




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**





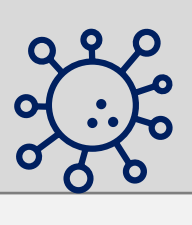

Are PED reported in European public assessment reports (EPARs)?
How and to what extent are PED reported?
What are the learnings in the field of COVID-19 and Oncology?

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 ABBREVIATIONS

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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