THE IMPACT OF THE NEW PHARMAVOGILANCE LEGISLATION ON THE HARMONISATION OF DIRECT HEALTHCARE PROFESSIONAL COMMUNICATIONS ACROSS EUROPE

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Declaration of interest: This study was performed under the umbrella of the Copenhagen Centre for Regulatory Science (CORS). CORS is a cross-faculty university anchored institution involving various public (Danish Medicines Agency, Copenhagen University) and private stakeholders (Novo Nordisk, Lundbeck, Ferring pharmaceuticals, LEO pharma) as well as patient organisations (Rare Diseases Denmark). The centre is purely devoted to the scientific aspects of the regulatory field and with a patient-oriented focus and the research is not company-specific product or directly company related.

Introduction

Background

Until today, significant inequalities in healthcare persist around the world and within Europe. In order to realise more equality in quality of healthcare, safety information should be equally harmonised across the EU. This is one of the objectives of the new pharmacovigilance (PV) legislation effective from 2012, giving particular consideration to the harmonisation of Direct Healthcare Professional Communications (DHPCs) across Europe. DHPCs (or ‘Dear Doctor-letters’) are communications by which valuable safety information is sent directly to individual healthcare professionals, to inform them of newly surfaced safety information.

Aims

To determine if the pharmacovigilance legislation had an impact on the harmonisation of DHPCs issued among countries under the jurisdiction of the EMA. A priori, a higher rate of harmonisation in the availability of DHPCs in the EU was expected to be seen in the years after the new pharmacovigilance legislation had come into effect compared to the period before that.

Methods

Data collection

The impact of the PV legislation was studied using a pre-post study design including DHPCs from 6 EU countries; Austria, Czech Republic, France, Germany, Ireland, and Spain. DHPCs disseminated between 2007 and 2011 and between 2013 and 2017 by the national competent authorities (NCA) of the 6 countries were identified through their respective webpages in April ‘18.

DHPCs which did not fulfil the GVP module XV list of situations for which a DHPC should be disseminated were excluded. For all letters, information about the dissemination date, the medicine concerned (recorded by ATC code), a statement on NCA or EMA involvement and the general topic was collected. The authorisation procedure, either by which valuable safety information is sent directly to individual healthcare professionals, to inform them of newly surfaced safety information.

Results

A total of 1939 DHPCs were identified from the 6 NCAs. Of these, 1325 were included in the primary search, in an additional search 10 more letters were identified and included (figure 1).

The number of DHPCs per year fluctuated over time, with a peak in total volume in 2013 and a relatively low volume in 2009 (figure 2). Overall, more letters were send out between 2013 and 2017 (441) than the period before the implementation of the PV legislation (709).

The proportion of harmonised DHPCs was significantly higher after the enactment of the new PV legislation than before (67.3% versus 60.5%, p < 0.01). Within the sensitivity analysis, an increase in harmonisation was observed from 29.6% to 52.3% (p < 0.001) in DHPCs issued in all six countries (figure 4).

Conclusion

A moderate improvement in harmonisation of DHPCs disseminated between 2013-2017 and 2007-2011 in six EU Member States was found, largely due to a shift to more fully harmonised messages. It remains unclear whether the harmonisation can be attributed to the impact of the new PV legislation or to national changes instead.

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