Medicines & Healthcare products
Regulatory Agency

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[redacted]

17th April 2024

FOI 24/274 – Side effects reports of melanotan II products

Dear [redacted]

Thank you for your email dated 19th March 2024 where you asked for information on the following under the Freedom of Information (FOI) act:

1. *The total number of side effects reports received by MHRA through the Yellow Card reporting scheme related to the use of melanotan II products from the period of 2012-2022.*
2. *Any actions taken, or recommendations made by MHRA in response to these reports.*

It may be useful to first provide some background information on products containing Melanotan II. Products containing Melanotan II are not always classified as medicines. Products containing Melanotan II are classified as medicines if they are injectable or pens. If a product contains Melanotan II and is in the form of a nasal spray, it will be determined as a medicine only if sold with claims to treat or prevent disease.

The MHRA regulates medicines for human use, medical devices and blood products for transfusion. Whilst we accept and include Yellow Card reports for unauthorised medicines on our medicines database, their contents are unknown and there are no safeguards that these products meet our standards for quality, safety or effectiveness. These products may cause serious side effects, so our advice to those who have used Melanotan II 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, supply and advertising of unauthorised medicines is not permitted under the Human Medicines Regulations.

Following a search of our database, 16 UK spontaneous suspected Adverse Drug Reaction (ADR) reports for Melanotan II were received between the 1st January 2012 and the 31st December 2022.

Please note that the inclusion of a report on our ADR database does not necessarily mean that the events were caused by the product. 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, as this scheme is associated with an unknown and variable level of 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.

The MHRA have not made any recommendations or taken any specific actions in response to these Yellow Card reports. However, 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

I hope the information provided is helpful. 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
Safety and Surveillance Group