



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

[MHRA Website](#)

Our Ref: **FOI2025/00805**

1 September 2025

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 31 July. You wrote:

I would like to request, under the Freedom of Information Act, anonymised Yellow Card data relating to adverse event reports involving Melanotan II (oral form / tanning drops) submitted between 2020 and 2025.

If possible, please include:

- * *Nature of the reported event (e.g. melanoma, skin reaction, neurological effect)*
- * *Age/gender (if recorded)*
- * *Route of administration (oral ingestion vs injection/nasal)*

MHRA Response

We confirm that we hold the information you have requested and provide it below.

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for the regulation of medicines (for human use), medical devices and blood products for transfusion in UK.

There are no authorised medicines in the UK containing Melanotan.

Products for tanning the skin, in the absence of medicinal claims, would not be considered medicinal products.

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 and this includes consideration of a number of factors, including its effect on the body and the manner in which it is used. As outlined on page 10 of [our guidance](#), a product that merely modifies physiological functions but has no claimed beneficial effect on human health will not, generally speaking, fall within the definition of a "medicinal product".

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. The specific action taken is determined by consideration of all the available evidence and relevant legal precedents. For more details on how we decide if a product is a

medicine, see our guidance page on what a medicinal product is, available on the [Borderline Products: how to tell if your product is a medicine](#). If a tanning product that satisfies the definition of a medicine is identified on the UK market, we will carry out the appropriate regulatory action. The definition of a medicine does not allow us to consider mode of administration in isolation and therefore being an injectable product does not automatically make it a medicine.

To conclude, a tanning product will be considered a medicine if it is captured by the definition of a medicinal product set out in the Human Medicines Regulations 2012. In the absence of medicinal claims, products for tanning the skin will not generally be regulated as medicinal products.

With regards to data MHRA has received through the Yellow Card scheme, we can confirm that from 01.01.2020 up to and including 31.07.2025 (data run 15.08.2025) the MHRA received 2 UK spontaneous suspected Adverse Drug Reaction (ADR) reports for melanotan II.

See below breakdown of the 2 reports by patient age, patient sex, and reported suspected reactions. Please be aware that on a Yellow Card report it is not mandatory to provide patient age, patient sex or drug route of administration.

We can confirm that neither of the 2 reports reported the route of administration of melanotan II.

Table 1: All UK Spontaneous Suspected ADR Reports for Melanotan II received 01.01.2020-31.07.2025 (data run 15.08.2025): Breakdown by Sex

Patient sex	Number of reports
Female	2

Table 2: All UK Spontaneous Suspected ADR Reports for Melanotan II received 01.01.2020-31.07.2025 (data run 15.08.2025): Breakdown by Age

Patient Age Category	Number of reports
Adult	1
Age not reported	1

Table 3: All UK Spontaneous Suspected ADR Reports for Melanotan II received 01.01.2020-31.07.2025 (data run 15.08.2025): Breakdown by Reported Suspected Reactions

Reaction MedDRA ¹ Preferred Term Name	Reaction count
Abdominal pain	1
Ulcer	1
Vomiting	1
Total number of reactions	3
Total number of reports	2

¹ MedDRA (Medical Dictionary for Regulatory Activities) is a clinically validated international medical terminology dictionary. It is organised by System Organ Class (SOC), divided into High-Level Group Terms (HLGT), High-Level Terms (HLT), Preferred Terms (PT) and finally into Lowest Level Terms (LLT).

Please also note that when considering the spontaneous data within this response, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have been. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.
- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different medicines. Reporting rates are influenced by the seriousness of the reaction, their ease of recognition, the extent of use and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines, medicines during the first one to two years on the market and then falls over time. If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

Re-use of our information

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>

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