HPR138

HOW ARE PATIENT EXPERIENCE DATA REPORTED IN REGULATORY EVALUATION OF MEDICINAL PRODUCTS ? *A document analysis of European public assessment reports*

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BACKGROUND & OBJECTIVE

Patient experience data (PED) covers diverse **types of data**: Patient reported outcomes (PROs); Patient reported experiences (PREs); Patient preferences (PP); Patient input (PI)

Increased importance on the **use of PED** in **healthcare decision making**

Unclear **if, how and to what extent PED** is currently considered by the European Medicines Agency (EMA) **in marketing authorization**

Are PED reported in European public assessment reports (EPARs)?

How and to what extent are PED reported?

What are the learnings in the field of COVID-19 and Oncology?

METHODS

Document analysis of EPARs

- Published between 1/1/2015 – 30/9/2022

ANALYSED EPARs	
COVID-19	
Vaccines	6
Treatments	8
ONCOLOGY	
Breast neoplasms	28
Neuroendocrine tumours	11
Neuroblastomas	1
Ovarian neoplasms	5
Endometrial neoplasms	2

RESULTS – *Preliminary findings*

Patient input

- Reported in 51 (84%) of the analysed EPARs
- Full user consultation for the package leaflet
  - In 6 (43%) of the COVID-19 EPARs
  - In 39 (83%) of the Oncology EPARs
- Electronic diaries
  - In 8 (57%) of the COVID-19 EPARs
  - In 2 (4%) of the Oncology EPARs

Patient reported outcomes

- Reported in 2 (14%) of the COVID-19 EPARs
- Reported in 23 (49%) of the Oncology EPARs
- Section: ‘results section’; few times in the ‘benefit-risk’ section

Patient preferences

- Reported in 1 (2%) of the Oncology EPARs

Patient reported experiences

- Reported in 1 (2%) of the Oncology EPARs

CONCLUSION – *Preliminary findings*

- **Patient input** most common type of PED in Oncology and COVID-19 products
- More **transparency & guidance** needed on:
  - What **PED** are and what it entails **(definitions)**
  - How and where **to include PED** in **regulatory submissions**
  - Whether **PED** are **considered by the EMA**

LIST OF ABBREVATIONS

PED: patient experience data; EMA: European Medicines Agency; EPAR: European Public Assessment Report; PI: patient input; PRO: patient reported outcome; PRE: patient reported experience; PP: patient preference

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