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Editorial

EDITORIAL NOTE ON BLACK TRIANGLE DRUGS

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EDITORIAL

Any drug or vaccine that fits one of the following requirements is given the Black Triangle symbol:

- A Novel active substance or a biosimilar medicine.
- A Novel drug or active ingredient combination.
- A New administrative route
- A New medicine distribution system.

Although the black triangle has been used in the UK for many years to identify drugs that are subject to extensive safety monitoring, it has been part of an EU-wide system since 2013, and is now known as extra monitoring. Medicines that are being closely watched by European regulatory authorities are marked with a black triangle symbol (an inverted equilateral black triangle) to alert patients and healthcare providers.

If a new drug contains a novel active ingredient or is a biological medical product such as plasma derived medicines, vaccines, or biosimilars, a black triangle is assigned when it is licenced for the first time. Other factors include particular authorisation requirements, such as the marketing authorisation holder conducting a Post-Authorisation Safety Study (PASS) following approval, or limits on the safe and effective use of the medical product, such as a controlled access plan. In certain situations, the black triangle might be allocated or re-instated at a later stage of a medicine's life cycle if a new safety risk is discovered that necessitates monitoring.

On the Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), in publications such as the BNF/ MIMS, on advertising and instructional materials for HCPs, and on patient support materials, the black triangle sign appears next to the name of applicable drugs. It is not printed on the outside of pharmaceutical packages.

A black triangle next to a British medicine's trade name denotes that the drug is either new to the market or that it is being used for a new purpose or via a new method of administration. Medicines are finally classified as being under extra monitoring measures by regulatory authorities in the European Union (EU). In the patient information booklet and the summary of product features for healthcare professionals, medicines that are subject to further monitoring will have an inverted Black Triangle and a short line that says "This medicinal product is subject to additional monitoring."

This is because clinical trials often involve just a small number of qualified people who take the treatment for a short length of time, thus we only have limited knowledge regarding their safety. According to the European Medicines Agency's new pharmacovigilance standards, black triangle medications are identified by an inverted black triangle. Any drug or vaccine with a novel active material, a biosimilar medicine, a new combination of medicines or active substances, a new method of administration or drug-delivery technology, etc. is given the Black Triangle emblem. This promotes safe drug usage by encouraging the reporting of adverse responses.

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