PhVWP

Patients & Consumers Experience

Albert van der Zeijden
Cristina Cabrita
Greetje Goossens

PCWP, London, 28 February 2012

What is the PhVWP?

- Expert Group to the CHMP (Committee for Medicinal Products for Human Use)

- What is the aim?

  - Investigate Adverse reactions of medicines authorized in EU
  - Advice on the safety of medicines
  - Support to CHMP to identify, assess and manage the risk of a medicine product

Composition of the PhVWP

- Chairperson (Dr. June Raine)
- 1 member per Member State, Norway, Iceland and Liechtenstein
- Co-opted members with specific expertise (eg. pharmacoepidemiology, statistics,…)
- Observers:
  - 1 European Commission
  - 2 patient observers
  - EMA staff

How it works?

- It always starts with a signal detection:
  - EudraVigilance
  - Database of NCA
  - Periodic safety reports
  - Scientific literature, other…

How it works

PhVWP

- analyses potential signals
- advises on confirmation and quantification of risk
- compares the risk to the benefit

If it is confirmation of a safety probem
Measures are to be taken

Measures

- Activate the risk management plan, which could involve communication programs, educational programs for patients/consumers and or healthcare professionals;
- Change PIL and/or SPC;
- Direct Healthcare Professional Communication (DHPC);
- Suspend the medicine;
- Withdraw the medicine;
- Reduce the number of pills per package;
- Change the medicine status (OTC to prescription).

Patients&Consumers in the PhVWP

The goal:

- transparency of regulatory/pharmacovigilance activities towards the society
- to include patients' / consumers perspective in the regulatory activities, to make sure that decisions meet the needs

→ Connection between the regulatory world and the reality of patient care

Patients& Consumer role

- Patient& Consumer perspective in discussions, assessments and actions to be taken: questions and contribution
- Advice on communication strategy (content of communication, channels, target groups) e.g. DHPC
- Review of product information (PL, EPAR, SmPC), and ensure readability
- Discussion on policy and regulatory issues
- Connection with concerned patient groups

Patients& Consumer role

Ad Hoc:

- Drafting group on transparency and communication (elaboration on guidelines on risk communication)
- Drafting group on new PV-legislation
- Meetings with external stakeholders
- Involvement in external conferences/workshops

Example

- **Web-educational-materials:** are developed in a context of risk management plan, these materials are not harmonized and are of national competence. When a member state propose to have an harmonize view on this programs several suggestions were made and were contemplated one the draft proposal- Ongoing
- e.g.
- Say to whom is directed (target audience)
- Information should be unbiased, objective,
  - Information given should be in accordance with SPC and PIL and other data should be supported by clear references
- Competent authorities should always have passwords to access the content
- Patient/consumer data should be confidential
- This web-sites shouldn’t have link to social networks as Facebook, or others like twitter even if this is push
- Measures to evaluate the program should be measurable

How is the participation Perceived

- *Patients provide insight into new safety signals and risk assessments*
- *Patients improve the quality of product information*
- *Patients make a practical contribution to enhance the value of risk communication*
- *Patients provide inside knowledge of how to ensure risk communications reach the appropriate target audiences*
- *Patients input into strategic discussions on a wide range of topics from ADR reporting systems to drugs and driving*

Dr. June Raine, Chair of the PhVWP

In Practice

- 3 days from Monday to Wednesday every month
- Constantly changing. Some 30 + items on particular medicines the first two days: signals, conclusions of assessment reports, CHMP questions , adoption of reports etc.
- Policy and regulatory affairs
- Side activities: Drafting groups, video-conference with FDA, working groups etc.
- One teleconference before the meeting

Impressions

- First meetings are complex and very intense , many issues, jargon, missing the context
  - Workload
  - Personal investement
  - Motivation

Considerations for the future

- There is support but
  - Manual to new comers to help them understand the regulatory framework, acronyms would be very useful

Personal views

- **Thank you**