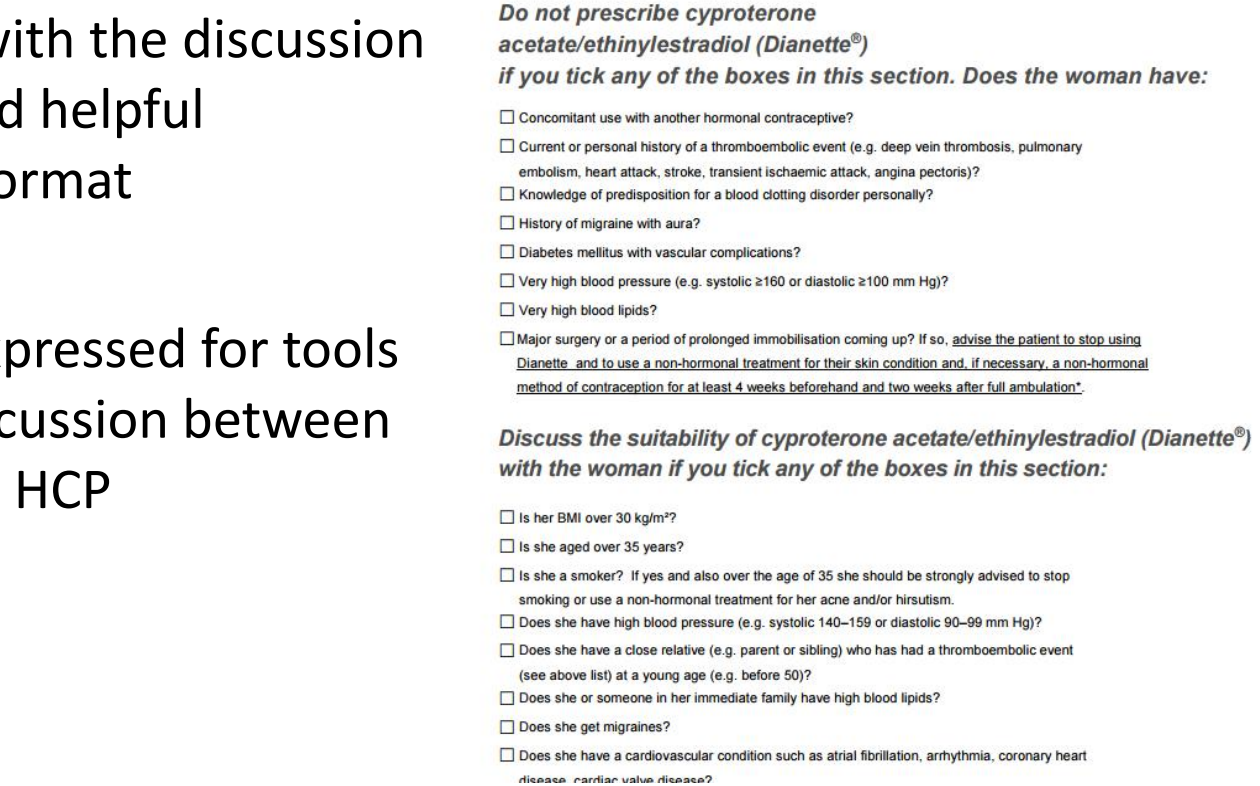
Feedback – educational materials

- Most organisations unfamiliar with educational materials
- Confusion regarding their objectives
- Unaware of NCA role in their approval
- Uncertainty regarding the independence of the materials
- Availability via a range of channels suggested
- Importance of concise information & plain language highlighted

Feedback – educational materials

- Examples provided with the discussion document considered helpful especially checklist format

- Strong preference expressed for tools which encourage discussion between the patient and their HCP



Do not prescribe cyproterone acetate/ethinylestradiol (Dianette®) if you tick any of the boxes in this section. Does the woman have:

- ☐ Concomitant use with another hormonal contraceptive?
- ☐ Current or personal history of a thromboembolic event (e.g. deep vein thrombosis, pulmonary embolism, heart attack, stroke, transient ischaemic attack, angina pectoris)?
- ☐ Knowledge of predisposition for a blood clotting disorder personally?
- ☐ History of migraine with aura?
- ☐ Diabetes mellitus with vascular complications?
- ☐ Very high blood pressure (e.g. systolic ≥160 or diastolic ≥100 mm Hg)?
- ☐ Very high blood lipids?
- ☐ Major surgery or a period of prolonged immobilisation coming up? If so, advise the patient to stop using Dianette and to use a non-hormonal treatment for their skin condition and, if necessary, a non-hormonal method of contraception for at least 4 weeks beforehand and two weeks after full ambulation*.

Discuss the suitability of cyproterone acetate/ethinylestradiol (Dianette®) with the woman if you tick any of the boxes in this section:

- ☐ Is her BMI over 30 kg/m²?
- ☐ Is she aged over 35 years?
- ☐ Is she a smoker? If yes and also over the age of 35 she should be strongly advised to stop smoking or use a non-hormonal treatment for her acne and/or hirsutism.
- ☐ Does she have high blood pressure (e.g. systolic 140–159 or diastolic 90–99 mm Hg)?
- ☐ Does she have a close relative (e.g. parent or sibling) who has had a thromboembolic event (see above list) at a young age (e.g. before 50)?
- ☐ Does she or someone in her immediate family have high blood lipids?
- ☐ Does she get migraines?
- ☐ Does she have a cardiovascular condition such as atrial fibrillation, arrhythmia, coronary heart disease, cardiac valve disease?

Conclusions

HCPs are the most trusted source of medicines information

Face to face discussion is the most preferred channel for receiving information

- Educational materials should also function as tools to encourage discussion between the patient and the HCP

Familiarity with educational materials is low

- Publication of educational materials on NCA websites
  - Enhance transparency
  - Allow immediate access to the most up-to-date version of the materials
  - May help to demonstrate NCAs role in approval of materials

Conclusions

Targeted safety information preferred where possible

Awareness of the regulatory system and how it works amongst patients and consumers needs to be enhanced

- Development/strengthening of links between National Regulatory Agencies and EUPATI national platforms/Patient/Consumer Organisations may help optimise the dissemination of safety information to the relevant audiences

Transparency is important to patients and consumers

- Communicate at the beginning of a safety review – will enhance transparency and trust
- A preference for real time safety information reflects the need for sustainable communication and the need to exploit digital media for messages likely to evolve over time

Questions?

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