IRISH MEDICINES BOARD

# ADDITIONAL MONITORING: BLACK TRIANGLE INTRODUCED AS PROMPT TO REPORT SUSPECTED ADVERSE REACTIONS

## 1 ABOUT THIS DOCUMNENT

Additional Monitoring is a new tool for increasing the involvement of healthcare professionals and patients in the vigilance of medicines.

This document outlines how the application of a new additional monitoring symbol will play a role in enhanced monitoring of medicines and vaccines.

## 2 BACKGROUND TO ADDITIONAL MONITORING

New EU laws on the safety-monitoring of medicines, called the pharmacovigilance legislation, started to come into effect in 2012. As the competent authority for medicines in Ireland, we at the Irish Medicines Board (IMB) are continuing to work with a wide range of stakeholders including the European Medicines Agency (EMA) and other national regulators on the implementation and operation of the provisions established by the new legislation.

Autumn 2013 will see a further and perhaps one of the most publicly visible provisions come into effect with the introduction of the 'additional monitoring' symbol; a black inverted triangle. This symbol will be used in Ireland and across Europe to highlight those medicines that are being monitored particularly closely by regulatory authorities. Ultimately, the symbol will act as a prompt to healthcare professionals and patients that any reactions associated with the use of these medicines should be reported to the IMB. The IMB views additional monitoring as one of the key public health deliverables of the pharmacovigilance legislation and sees the application of the symbol as a valuable opportunity to directly involve patients and healthcare professionals in the reporting of specific observations they notice when using the medicinal product.

## 3 INVERTED BLACK TRIANGLE

Medicines under additional monitoring will now display the inverted black triangle on the patient focused package leaflet and in the information for healthcare professionals (the summary of product characteristics (abbreviated as the SmPC or SPC). The triangle will appear in both documents alongside a short explanatory sentence. In each case, the text will clearly indicate that 'This medicinal product is subject to additional monitoring'. The symbol will not appear on the outer packaging or labelling. The symbol will be included on any educational (risk minimisation) materials approved by the IMB.

▼ This medicinal product is subject to additional monitoring.

Healthcare professionals and patients will begin to see the inclusion of the inverted black triangle on the product information of certain medicines from autumn this year. While the EMA first

announced the list of existing medicines subject to additional monitoring in April, the inclusion of the symbol on product information is proceeding on a phased basis in order to gradually substitute older stock on the market. Any new medicine authorised after 1 September 2013 which is subject to additional monitoring will include the black symbol in the product information.

## 4 LIFECYCLE BENEFIT-RISK MANAGEMENT OF MEDICINES

As highly regulated healthcare products, a medicine is authorised only when a regulator such as the IMB judges that the product is of high quality and that the benefits outweigh the risks. Once a product is placed on the market, the monitoring of benefits and risks continues throughout the product lifecycle through a system known as pharmacovigilance. This is because the tests and studies designed to show that a medicine is efficacious are generally not carried out for a sufficiently long period of time or in enough people to identify all of a medicine's risks and these can only be detected when a medicine is used in widespread medical practice. As no regulator wants to unnecessarily delay effective new medicines being made available to patients who need them, a robust system for post authorisation monitoring of benefits and risks of medicines is essential to ensure that we can promptly detect and minimise risks so that harm is prevented.

As part of an expanded regulatory toolbox to support risk management, regulators now have an option to further enhance the safety review of a medicine by assigning it additional monitoring status and requiring the incorporation of the inverted black triangle in the Summary of Product Characteristics targeted at Healthcare Professionals and in the Package leaflet for patients. This will signify that it is being monitored and scrutinised even more closely than other medicines.

## 5 ROLE OF HEALTHCARE PROFESSIONALS AND PATIENTS

Healthcare professionals play a crucially important role in pharmacovigilance and their willingness to report suspected adverse reactions is and will continue to be a cornerstone of drug safety systems. The healthcare professional role is not confined to the reporting of adverse drug reactions and a key aspect is their role in communicating and managing risk at the individual patient level. This expertise will be important in supporting understanding of the new concept of additional monitoring amongst the users of medicines. It should be emphasised that the inclusion of a black triangle on the package leaflet does not mean a medicine is not safe. The decision to enhance monitoring is generally because there is less information available about the medicine compared to other more established products. The objective is that this symbol will encourage both healthcare professionals and users of these specific medicines to report to the IMB any suspected reactions to the particular medicine.

## 6 CATEGORIES OF MEDICINES SUBJECT TO ADDITIONAL MONITORING

The following categories of medicines will be subject to additional monitoring:

- Medicines that contain a new active substance that was not contained in any authorised medicine in the EU on 1 January 2011;

- Biological medicines authorised after 1 January 2011 - this applies to all biological medicines including biosimilars;

- Medicines for which the marketing-authorisation holder is required to carry out a post-authorisation safety study (PASS);

- Medicines given conditional approval or authorised under exceptional circumstances and medicines authorised with specific obligations on the recording or monitoring of suspected adverse drug reactions.

In addition to these medicines, medicines can be included on the list based on a recommendation from the EMA's Pharmacovigilance Risk Assessment Committee.

## 7 LIST OF ADDITIONALLY MONITORED MEDICINES

The up to date list of medicines subject to additional monitoring to include the inverted black triangle in product information in the coming months are currently listed on the European Medicines Agency website. This list is also accessible via the IMB website by visiting the 'EU Pharmacovigilance Legislation' section of www.imb.ie.

A medicine can be included on this list when it is approved for the first time or at any time during its life cycle. A medicine remains under additional monitoring usually for five years or until the PRAC is satisfied that it can be removed from the list. The list is dynamic and is reviewed every month.

There may be a delay between the decision to add or remove a medicine from this list and the time when its updated package leaflet comes into circulation. This is because it takes some time to gradually replace older stock already on the market.

## 8 CONCLUSION

The introduction of the new additional monitoring process and the associated inverted black triangle is intended to further protect public health by strengthening the current European-wide system for monitoring the safety of medicines. The receipt of suspected side effects reports is also a critically important part of this system. The black triangle makes it possible to quickly identify medicines that are subject to additional monitoring. By introducing the symbol, it is intended to encourage healthcare professionals and patients to report any suspected side effects associated with these medicines so that any new emerging safety data can be quickly assessed.

Healthcare professionals are encouraged to continue to report any suspected reactions by:

- Using the IMB's online form. A downloadable version of the form is also available, which can be filled in manually and sent to the IMB by freepost.

- Calling the IMB on (01) 676 4971.

IMB
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