Mr Patrick Batty
Vigilance and Risk Management of Medicines
Medicines and Healthcare Products Regulatory Agency
151 Buckingham Palace Road
London SW1W 9SZ

9th December 2014

Your ref: GENQ-00099550

Dear Patrick,

Re: Awareness of the risk of tuberculosis with TNF-alpha inhibitor treatment

Thank you for the MHRA letters dated 15th July and 2nd December 2014, and for forwarding data on spontaneous UK adverse drug reaction reports of tuberculosis infections with TNF-alpha inhibitors for dermatological and non-dermatological indications.

All dermatologists prescribing biologic agents should be screening for tuberculosis prior to initiating treatment and then at annual follow-ups during the course of treatment. Members of the British Association of Dermatologists (BAD) are aware of the risk and need for screening and monitoring, which have been highlighted in both iterations of our national clinical guidelines for use of biological interventions in psoriasis in 2005 and 2009. Work has commenced on the next update, which we anticipate to be published in 2016.

Reminding our membership of this issue could be done via an article in our quarterly newsletter or electronic email alerts and circular.

The BAD recently produced a single-sheet UK biologics checklist, available for our members to order, which contains sections for tuberculosis screening and monitoring. This will be updated in line with publication of the guidelines update, as appropriate.

It is also worth noting that the British Association of Dermatologists Biologic Interventions Register (BADBIR), a national registry which seeks to assess the long-term safety of biologic therapies for psoriasis, records all adverse events including tuberculosis.

Following email discussions with the relevant committees I can also report the following:

- it was felt that perhaps recognition in primary care of atypical symptoms in patients receiving biologic therapies *may* be poor, mainly due to the settings (secondary or tertiary care) in which these drugs are prescribed

- there are potential opportunities to highlight the risk by referring to the NICE pathway for psoriasis and in particular the section on biologic therapies, although in its current form some amendments to this section are required
- we have requested information on the availability of an alert card from relevant biologic manufacturers (Abbvie, Janssen-Cilag, MSD and Pfizer) as we are only aware of the availability of such a card from UCB (for certolizumab, although it is not licensed for psoriasis)
- we are discussing the possibility of developing a generic BAD biologic alert card which could be packaged together with our aforementioned biologics checklist

Our patient information leaflets (PILs) on adalimumab, etanercept and infliximab, which are available online and printed in clinics as hand-outs to patients, also highlight the risk.

Yours sincerely,

Dr M. Firouz Mohd Mustapa
Clinical Standards Manager
British Association of Dermatologists