

## **Ti-Tre Tablets 20mcg**

### **Exempt Medicinal Product All In-date batches**

19<sup>th</sup> June 2012

Dear Pharmacist,

The Irish Medicines Board would like to make you aware of a potential quality issue with the exempt medicinal product **Ti-Tre 20mcg tablets**. To date, the IMB has received two reports relating to a lack of efficacy with one batch of the product, which occurred in Ireland and were notified to the IMB in 2011. Testing of this batch was undertaken by the Italian Medicines Agency (AIFA), as the product is manufactured in Italy. Units tested did not meet specifications for uniformity of content. As a result, a recall of all batches of Ti-Tre has been initiated in Italy. Manufacture of the product has ceased and as a result, Ti-Tre will no longer be available once stocks at Irish wholesalers become exhausted.

**Update: As of August 2012, replacement, unaffected Ti-Tre stock is available from wholesalers.**

On receipt of a prescription for this product, consideration should be given to contacting prescribers to refer them to the information above and to discuss possible alternative products. No new patients should be initiated on Ti-Tre tablets.

As this product is not authorised in Ireland, the IMB has no data on its quality, efficacy or safety and cannot comment on whether Ti-Tre is interchangeable with other liothyronine-containing products. However, based on potential concerns regarding lack of efficacy in association with Ti-Tre and in the context of the regulatory action taken in Italy where the product is authorised, the IMB wishes to highlight this information to healthcare professionals. Patients currently supplied with Ti-Tre should be reviewed at their next scheduled appointment to consider the need for an alternative product, as appropriate. Clinical assessment and evaluation of relevant laboratory results should guide the need for dose adjustment and patient monitoring.

Any suspected adverse reactions should be notified to the IMB via the online or downloadable reporting options available from the IMB website [www.imb.ie](http://www.imb.ie).

All medical queries should be directed by email to [vigilance\\_assessment@imb.ie](mailto:vigilance_assessment@imb.ie).

Yours sincerely,

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**Rob Smyth**  
**Market Compliance Technical Officer**