

Determination Letter – Medicinal Product

11th May 2018

Classification of Borderline Products

The product – *TAC sciences Tattoo anaesthetic cream* has been reviewed by the Borderline Classification Committee on 11th May 2018.

Kindly note, that as per Medicines Act 2003, as amended, a:

"medicinal product" means a substance or combination of substances -

(a) presented as having properties for treating or preventing disease in human beings;

or

(b) which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis;'

On the basis of the information submitted the Borderline Classification Committee considers the product referred to above as being:

- a medicinal product due to its presentation -
 a medicinal product due to its content -

I would like to draw your attention to the fact that, in terms of the Medicines Act 2003 Part III Title I Article 20:

'No person shall place a medicinal product on the market in Malta unless he is in possession of a marketing authorisation from the Licensing Authority, in accordance with the provisions of this Act or any regulations or rules made thereunder'.

It is prohibited to market these products without a Marketing Authorisation If you intend to market the products you are requested to submit the necessary applications so that the registration process may be initiated. Further information on the registration procedures can be found on the Medicines Authority website <http://www.medicinesauthority.gov.mt/marketingauth.htm>

If the product is already on the market you are requested to refrain from bringing further consignments into Malta with immediate effect. Furthermore the product should not be advertised in any manner whatsoever until the registration process is finalised.

Should you fail to abide by the contents of this letter the Authority may take any action it deems necessary.

If you disagree with the decision taken by the Borderline Classification Committee, you may file an appeal with the Borderline Appeals Board via email classcomm.adm@gov.mt within 20 days of the date of receipt of this letter.

Should you have further queries please contact the Borderline Classification Committee Secretariat on email: classcomm.adm@gov.mt.

Yours sincerely,



Ms Helen Vella
Chair, Borderline Classification Committee
Medicines Authority

Cc Malta Competition and Consumer Affairs Authority
Port Health Services