Abstract

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 Trimetazidine in Bulgaria, Czech Republic, Estonia, France, Hungary, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, and Spain

Date of abstract: 18 January 2016 (Version 2.0)
Authors: Dorothea von Bredow, PhD, Project Manager, IMS RWES Germany;
Dr. Massoud Toussi, Principal, Medical Director IMS RWES France

Keywords

Cross-sectional; Survey; Prescribing Conditions; Trimetazidine; PASS

Rationale and background

In September 2012, the Committee for Medicinal Products for Human Use (CHMP) restricted the use of Trimetazidine (TMZ) to an add-on therapy for patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line anti-anginal therapies. TMZ was no longer indicated in ophthalmology and otolaryngology.

The survey presented here is designed to evaluate the effectiveness of these risk minimization measures (RMM) regarding the knowledge, attitude and prescribing behaviour of the physicians in the targeted countries.

Research question and objectives

The primary endpoint was the proportion of physicians knowing and prescribing TMZ, who received, understood and agreed to implement the updated information about TMZ provided in the DHPC. Secondary objectives were to determine the number of prescriptions within the licensed indication and prescribing conditions in terms of patient characteristics (age, gender) and prescription information (form of administration, dosage, new or repeated prescriptions, planned duration of usage, treatment situation, reason for choosing TMZ, discontinuation plan for patients already on TMZ).

Study design

This is a multi-national, cross-sectional, non-interventional and anonymous survey.

Setting

The survey was conducted among prescribers, or potential prescribers (ENT-specialists, ophthalmologists, cardiologists, others (GPs, internists, geriatricians) of TMZ in Bulgaria, Czech Republic, Estonia, France, Hungary, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, and Spain.

Subjects and study size, including dropouts

Survey, 15,957 physicians were targeted, while 3,938 were contacted successfully. Among them, 2,264 agreed to participate in the survey. 37 physicians were screened-out for being affiliated with a pharmaceutical company or a regulatory body, 261 due to not knowing TMZ and 639 due to not prescribing TMZ within the last year. 204 physicians opted out during the survey, 1,123 completed the questionnaire (83 ENT-specialists, 66 ophthalmologists, 199 cardiologists, 775 GPs/ internists/ geriatricians) and reported 7,617 prescriptions.

Variables and data sources

Physician related data about their knowledge and prescribing attitude for TMZ and prescription data were recorded.

Results

One-fifth of the participating ENT specialists were not willing to comply with the updated safety information, particularly in France and Portugal. Country-specific differences were observed in prescribing behaviour: 95-100% of ENT specialists and ophthalmologists were screened out completely in Bulgaria, Estonia, Hungary, Latvia, Lithuania and Slovakia due to not knowing or not using TMZ. Furthermore, in Bulgaria, Czech Republic, Estonia, Latvia, Hungary, Romania and Slovakia, the willingness of prescribers to comply with the latest safety information was substantially higher (98 to 100%) than in France, Lithuania, Poland, Portugal and Spain (86 to 89%). Prescription information indicated similar results: most prescriptions by cardiologists were within the label, whereas ENT specialists or ophthalmologists did not use TMZ at all, or if they did, the prescriptions were frequently off-label.

Discussion

In summary, the results indicate that there are different prescribing behaviours among physicians: Approximately two-thirds of the contacted ENT specialists and 80% of the ophthalmologists did not prescribe TMZ and were therefore screened-out. Particularly in Bulgaria and Hungary where use of TMZ was licensed for ENT indications prior to September 2012, this may be a result of the RMM, though it is not known whether this is also true for other countries. However, the data show that only a minority of all prescriptions in the survey were issued by ENT specialists or ophthalmologists. Yet, when TMZ was prescribed by these specialists, it was usually not within the licensed indication, suggesting a lack of knowledge among some of the prescribers, particularly in France, Spain and Portugal where further training may be required.

Among cardiologists, the screen-out rate for not knowing or prescribing TMZ was much lower. Considerable knowledge and willingness to comply with the safety information was available among cardiologists, as shown by their prescribing behaviour, but further improvements are desired.

The impact of the updated safety information on the overall number of prescriptions before and after introduction of the RMMs is investigated in a parallel drug utilization study.

Marketing Authorisation Holder(s)

Consortium of companies represented by Lupin (Europe) Limited. Please refer to Annex 1; List of Companies (and/or their Affiliates and licensors) that are part of the consortium.

MAH contact person:

Katja Gleisner, Head of Pharmacovigilance / EU Qualified Person for Pharmacovigilance (EU QPPV), Lupin (Europe) Limited, located at:

Hormosan Pharma GmbH
Wilhelmshöher Straße 106
60389 Frankfurt/Main - Germany
E-Mail: KGleisner@hormosan.de
Phone: +49 (0) 69 - 47 87 30

Names and affiliations of Principal Investigator

IMS Health Real World Evidence solutions (IMS RWES)
Tour Ariane, 5-7 Place de la Pyramide,
92088 La Défense Cedex, France.
Dr. Massoud Toussi, Principal, Medical Director, IMS RWES, France