Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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www.gov.uk/mhra

Dear [redacted]

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 regulating all medicines and medical devices in the 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. Melanotan II containing products are unlicensed medicines in the UK, and as such the safety, quality and effectiveness has not been demonstrated. These products may cause serious side effects, so our advice to those who have used Melanotan injections or nasal sprays is to stop using them immediately and if you have suffered side effects, speak to your doctor and report them to the MHRA through our Yellow Card Scheme.

It is important to note that the sale and advertising of these products is illegal. The MHRA has repeatedly taken action to remove Melanotan products from the market for over 10 years and will continue to do so where products fall within the definition of a medicinal product.

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.

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

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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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