IRISH MEDICINES BOARD

Notice Information: - Warning
27 February 2009

Part 1. Product Information

a)	Title:	Melanotan Powder for Injection
b)	Product Name/Type:	Melanotan Powder for Injection
c)	Active Substance:	Said to be a synthetic analogue of alpha-melanocyte stimulating hormone (a -MSH)
d)	Reference:	IMB Reference: QDR-H-09-062
e)	Serial/Batch Number & Expiry Date:	Serial/Batch Number(s): All Expiry Date: Various
f)	Authorisation Number:	None. This product is not authorised by the IMB
g)	Authorisation Holder:	None
h)	Manufacturer/Supplier:	Unknown
i)	Recall Classification:	Patient Level Recall Required: Yes Timeframe: Ongoing

Part 2. Target Audience

a) Target Audience:

- The General Public
- General Practitioners
- Pharmacists

Part 3. Problem/Issue

a) Problem/Issue:

This unauthorised product is marketed on the internet as a drug that assists tanning. There is no indication at this time that Melanotan is available from retail outlets in Ireland. The product may be presented as Melanotan I or Melanotan II . Melanotan II claims to have the added effects of increased libido and appetite suppression.

The product consists of a vial of powder that may or may not be labelled. It may be supplied with or without a second vial, containing what is labelled as 'Bacteriostatic water'. The 'Bacteriostatic water' is intended to be mixed with the powder prior to injection. Size and appearance of the vials may vary. Melanotan is typically injected using an insulin-type needle.

The Irish Medicines Board (IMB) wishes to advise that it has recently detected the presence of microbial contamination in the water vial supplied with a pack of Melanotan II . Microbial contamination of an injectable product exposes any recipient to the risk of serious infection.

In addition to the detection of microbial contamination, Melanotan (I and II) is not authorised for use in Ireland, or anywhere throughout the EU, so there can be no guarantees as to its quality, safety or effectiveness.

We can also state that, in September 2007, the US Food and Drug Administration (FDA) advised consumers to stop using Melanotan II as it was an unapproved drug and that there was no evidence that it was safe or effective for its labelled uses. The FDA also issued a Warning Letter to the owner of the company that was illegally selling and marketing the product on its website.

In November 2008 the UK Medicines and Healthcare products Regulatory Agency (MHRA) warned people not to use Melanotan (I and II) as it is an unlicensed medicine and may not be safe. It also warned eighteen different companies in relation to their selling or advertising of the product.

Part 4. Action to be taken

a) Action to be taken:

• Any patients or members of the public who are using the above product(s) are advised to immediately cease taking the product and to consult with their pharmacist or doctor. When speaking to their doctor or pharmacist, patients or members of the public may find it helpful to take a copy of this IMB notification with them. This can be downloaded from the IMB website at www.imb.ie . Patients should continue to take any medication prescribed by their doctor.

• Any persons holding stock of any of this product, or who have supplied any packs of this product to others, should put the packs in a safe place immediately and notify the IMB at the contact details below to arrange for return of the product.

The IMB wishes to advise that prescription medicines should never be bought over the internet. Products such as this are not authorised in Ireland, and cannot be regarded as safe. These types of products are illegal medicines and should not be purchased for use over the internet or by any other route.

Part 5. Enquiries

a) All enquiries should be made to:

The IMB contact person for this issue is:

Mr. Rob Smyth,

Market Compliance Technical Officer,

Irish Medicines Board,

Earlsfort Terrace,

Dublin 2,

Ireland

Tel: +353-1-6764971 (office)

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Part 6. Keywords

a) Keywords: Melanotan Powder for Injection