Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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Dear Ms Layhe,

20th December 2021

FOI 21/1237

Thank you for your email dated 18th November 2021 where you requested the number of reports received via the Yellow Card scheme for melanotan II products including nasal sprays and injections between 2011-2021.

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for the regulation of medicines (for human use), medical devices, blood and blood products in UK by ensuring they work as expected and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

Products containing melanotan II will be considered medicines if they are captured by the definition of a medicinal product set out in the Human Medicines Regulations 2012. If a product falls under the definition of a medicine, it must hold the appropriate authorisation to be legally sold and supplied in the UK. We determine whether a product is a medicine on a case-by-case basis, by considering a number of factors including its effect on the body and the manner in which it is used. If a product is classified as a medicine and is not appropriately authorised, we take action to ensure regulatory compliance including the removal of the product from the UK market where necessary.

If a tanning product that falls within the definition of a medicinal product is identified on the UK market MHRA will carry out the appropriate regulatory action. We have repeatedly taken action to remove melanotan products so identified from sale for over 10 years and will continue to do so.

However, a tanning product will only be considered a medicine if it is captured by the definition of a medicinal product set out in the Human Medicines Regulations 2012. The definition of a medicine does not allow us to consider mode of administration in isolation so injectable tanning products containing melanotan II are not automatically medicines. Similarly, where no medicinal claims are made, nasal tanning sprays containing melanotan II will not generally be regulated as medicinal products.

Between 2011 and 2021 we have received 13 suspected Adverse Drug Reaction (ADR) reports via the Yellow Card scheme associated with melanotan II. A yearly breakdown is provided in Table 1.

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Table 1: UK suspected ADR reports with Melanotan II received between 01/01/2011 and 09/12/2021

Year of receipt	Number of ADR reports
2011	3
2012	2
2013	1
2014	3
2015	0
2016	0
2017	0
2018	2
2019	2
2020	0
2021	0

Please note that the inclusion of a report on our ADR database does not necessarily mean that the events were caused by the drug. We encourage reporters to report suspected adverse reactions i.e. the reporter does not have to be sure that the drug caused the reaction – a mere suspicion will suffice. Therefore, reports submitted to the MHRA may be adverse reactions to the drug or may be purely coincidental events that would have occurred anyway in the absence of drug administration (e.g. events due to underlying medical conditions).

Furthermore, the number of reports received via the Yellow Card Scheme does not directly equate to the number of people who suffer adverse reactions to drugs for a number of reasons, as this scheme is associated with an unknown and variable level of under-reporting. ADR reporting rates may be influenced by the seriousness of reactions, their ease of recognition, extent of use of a particular drug and promotion and publicity about a drug.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.
Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

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