EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Patients/healthcare professionals involvement in benefit/risk assessments

Pharmacovigilance stakeholders forum 15 Sept 2014

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EMA interaction with patients and healthcare professionals

- Since the beginning the EMA has been engaging with these stakeholders
- Based on “Frameworks of interaction”, adopted by EMA Management Board
- Any organisation representing EU patients, consumers or healthcare professionals may work with the Agency, if they meet defined eligibility criteria
- Large network of organisations and individuals involved in many EMA activities

New Pharmacovigilance legislation

Creation of the PRAC;

- Patients and healthcare professional representatives included as full members
  - First time involved within committee discussions on benefits & risks
  - Patient's role is to ensure that their perspectives (based on real-life experience as end users) are delivered throughout the committee's activities and outcomes
  - HCPS' role is to ensure that the potential impact of regulatory decisions in clinical practice are taken into account and to highlight specific areas where additional input from the wider healthcare professionals' community can support the committee's activities

Involvement in implementation of pharmacovigilance legislation

The Patients and Consumers Organisations Working Party (PCWP) & The Healthcare Professionals Working Party (HCPWP):

- Involved throughout different phases of the implementation, particularly;
  - ADR reporting
  - Additional monitoring - Black symbol
  - Development of Public hearings
  - Participation in dedicated pharmacovigilance stakeholder forum meetings
  - Dissemination via their networks

Eligible organisations: patients / consumers

Eligible organisations: healthcare professionals

Requirements for involvement in benefit/risk evaluations

- Identify situations where they bring added value
- All participants treated as any other EMA experts and declare any potential conflicts of interest and sign a confidentiality agreement
- Ensure that patients' and healthcare professionals' views come from independent sources
- Receive personalised support

Patients / healthcare professionals routinely involved throughout medicine lifecycle

Medicines development:

- Participation in scientific advice/protocol assistance procedures

Medicines evaluation: pre and post authorisation

- Participation in scientific advisory group (SAG)/ad-hoc expert group meetings convened by CHMP/PRAC
- Participation in ad-hoc written consultations on specific medicines with scientific committees and working parties

Communication on medicines:

- Review of SmPC, PL, DHPC & safety communications

Further developments

Patients to be involved in CHMP meetings

Patients (affected by the disease/condition under discussion) will be invited to participate directly within oral explanations at the CHMP;

- Where their involvement can bring added value to the B/R discussion (case-by-case)
  - Likely negative recommendation where there remains an unmet medical need, or restriction of an indication where a significant impact is expected;
  - Likely recommendation to withdraw, suspend or revoke a marketing authorisation, or restrict an indication of an authorised medicine, with expected high impact in patient population
- Initial pilot phase; analysis and outcome report after one year
- Similar developments could be discussed in PRAC..

Examples of involvement within benefit / risk discussions

Written consultations, examples…

Humalog / Liprolog - Extension of indication : concerns regarding introduction of a new high strength and how to ensure its safe and correct use

- Consultation with patients & HCPs to obtain input on how best to minimise potential risk of medication errors
  - Input received prompted the PRAC & CHMP to request further changes to the labelling (differentiations of strengths).
  - The MAH subsequently amended the labelling and other measurements in the risk minimisation plan.

Face to face consultations, examples…

Article 107i referral procedure – methadone – PRAC review into misuse of oral methadone containing povidone leading to ADRs

- Patient expert participated in expert group meeting;
  - provided valuable information on current use and misuse of oral methadone, adherence to therapies and views of associated risks,

Face to face consultations, examples…

Article 31 referral procedure - hydroxyethyl-starch-containing solutions for infusion (HES) – PRAC review on increased risk of mortality in patients with sepsis and an increased risk of kidney injury requiring dialysis in critically ill patients following treatment with HES solutions.

- Nephrologists and intensivists participated in expert group meeting;
  - provided valuable information on the current utilisation of HES and the efficacy and safety of HES in clinical practice

Face to face consultations…

Article 31 referral procedure - review of Valproate ; PRAC review of new information on risk of long-term developmental problems in children whose mothers took Valproate

- Patient meeting– included epilepsy, bipolar disorder and migraine patient organisations and organisations representing the patients, families and carers affected by valproate
  - Very constructive exchange of information; patients shared their personal experiences and provided input on how best to raise awareness for all concerned; in turn allowed PRAC to explain the assessment process
  - The need to consult with HCPs was very much emphasised by patients
- PRAC also initiated consultation with relevant HCPs organisations to obtain information on communication, awareness & understanding of risks
  - Valuable input will be taken forward by the PRAC in reaching its recommendation

The impact of interaction

- Today *real life* aspects from patients included within EMA *scientific* assessments
- Healthcare professionals bring the *reality* of clinical practice into the *regulatory* discussions
- Increases transparency and builds confidence in the regulatory system
- Involvement at operational level leads to tangible impact on outcomes e.g.
  - Patients' views on benefit-risk deliberations contribute to final recommendations from the committees
  - Review of product information and safety communications - comments are taken into account and lead to amendments
  - Overall improves the outcome of regulatory decisions

Thank you