EMA framework for engagement

Multi-stakeholder workshop on patient experience data in medicines development and regulatory decision-making

Presented by Maria Mavris on 21 September 2022
Patients and Consumers Liaison, EMA
Framework with patients, consumers and their organisations

Updated framework establishes the basis for:

- supporting access to individual patients’ real-life experiences
- promoting the generation, collection and use of evidence-based patient experience data for benefit-risk decision-making;
- enhancing patients and consumers understanding of medicines regulation and their role
- contributing to efficient and targeted communication to patients and consumers to support their role
Engagement framework pillars:

1. A network of European patients’ and consumers’ organisations
2. Patients’ and Consumers’ Working Party (PCWP)
3. A pool of individual patients, consumers or carers
4. Capacity-building and training
5. Range of engagement methodologies
6. Patient experience data
7. Interaction with the EU Regulatory Network

Eligible patients and consumers organisations
Patient engagement – added value and impact

Scientific Advice
- 4 year study published
- Added value of patient input quantified and demonstrated

Review of documents
- Comments and suggestions by patients incorporated into published documents
- Template structure changed

CHMP early contact
- 17 month pilot completed
- Positive impact – will be maintained as new methodology

Safety monitoring
- Public hearings – recommendations leading to risk minimisation measures

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Classified as internal/staff & contractors by the European Medicines Agency
Conclusion

• Further development of patients’ capacities, including training and other support measures

• EMA looks to incorporate additional engagement methodologies

• Expand use of real-world evidence, patient reported outcomes, patient preferences and patient experience data, which is beneficial for public health in the EU
Thank you

Further information

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