Guideline on Additional Monitoring

NATIONAL MEDICINES REGULATORY AUTHORITY

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Content

Additional Monitoring

1. Additional monitoring using the Black symbol and explanatory statements

The concept of additional monitoring originates primarily from the need to enhance the ADR reporting rates for newly authorized products for which the safety profile might not be fully characterized or for products with newly emerging safety concerns that also need to be better characterized.

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 thereby informing the safe and effective use of medicinal products.

These medicinal products will be readily identifiable by an inverted equilateral black ▼ triangle. That triangle will be followed by an explanatory statement in the summary of product characteristics (SmPC) and package leaflet as follows:

"This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals and patients are asked to report any suspected adverse reactions. See section ..... for how to report adverse reactions."

This explanatory statement should encourage healthcare professionals and patients to report all suspected adverse reactions.

2. Medicinal products subject to "Additional monitoring" status

Medicinal products may be assigned the status of Additional monitoring by the NMRA at the time of granting a marketing authorization (e.g. new active substance) or at later stages of the product life cycle (e.g. new safety concern).

Medicinal products subject to additional monitoring are:

- medicinal products included in the European Medicines Agency "EMA" list for additional monitoring which is updated monthly by the EMA and accessible through the link https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/medicines-under-additional-monitoring/list-medicines-under-additional-monitoring;
- products for which a PASS was requested at the time of marketing authorization or post authorization

- products authorized with specific obligations on the recording or suspected adverse drug reactions
- products which were granted a conditional marketing authorization or authorized under exceptional circumstances
- other products as decided by the NMRA

As seen appropriate; the NMRA may also decide to add or remove any medicinal product from the additional monitoring list published by EMA as effective in SriLanka, in such case a complimentary list will be published on NMRA website. And the NMRA will notify the concerned MAH when an authorized medicinal product has been included in the complimentary list of additional monitored products

In this regard, the decision to include under the additional monitoring a medicinal product subject to conditions should consider the usefulness of the additional monitoring status in relation to other additional pharmacovigilance activities proposed in the risk management plan, for example in relation to the objectives of PASS.

3. Duration of inclusion in the additional monitoring list

The initial period of time for inclusion is 5 years after the marketing authorization date.

Furthermore, the period of time for inclusion in the list of medicinal products authorized subject to conditions is decided by the NMRA and is linked to the fulfillment of the conditions and obligations placed on the marketing authorization.

If new conditions are imposed to the marketing authorization during a product's lifecycle, it is envisaged that a medicinal product previously removed from the list can be added to the list again if criteria for inclusion are met again.

4. Roles and responsibilities of the MAH

- MAH should monitor the EMA list for medicinal products under additional monitoring as applicable to its products as well as the NMRA complementary list;
- MAH shall include in the SmPC and Package leaflet of their medicinal products subject to additional monitoring the ▼ black triangle symbol and the standardized explanatory statement on additional monitoring;
- MAH should submit the relevant variation to include/remove the black symbol, the statement, and the standardized explanatory sentence from the SmPC and PL, where

applicable (If the decision to include or remove a medicinal product from the list is done outside a regulatory procedure);

On the other hand, If the decision to include or remove a medicinal product from the list is done during the assessment of a regulatory procedure (e.g. marketing authorization application, extension of indication, renewal) the SmPC and the package leaflet should be updated before finalization of the procedure in order to include or remove the black triangle symbol and explanatory statement from the product information.

- MAH should include information on the status of additional monitoring in any material to be distributed to healthcare professionals and patients
- MAH should make all efforts to encourage reporting of adverse reactions, as agreed with NMRA;
- MAH should provide evidence to the NMRA on the status of any conditions imposed by them;

For more guidance on additional monitoring, refer to the *EMA Guideline on good pharmacovigilance practices (GVP) Module X*