Risk-reduction measures

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Systematic measures are in place to ensure the safety and proper use of the medicine from the moment it is placed on the market and throughout its authorisation. These measures are included in the Summary of Product Characteristics (SmPC) intended for healthcare professionals, in the package leaflet intended for patients, and the packaging of the medicine. Medicines may also be subject to specific prescription and dispensing conditions.

Additional measures may be implemented in light of the assessment of the signals in order to prevent or reduce the occurrence of adverse reactions, their severity and/or the impact on the patient: request for a change in the marketing authorisation, change in the conditions of prescription and supply, communication with healthcare professionals and/or the general public, etc.

These measures can be implemented at national or European level and can be combined with each other.

Additional risk-reduction measures (MARR)

“Additional risk-reduction measures (MARR)” can also be implemented following the evaluation of a signal. They take the form of letters to health professionals, restricted access programmes, pregnancy-prevention programmes (PPG) and information or educational documents for healthcare professionals and/or patients and their relatives (guides, checklists, brochures, patient cards, training slide shows, etc.).

The application of these measures is the responsibility of the MA holder and is overseen by ANSM, which ensures that all documents are tailored to a given product's safety concerns and conditions of use. Such documents cannot be used for promotional purposes and their presentation must be distinguishable from that of pharmaceutical advertisements.