

PATIENT ORGANIZATIONS' BARRIERS IN PHARMACOVIGILANCE AND STRATEGIES TO STIMULATE THEIR PARTICIPATION

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Key Points

- Patient organizations face both external and internal barriers in being more involved with pharmacovigilance
- Strategies to stimulate patient organizations participation are the creation of more awareness campaigns, education for patient organizations and more proactive approach from national competent authorities, among others
- An environment where patient organizations can actively engage and contribute as stakeholders will benefit pharmacovigilance

INTRODUCTION

European drug regulations aim for a patient centered approach, including involving patients in the pharmacovigilance (PV) systems. However many patient organizations (POs) have little experience on how they can participate in pharmacovigilance activities.

The **aim of this study** was to understand POs perception towards PV, the barriers they face when implementing PV activities, their interaction with other stakeholders and suggest methods for the stimulation of POs as promoters of PV.

METHOD

A sequential qualitative method study was conducted and integrated with the quantitative study performed by Matos, Weits and van Hunsel [1] to complete a mixed method study.

RESULTS

The qualitative phase expands the understanding of the quantitative results from a previous study by broadening the knowledge on external barriers and internal barriers that patient organizations face when implementing pharmacovigilance activities.

The strategies to stimulate patient organizations participation are the creation of more awareness campaigns, do more research which creates awareness, education for patient organizations, communication of real pharmacovigilance examples, creation of a targeted pharmacovigilance system, create a pharmacovigilance communication network which provides feedback to patients, improvement of understanding all stakeholders and more proactive approach from national competent authorities.

Table 1. Overview Interviewed POs

Interview order	Country	Disease	Type of organization	Interviewee Gender	Interview date
1	Norway	Hearing disorders	Pan European	Female	8-3-2019
2	Spain	Multiple Diseases	PO Coalition	Male	11-3-2019
3	Netherlands	Multiple Diseases	Umbrella	Male	13-3-2019
4	United Kingdom	Spinal Muscular Atrophy	National	Female	21-3-2019
5	International (UK interviewee)	Multiple diseases	Umbrella	Male	21-3-2019
6	Luxemburg	Epilepsy	National	Female	22-3-2019
7	Portugal	Diabetes	Umbrella	Male	28-3-2019
8	Germany	Multiple diseases	National	Female	29-3-2019
9	Sweden	Melanoma	Pan European	Female	5-4-2019
10	Ireland	Mental Disorders	National	Male	5-4-2019
11	Croatia	Myeloma	National	Female	8-4-2019
12	France	Multiple (rare)diseases	Umbrella	Male	17-4-2019
13	Netherlands	Pituitary disorders	National	Male	16-4-2019
14	Portugal	Rheumatic diseases	National	Female	18-4-2019
15	Croatia	Multiple Diseases	Umbrella	Male	24-4-2019
16	Switzerland	Prostate and Testicular Cancer*	National	Male	29-4-2019

CONCLUSION

Both study phases show congruent results regarding patients' involvement and the activities patient organizations perform to promote drug safety. Patient organizations progressively position themselves as stakeholders in PV, carrying out many activities that stimulate awareness and participation of their members in drug safety but still face internal and external barriers that can hamper their involvement.

ACKNOWLEDGEMENTS & REFERENCES

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[1] Matos C, Weits G, van Hunsel F The Role of European Patient Organizations in Pharmacovigilance. Drug Saf. 2018.

