The EMA: Patient involvement in EMA Committees, the PRAC in Particular

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Meeting of the PCWP with all eligible organisations:

December 11, 2013

Content

- Patient involvement in EMA committees
- Short history of involvement in pharmacovigilance
- The role of a patient expert at the PRAC
- Personal observations
- How to follow the PRAC

Patient involvement in EMA committees and the PCWP (I)

- Patients' and Consumers' Working Party: 15 organisations represented; 36 eligible organisations
- Management Board: 1 patient
- Committee for Medicinal Products for Human Use (CHMP): 0 patients. Scientific Advisory groups: 1 or 2 patients
- Committee on Orphan Medicinal Products (COMP): 3 patients

Patients involvement in EMA Committees (II)

- Committee for Advanced Therapies (CAT): 2 patients
- Paediatric Committee (PDCO): 3 patients
- Committee on Herbal Medicinal Products and Committee for Medicinal Products for Veterinary use (CVMP): 0 patients
- Co-ordination Group for Mutual Recognition and Decentralised Procedures-human (CMDh): 0 patients.

Directive 2010/84/EU and Regulation (EU) no 1235/2010

- Pharmacovigilance rules are necessary for the protection of public health in order to prevent, detect and assess adverse reactions to medicinal products placed on the Union market, **as the full safety profile of medicinal products can only be known after they have been placed on the market.**

Patients' Involvement in Pharmcovigilance activities

- 2009: trial, observer and alternate at three meetings of the PhVWP
- 2010 -2012: Observer and alternate at the PhVWP
- From April 2013; Member and Alternate at the PRAC
- Involved patient representatives: David Haerry, Greetje Goossens, Christina Cabrita, Marco Greco and Albert van der Zeijden

The role of the patients' representative

- Same as all other members, with special expertise
- To add patients' experiences and perspectives to the expertice of regulators and other experts
- Not the watchdog of patients organisations wanting a particular outcome
- To contribute to the opinion building on benefit risk assessments of medicines, the readability of texts like PL's, DHPC's etc.

A regular PRAC agenda (66 pages, 209 items): November 2013

- EU referral procedures for safety reasons: urgent EU procedures (4 items)
- EU referral procedures for safety reasons: other EU referral procedures (11 items)
- Signal assessment and prioritisation (12 items)
- Risk management plans (RMP) (53 items)
- Periodic safety update reports (PSUR) (38 items)
- Post authorisation safety studies (PASS) (23 items)

A regular PRAC agenda (more)

- Renewals of marketing authorisation, conditional renewals and annual reassessments (15 items)
- Product related pharmacovigilance inspections (4 Items)
- Other safety issues for discussion requested by the CHMP or the EMA (6 items)
- Other safety issues for discussion requested by the member states (3 items)
- Organisational, regulatory and methodological matters (Orgam) (40 items)

Observations

- Cannot read all documentation, but no single person can
- Meetings 4 days, 11 month’
- Long working hours, commonly 8.30 to 19.30 on Tuesday and Wednesday
- Patients’ representative must have experience with regulatory affairs on the EU level
- Lots of jargon and abbreviations
- EMA staff very supportive
- Cooperation of representative and observer enriches the input of both

Follow the PRAC, publicly available information

- The agenda of the PRAC, on the Tuesday of the meeting
- The minutes of the PRAC meeting: a month after the meeting
- Highlights of the just ended meeting: the day after the meeting from 14.00 GMT
- Always available: the meeting dates, the members of the PRAC and their DOI and CV