



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicinal products subject to additional monitoring

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Legal basis

In order to strengthen the monitoring of certain medicinal products and in particular to encourage the spontaneous reporting of ADRs, the new EU Pharmacovigilance legislation has introduced the concept of additional monitoring.

“The Agency shall, in collaboration with the Member States, set up, maintain and make public a list of medicinal products that are subject to additional monitoring” [Article 23 (1) of the Reg]

“Each member state shall [...] make publicly available the list of medicinal products referred to in article 23 of the Regulation” [Article 106 (d) of the Dir]



General principles for assigning additional monitoring status to a medicinal product (I)

- ❖ All medicines are authorised on the basis that the benefit of treatment is judged to outweigh the potential harm.
- ❖ However, adverse reactions which occur rarely or after a long time may become apparent only once the product is used in a wider population.
- ❖ In addition, the benefits and risks of a medicine used in everyday medical practice where patients may have more than one disease or treatment is frequently not studied before authorisation.



General principles for assigning additional monitoring status to a medicinal product (II)

- ❖ As for all medicinal products, marketing authorisation holders and competent authorities continuously monitor any information that becomes available and assess the impact on the risk-benefit profile of the medicinal product.
- ❖ However, for certain medicinal products enhanced post-authorisation data collection is needed to ensure that any new safety hazards are identified as promptly as possible and that appropriate action can be initiated immediately.
- ❖ Additional monitoring status can be assigned to a medicinal product at the time of granting marketing authorisation or at any time of the product life cycle.



Criteria for including a medicinal product on the list

- ❑ The additional monitoring status is particularly important when granting marketing authorisation for medicinal products containing a new active substance and for all biological medicinal products, which are priorities for pharmacovigilance (Mandatory scope [Article 23 (1) of the Regulation])
- ❑ Competent authorities may also require additional monitoring status for a medicinal product which is subject to specific obligations (e.g. to conduct a post-authorisation safety study) (Optional scope [Article 23 (2) of the Regulation])



Criteria for defining the time period of maintenance on the list

The Agency shall remove a medicinal product from the list

- ❑ 5 years time after the URD
- ❑ time considered necessary to fulfil the conditions and obligations placed on the marketing authorisation.

The Commission or the NCA, as appropriate, may, following the recommendations of the PRAC, extend that period until such time as they conclude that the conditions are fulfilled



Communication and transparency

- ❖ The additional monitoring status will be communicated to healthcare professionals and patients in such a way that it increases reporting of suspected adverse reactions but without creating undue alarm.
- ❖ A publicly available list of medicinal products with additional monitoring status will be kept up to date by the Agency and national competent authorities.
- ❖ Healthcare professionals and patients should be enabled to easily identify those products through their product labelling:
 - ❖ The SmPC and the package leaflet shall include the statement “This medicinal product is subject to additional monitoring”. This statement shall be preceded by a black symbol and followed by an explanatory sentence explaining the concept of additional monitoring.



In summary

- The concept of additional monitoring focuses on the need to address uncertainty regarding the knowledge of the benefit-risk of a given product at the time of authorisation or at any stage during its lifecycle.
- The main goals are to collect additional information as early as possible to further elucidate the risk profile of products when used in clinical practice and to increase awareness about the safe and effective use of certain medicinal products.



THANK YOU FOR YOUR ATTENTION

Pleased to answer your questions