Risk management measures

The risk management system was introduced into European legislation in 2004. However, the pharmacovigilance legislation came into effect in July 2012. It represented the most significant change relating to regulation of human medicines in the European Union (EU) since 1995, with major implications for applicants and holders of EU marketing authorizations as well as for patients, healthcare professionals and regulators. Accordingly, submission of the Risk Management Plan (RMP) became mandatory for each new marketing authorization (MA).
Module V of the "Guidelines on good pharmacovigilance practices" (GVP) is the reference guideline.

In compliance with the Implementing Regulation No. 520/2012, the RMP contains:

1. the identification or characterization of the safety profile of the medicinal product, with emphasis on important identified potential risks, missing information and the safety concerns which need to be managed proactively or further studied (the 'safety specification');
2. the planning of pharmacovigilance activities designed to characterize and quantify clinically relevant risks, as well as to identify new adverse reactions (the 'pharmacovigilance plan');
3. the planning and implementation of risk minimization measures, including the evaluation of the effectiveness of such activities (the 'risk minimization plan').

When should an RMP be submitted?

- Companies shall submit an RMP to AIFA's Marketing Authorization Office upon application for a marketing authorisation.
- For medicines without an RMP, an application may be requested involving a significant change of the marketing authorisation (Variation Type II – C.1.11) or pursuant to Regulation No. 1234/2008, through AIFA's Front End System.

When should an RMP update be submitted?

RMPs are continuously modified and updated throughout the lifecycle of a medicinal product as new information is available. Companies are required to submit an updated RMP in the following cases:

- Upon AIFA's request;
- Whenever the risk-management system is modified, especially after receiving new information which may lead to a significant change of the benefit-risk profile or as a result of achieving an important pharmacovigilance or risk-minimisation milestone.

Educational materials

Educational materials are aimed at minimizing an important risk and/or maximizingthe risk-benefit ratio of a medicinal product. The Risk Management Measures (henceforth MGR) Office evaluates the Educational materials that are enclosed in the RMP. The evaluation procedure is finalized through either an approval letter or an amendment request.

How to submit the evaluation request of Educational materials:

The draft educational material shall be submitted to AIFA's MGR Office. The authorization request of Educational materials shall be prepared in compliance with the "Guideline on good pharmacovigilance practices"(GVP) Module XVI and Module XVI Addendum I.
An electronic copy of the documentation to be approved shall be sent on physical support (CD, DVD, etc.) or by e-mail to the following address: mgr@aifa.gov.it (please note that the files sent via e-mail cannot exceed 10MB).

The documentation should include the following*:

- Cover letter
- Distribution plan (which must include a proposal of target to be reached, methods and times of the related distribution)
- A proposal of Educational material in Italian in editable format, in order to allow revisions by the MGR Office
- A copy of the last RMP approved

** For the list of documents required, please refer to GVP Module XVI and Module XVI Addendum I.*

References

*Module XVI - Risk minimization measures: selection of tools and **effectiveness indicators** (Rev. 2)*

Module XVI Addendum I - Educational materials

Risk minimization measures

Risk minimization measures aim to promote the safe and effective use of a medicinal product. Routine risk minimization activities apply to every medicinal product and involve the use of tools such as the Summary of Product Characteristics (SPC), the Package Leaflet, labeling and conditions for the supply of the medicinal product.

However, for some medicinal products additional measures are needed to ensure their safe and effective use. Additional risk minimization measures may include documents for healthcare

professionals (DHPC, information guides etc.) and/or for patients (information guides, brochures, diaries, patient alert cards).

Patient Alert Card

The Patient Alert Card (PAC) is delivered to patients (or their caregiver/s) by healthcare professionals. In some cases, it can be part of the medicinal product packaging.

The PAC contains important information in a short, concise format to promote a safe and correct use of the medicinal product, which include times and methods of administration and the physician's or clinical center addresses. The information contained in the PAC is fundamental and should be carefully read before, during and after treatment with a medicinal product.
This section of the website contains PACs (if available) in their most recent revision.

Patients are recommended to bring the PAC with them and show it to health professionals in case of need.

PAC table

NOTICE: *In case of inconsistencies between the list and its attachments it is possible to send an e-mail to the following address:* mgr@aifa.gov.it