

1. ABSTRACT

1.1 Title

Evaluation of the Effectiveness of Risk Minimisation Measures: A Joint PASS Survey among Health Care Professionals to assess their Knowledge and Attitudes on Prescribing Conditions of valproate in France, Germany, Spain, Sweden and United Kingdom

Version n°2.0: 09 May 2017

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1.2 Keywords

Valproate, Safety, Dear healthcare professional communication, Educational Materials
Risk minimization measures.

1.3 Rationale and background

Children of women exposed to valproate and related substances during pregnancy are at a high risk of congenital malformations and/or serious developmental disorders. The summary of product characteristics (SmPC) was updated and dear healthcare professionals communication (DHPC) and educational materials (EM) were distributed to healthcare professionals (HCPs) aimed to ensure safe use of valproate as per recommendation by PRAC. This joint PASS survey was designed to assess the effectiveness of the DHPC and EM, whether part of the measures implemented, whether physicians understood and followed the updated prescribing conditions and safety warnings/information they received when prescribing valproate.

1.4 Research question and objectives

Research question:

Were the DHPC and EM effective in:

- increasing correct knowledge of physicians about prescribing conditions and safe use of valproate,
- influencing attitude when prescribing valproate

Objective:

To measure the proportion of targeted physicians who:

- only prescribed valproate for epilepsy and bipolar disorder in women if other treatments were ineffective or not tolerated
- ensured that the treatment was supervised by experienced physicians
- considered alternative treatments for female planned to be pregnant
- regularly reviewed the treatment need and re-assess the balance of the benefits and risks for female patients and girls reaching puberty on valproate
- informed patients of the risks of taking valproate during pregnancy and advised female patients taking valproate about effective contraception during their treatment.

1.5 Study design

An anonymous, cross-sectional, multinational and non-interventional survey among HCPs in France,

Germany, Spain, Sweden and United Kingdom.

1.6 Setting

The survey was conducted during 17th June 2016 to 25th August 2016 through a web questionnaire among prescribers of valproate in settings of 5 European countries.

1.7 Subjects and study size, including dropouts

Among a total of 1153 physicians who completed the questionnaire, 255 were from France, 254 were from Germany, 244 were from Spain, 136 were from Sweden and 264 were from the UK.

1.8 Variables and Data sources

The primary data on physician's demographics and practice information, knowledge, awareness about and attitude towards prescribing conditions and safety information/warnings and prescriptions records were collected.

1.9 Results

95.5% of physicians only prescribed valproate for epilepsy and bipolar disorder in women if other treatments are ineffective or not tolerated, 92.1% of physicians always informed patients about the risks of taking the drug during pregnancy before prescribing valproate and/or related substances to a female of childbearing potential, and 94.4% of the physicians advised the patient about using an effective contraception during the treatment before prescribing valproate and/or related substances to a woman of childbearing potential. Those who acknowledged receipt of both the DHPC and the EM have higher success rates in each criteria compared to those who mentioned they had received neither of them. In total, 86.5% of physicians responded that valproate should be prescribed for epilepsy with generalised seizures, 75.9% for epilepsy with partial seizures with and without secondary generalization, 62.5% for bipolar disorders and 37.2% for migraine prophylaxis.

1.10 Discussion

The survey found that the majority of participating physicians were knowledgeable about the indication and the safety aspects of prescribing and using valproate. The observed success rate on each criteria of success tended to be higher among physicians who acknowledged they received DHPC and/or EM compared to those who had not. Although a low recall of the receipt of DHPC or EM, the overall physician knowledge on the indication and safe use of valproate was relatively high. The low recall of receiving the DHPC and EM was similar to the rate observed in comparable surveys. Furthermore, such low recall rate could also reflect that physicians received a large amount of medical and promotional materials.

1.11 Marketing Authorisation Holders (MAHs)

Consortium of companies.

The full list of all MAHs (Companies and/or their Affiliates and licensors) and address is provided in Annex 3.2.

1.12 Names and affiliations of principal investigators

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