Title

**Measuring the effect of risk minimization measures**

PhD
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**Start of research**  
2010  
**Status**  
Doctorate 2015

Background
With the new European pharmacovigilance legislation effective since 2012, monitoring the outcome of risk minimization measures (RMMs) has become mandatory for regulators and marketing authorisation holders. However, the use of some drugs requires additional RMMs (aRMMs), such as a Pregnancy Prevention Programme, to address specific critical safety issues deemed not sufficiently covered by routine RMMs. It is important to determine the preventive effect of aRMMs in clinical practice.

Objective
To provide an overview of products with additional risk minimisation measures (aRMMs), including a description of these measures. To explore the implementation of aRMMs, their preventive effect in clinical practice, and the importance of suitable outcome measures and electronic healthcare databases.

Regulatory impact
To adequately minimize risks and to facilitate the impact assessment of aRMMs in clinical practice, clearly defined aRMMs that lead to unambiguous actions of healthcare professionals or patients are required. The use of aRMMs that are limited to provision of information are considered insufficient. Because aRMM put considerable burden on the healthcare system, care should be taken that their requirement is limited to aRMMs that target specific drug related critical safety issues deemed not sufficiently covered by routine RMMs.

Quote
The number of products with additional risk minimization activities is growing

Academic collaboration
Erasmus University Medical Center Rotterdam

Research track
Consumer use & safety

Research group
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Keywords
Risk Management, additional risk minimisation measure, clinical practice, pharmacovigilance, drug safety

Achievements


