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Commentary

Cost-Effectiveness of Periodic Safety Update Reports

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DESCRIPTION

A Periodic Safety Update Reports (PSUR) is a pharmacovigilance document used to assess the risk-benefit ratio of a medicinal product at a specific point after approval. The purpose of PSUR is to present a comprehensive and critical analysis the balance of benefits and risks of a device in the context of cumulative information on risks and benefits, taking into account new or emerging safety information.

European Medical Agency (EMA) and national competent will evaluate PSUR information to determine if new risks have been identified for a drug and/or if its benefit/risk balance has changed. A PSUR assessment can determine if a particular topic requires further research or if public health protection measures are needed such as updating information provided to healthcare professionals and patients.

Europe Union (EU) legislation introduces the principle of EU individual assessment when a substance is authorized in more than one Member State. The individual evaluation procedure is being phased in and has been in effect for centrally approved products since July 2, 2012. From April 2013, it applies to nationally approved products including products registered *via* MRP or DCP procedures if the active ingredient is also registered as a centrally approved product. An EU individual assessment of his PSUR for active substances contained only in nationally authorized products is expected to start at the end of 2014.

Until harmonized evaluation procedures for nationally certified products are introduced, the evaluation of the PSUR for these products will be based on the currently applicable procedures (EU, PSUR Work sharing and purely national procedures). In addition to facilitating transitional arrangements for a harmonized EU evaluation of PSURs, substances under the PSUR work sharing program and only included in nationally approved products with data lock points before August 2014. Substances that are kept in a separate list, is called the "List of PSUR Work share program substances and other substances contained in nationally certified products synchronized with DLP" and is maintained by CMDH. The PSUR is considered an important pharmacovigilance document by the authorities and is subject to intensive scrutiny during inspections in the EU. PSUR pharmacovigilance regulations are complex, effective scheduling across multiple products can be difficult, and costly duplication of effort can occur.

A Clinical Trial Development and Safety Update Report (DSUR) are required for trials at centers in each EU country. Again, there are standard requirements for content and timing of submissions.

Prime vigilance consultants and staff have years of experience in cost-effective planning and the production of regularly updated safety reports, PADERs and DSURs. Whether it's a single simple DSUR, PADER, or a complex PSUR, it can meet our needs.

The PSUR must include all currently available information about the product, in addition to any new information. The report should include all relevant data on the risks and benefits associated with the product and its impact on market acceptance. The following information may be part of the PSUR:

1. Non-clinical research
2. Voluntary reporting
3. Active monitoring system
4. Product quality survey
5. Product use data and drug use information
6. Clinical trials
7. Observational studies
8. Patient support programs
9. Systematic review and meta-analysis
10. MAH-sponsored sites
11. Reports compiled from previously published scientific literature or abstracts
12. Unpublished manuscripts
13. Licensing Partners, Other Sponsors, Academic Institutions and Research Networks
14. Competent Authority

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