EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Collaborations with GPs in evaluation procedures – experience and opportunities

EMA Workshop on the collaboration with General Practitioners/Family Physicians

19 April 2016

Presented by Heidi Janssen
Head of Endocrinology, Metabolism and Cardiovascular

Scientific Advisory Groups (SAGs) - Experience

- Provide independent recommendations to the Agencies scientific committees on scientific matters related to the evaluation of specific types of medicines or treatments
- Composed of independent European experts (core group + additional experts, as needed)

Experience:

- GPs have been involved in some SAGs: e.g. SAG Tresiba (insulin degludec) 200 UI/ml strength – concern of medication error
- SAG vaccines: GP as core member
- For some cases, value identified but difficulties to identify timely GPs

Scientific Advisory Groups - Opportunities

Opportunities:

- Increased involvement of GPs in SAGs for specific therapeutic areas and specific topics would be very useful
- Format for reflection by EMA and GPs: e.g. regular involvement in specific SAGs/ therapeutic areas, when SAG is discussing the need for risk minimisation measures and their implementation (labelling, educational material,…),…

Risk minimisation activities - experience

Experience:

- Review of EMA safety communications: hydroxyzine-containing medicines; ambroxol and bromhexine expectorants; codeine; adrenaline auto-injectors; HPV vaccines
- EMA/QRD consultation: heart failure medicine (How to minimise the risks of medication errors at the level of prescribing, dispensing and/or administering)
- EMA/PRAC consultation with HCPOs - in the context of the review on codeine (cough)
- Cross-Committee Task Force on patients registries-meeting

Risk minimisation activities - opportunities

Opportunities:

- Involvement of GPs in labelling and additional risk minimisation measures (aRMM) would be beneficial to:
  - increase clarity of messages,
  - inform on important points relevant for clinical practise (across Europe !)
  - support discussions on medication errors,
  - provide input regarding the content of the planned risk minimisation measures(educational material, physician guides, DHPC,…),…,
  - provide feedback on the implementation of risk minimisation measures and its modalities

Risk minimisation activities – opportunities (cont)

Format of involvement for reflection by EMA and GPs:

- Involvement of GPs when a HCP consultation process on labelling is organised during evaluation processes e.g. medication errors
- Review of product information and aRMM in the context of safety reviews (signals, referrals,…) and its communication
- Involvement at time of imposition of additional risk minimisation measures in terms of design and feasibility
- Provide input on the studies aimed to measure the impact of risk minimisation measures when targeted to GPs

Other areas of useful GP involvement in evaluation

- Evaluation of experience in real clinical practice with more engagement in post-marketing studies in order to continuously improve benefit-risk of medicines throughout their life-cycle for a best “place in therapy”
- Input in Guideline/Guidance development: e.g. during consultation phases of guidelines, EMA workshop => relevant areas could be identified

Input from General practitioners in evaluation activities: Opportunities

- Input in SAG/Ad-hoc expert group meetings
- Review of labelling aspects and aRMM including implementation
- Review of safety communications and DHPCs (including prevention of medication errors)
- Collection of data generated in clinical practice (eHealth records; registries; etc.)
- SCs/WPs consultations (standard of care; risk minimisation measures; product information)
- Participation in EMA workshops
- Participation in user tests and technical groups supporting implementation of new legal requirements