EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enablers and barriers to measuring impact – patient and healthcare professional engagement (3.1)

Session 4 - Reports from breakout sessions: gaps and observations

Workshop: Measuring the Impact of Pharmacovigilance Activities
London, 5-6 December 2016

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Session 3.1 Topics

1. **Defining engagement – awareness and perception of public health measures**
   Patrick Brown, University of Amsterdam

2. **ISPE paper "Evaluating the Effectiveness of Additional Risk Minimisation Measures via Surveys in Europe: Challenges and Recommendations"**
   Rachel Sobel, Pfizer Inc. and Terri Madison, Mapi Group

3. **Patient reporting in EudraVigilance – a measure of patient engagement?**
   Marin Banovac, European Medicines Agency

1. Discussion points

- Need to be sensitive to various actors in stakeholder engagement;
- **Trust** is essential
  - Trust in industry initiatives is a barrier – needs to be improved;
  - If this is not possible the routes of communication needs to be adjusted;
  - Differentiate ‘blind’ trust versus ‘critical’ trust;
- Regulators are a trusted source for information but success depends on health literacy (target the right groups and ensure they understand the message;
- Also avoid negative messaging (pill scare) and focus also on positive aspects such as benefits of the product (which helps to build critical knowledge and trust);
- Focus on continuous HCP **and** patient education (as long term strategy to share best practice, “education with the goal to cultural change”)

Examples

- Focus on very simple methods for raising attention (e.g. one single DHPC per action in each MS);
- Focus on universal tools for reporting ADRs;
- Need to focus on the research question, i.e. what are the objectives of the regulatory action and how can these be measured?
  - But requires common understanding of underlying concepts (GVP vs CIOMS);
- NCAs should take ownership and implement uniform measures, consider the right communication channels to reach HCP and patients;
- Complex regulatory context leads to difficulties in carrying out research (e.g. conducting surveys for generics where product identification is an issue);
- Address methodological issues with surveys (low response rates; low scientific reputation; challenges with regulatory classification of survey);

2. Key findings

- Insights from quantitative research methods may be enhanced through triangulation (i.e. survey data combined with data on behavioural outcomes and qualitative data);
- Engagement (HCPs and patients) should go beyond reporting but also focus on participation in studies;
- Careful evaluation whether each PhV activity needs an impact measure?
  - Consider before the measures are implemented and define measures of success (if possible);
  - Early planning of impact evaluation before taking regulatory actions (e.g. unintended consequences, what is the expected impact?);
- Collaborative approach to inform HCP and patients about safety measures (e.g. additional risk minimisation measures) to overcome regulatory limitations?

3. Challenges and gaps

- Surveys:
  - due to low response rates put operational challenges in context of the disease;
  - is a survey the right measure or do qualitative techniques like focus groups provide more meaningful information?
- Gap in understanding of patient perceptions and how patients value risk;
- Not solely focus on patients but also HCP engagement and consider multiple relations;
- Engage with the lay press to be more positive on pharmacovigilance and health-related communications;

4. Recommendations

- Long term goal would be that people should take more responsibility for their health, but that requires a change in attitude and competences to be supported by education;
- Closer collaboration with patient communities to establish their needs (2-way dialogue and include patients in all steps);
- Recognising the heterogeneity of risk communication;
- Standardised format for patient reporting (e.g. global format, easy to read and to enter the information)
- Communication should focus on proper use of medicines across countries;
- For specific suggestions and proposals on surveys see ISPE white paper;
- Capacity building and understanding where patients can provide input (e.g. regulatory processes, risk communication etc.)

5. Conclusions

The overall question of this session is how engagement can be an enabler (or barrier?)?

To answer this we need to understand and establish

- **Awareness of pharmacovigilance**
- **Trust of patients and HCPs in the regulatory system**
- **Confidence that their contribution to impact assessment will make a difference**
- **Feasible methods** to measure engagement as a prerequisite for impact research (cost, time, skills, data protection, technical means, social media etc.)