Patient Experience Data (PED) - Update on progress

Joint PCWP/HCPWP meeting, 28 June 2023

Presented by Rosa Gonzalez-Quevedo, PhD
Public and Stakeholders Engagement Department

An agency of the European Union

Outline

- Status of PED in the EU
- Progress on actions agreed at the 2022 Patient Experience Data Workshop
- Conclusions

Status of PED in the EU

- Reinforcing patient relevance in evidence generation is a **key priority** in **EMANs** and the **Regulatory Science Strategy**
- Although there has been much progress in the EU in recent years, **PED are still not systematically included** in all aspects of medicines development and regulation
- **Stakeholder agreement on the relevance of PED** for medicines development and benefit-risk evaluation
- PED is also relevant in the context of **the implementation of the new Health Technology Assessment (HTA) regulation**, thus in **value assessments** that inform subsequent decisions by payers
- **Guidance work ongoing at ICH for global harmonisation** of Patient Experience Data (PED)

Actions – Overall strategy on Patient Experience Data

✓ On the basis of the workshop's outcomes, **EMA will enable discussions within the Network on current status, next steps and how to monitor progress**

- EMA is preparing a list of actions and priorities that will be shared with stakeholders, including PCWP and HCPWP

Actions - Need for regulatory guidance

- ✓ **The Agency will elaborate a reflection paper** to provide advice on the best EU approach to generate and collect PED
  - EMA has set up an internal working group to coordinate cross-Agency expertise and draft the reflection paper, in collaboration with Network experts
  - Drafting planned for Q3-Q4 2023 and public consultation by Q1 2024

- ✓ **ICH guidance:**
  - EMA supports PED global development and will contribute to ICH work on PED guidelines

Actions - Alignment among decision-makers needed

- ✓ Agreed to continue **multilateral stakeholder cooperation** to obtain the best regulatory outcomes, and to explore additional engagement opportunities (e.g., focus groups or workshops) for key topics
  - Currently, the priority for EMA is to draft the reflection paper and publish it for consultation
  - Any other multistakeholder discussion (such as focus groups or workshops) will be considered during the public consultation.
  - EMA has held discussions with:
    - EUnetHTA
    - PCWP/HCPWP
    - FDA patient cluster
    - Big Data Steering Group
    - Industry discussions for Industry Platform meeting

Actions - Need for further transparency on decision-making

- ✓ EU regulators will explore how to **better reflect in the assessment report (AR) the way PED is assessed** as well as the rationale for acceptance/exclusion for Benefit/Risk decision-making
  - Agreed to introduce a section on PED on the AR template
  - Internal reflection being initiated
- ✓ Further consideration should be paid to the way **PED is reflected in the product information**
  - To be considered at a later stage – priority given to AR template

Actions - Need for further transparency on decision-making

- ✓ For orphans, **PED is also important for discussing significant benefit** at time of reviewing the maintenance of the status at time of marketing authorisation application, and it can also be explored how to best reflect PED in the orphan maintenance assessment report
  - Further discussion with industry and stakeholders

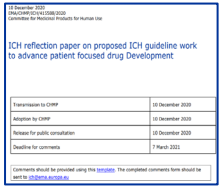
Actions - Digitalisation of patient-generated health data

- ✓ **Integration with ongoing activities in the European Health Data Space and the Big Data work plan 2022-2025** are ongoing, and the patient voice will continue to be gathered and used in these forums.
- ✓ In particular, recommendation 3 on data discoverability includes a **review on the utility of eHealth data in Q4 2023**
  - Working closely with BDSG – BDSG workplan is being updated with actions on PED

Actions - Need for resources and technical expertise

- ✓ As part of the overall strategic plan to advance PED generation, the Agency will look into different **options to increase capacity and adequate training**
- ✓ This includes **training in areas relating to digital data** included in the Big Data work plan 2022-2025, specifically in the recommendation 4 on strengthening the EU Network skills by offering training modules to patients, healthcare professionals & academics in Q4 2023
    - Survey Patients training needs – Q1 24

Conclusions



- **PED is a new scientific discipline** – balance difficult methodological discussions with stakeholder engagement
  - **Collaboration of multi-disciplinary experts cross-Agency and EU Network is needed** to coordinate activities and provide content input into the deliverables
- The **EMANS' delivery plan** and **CHMP's 2023 workplan** incorporate two key deliverables:
  - **Reflection paper** on the best EU approach to generate, collect and analyse PED
  - **Explore how to improve transparency in the AR**
- **EMA has started work on the deliverables** by pooling cross-Agency expertise on PED

Thank you for your attention

Further information

rosa.gonzalez-quevedo@ema.europa.eu & juan.garcia@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on **@EMA_News**