

Health Products Regulatory Authority
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace, Dublin 2

26 April 2016

**Re: Tuberculin PPD RT23 "SSI" 2 T.U. /0.1 ml Solution for Injection PA 798/1/2
Extension of expiry date of batch number 1646G until the end of May 2017**

Dear Healthcare Professional,

As you may be aware, Tuberculin PPD RT23 "SSI" 2 T.U. /0.1 ml Solution for Injection PA 798/1/2 is currently in short supply in Ireland. The Marketing Authorisation Holder for this product, Statens Serum Institut, has indicated that it expects to be in a position to supply a new batch of this product to the Irish market after quarter 4 2016.

The HPRA is aware that limited stock of batch 1646G of this product still remains on the Irish market. This stock is labelled with a May 2016 expiry date which corresponds to the two year shelf-life that is currently approved in Ireland. In order to ensure continuity of supply of this medicinal product, the HPRA has now agreed to a further extension of the expiry date of batch 1646G of the above product until the end of May 2017. The extension of the expiry date is supported by the stability data for this product.

This has been agreed on this occasion only in order to ensure continuity of supply of this medicinal product until such time as new stock becomes available. The extension of the expiry date only applies to batch 1646G and is not applicable to any other batch of this product.

Yours sincerely,



David Murray PhD
Pharmaceutical Assessor
Human Products Authorisation and Registration Department