

AbbVie welcomes the opportunity to provide comments on the draft Terms of Reference (ToR) for the post-market review of biological Disease Modifying Anti-Rheumatic Drugs (bDMARDs) to treat severe chronic plaque psoriasis. This Review provides an opportunity to ensure Australian chronic plaque psoriasis patients continue to receive the best treatment for their disease, consistent with relevant local clinical practice guidelines and the National Medicines Policy.

The medicines to be included in the Review are adalimumab, etanercept, infliximab and ustekinumab<sup>1</sup>. AbbVie notes that secukinumab has not been included. Secukinumab was approved at the March 2015 PBAC Meeting and listed on the PBS 1<sup>st</sup> September 2015 for chronic plaque psoriasis.

Given the significant impact psoriasis has on a patient's quality of life, which has been highlighted and acknowledged by WHO in their recent psoriasis report<sup>2</sup>, AbbVie believes a Stakeholder Forum should be conducted as part of this post-market review to fully understand the place of biologics in Australian clinical practice, with representatives from key clinical bodies, impacted patients and sponsor companies.

A review of the administrative burden of prescribing these agents should also be incorporated into the review.

Specific comments on the draft ToR are provided below.

**1. Review current clinical guidelines for the treatment of severe chronic plaque psoriasis and compare to the PBS restrictions for use of bDMARDs in this indication.**

AbbVie welcomes the opportunity under this ToR to review the clinical guidelines for the use of biologics in chronic plaque psoriasis. The PBAC restriction for the use of biologics (PASI score >15) is currently not aligned with Australian and international guidelines which generally recommend the use of biologics in patients with a PASI score >10 (Australian

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<sup>1</sup> The term bDMARD is not relevant to the indication of psoriasis. In clinical practice and the literature these products are referred to as biologic medicines. Collectively, these medicines will be referred to as "biologics" in this document

<sup>2</sup> World Health Organization. Global Report on Psoriasis. 2016. ISBN 978 92 4 156518 9.

treatment goals<sup>3</sup>, American Academy of Dermatology Guidelines<sup>4</sup>, European Guidelines<sup>5</sup>, British Association of Dermatologists Guidelines<sup>6</sup>, NICE guidance<sup>7</sup>).

A review of administrative barriers to access for patients that meet current prescribing criteria should be conducted within this ToR. AbbVie has received clinician feedback that some patients who are currently responding to treatment are experiencing disease flare while waiting for continuing scripts to be approved. A change to an Authority Required (Streamlined) listing, particularly for continuing scripts, would facilitate responding psoriasis patients to access their medication in a timely manner. A submission by AbbVie supporting this change was also provided to the Post-Market Review of Authority Required PBS Listings in September 2014, to which a response has not been received to date.

**2. Review and evaluate recent clinical evidence on the efficacy and safety of bDMARDs used in the treatment of severe chronic plaque psoriasis and compare to the evidence considered by PBAC in previous sponsor submissions.**

The efficacy of adalimumab in the real world is well established and AbbVie looks forward to providing the PBAC with all available data to supplement our comprehensive randomised controlled data in patients with psoriasis.

**3. Review the utilisation of PBS bDMARDs for the treatment of chronic plaque psoriasis and compare the patient response in practice to those observed in the clinical trial**

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<sup>3</sup> Baker C, Mack A, Cooper A et al. Treatment goals for moderate to severe psoriasis: An Australian consensus. *Australasian Journal of Dermatology* (2013) 54, 148–154

<sup>4</sup> Menter A, Gottlieb A, Feldman SR, van Voorhees AS, Leonardi M, Gordon KB, Lebwohl M, Koo JYM, Elmets CA, Korman NJ, Beutner KR, Bhushan R. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J Am Acad Dermatol*, 2008; 58:826-50.

<sup>5</sup> Nast A, Gisondi P, Ormerod AP, Saiag P, Smith C, Spuls PI, Arenberger P, Bachelez H, Barker J, Dauden E, de Jong EM, Fiest E, Jacobs A, Jobling R, Kemény L, Maccarone M, Mrowietz U, Papp KA, Paul C, Reich K, Rosumeck S, Talme T, Thio HB, van de Kerkhof P, Werner RN, Yawalker N. European S3 – Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *JEADV*, 2015; 29:2277-94.

<sup>6</sup> Smith CH, Anstey AV, Barker JNWN, Burden AD, Chalmers RJG, Chandler DA, Finlay AY, Griffiths CEM, Jackson K, McHugh NJ, McKenna KE, Reynolds NJ, Ormerod AD. British Association of Dermatologists' guidelines for biologic interventions for psoriasis 2009. *Br J Dermatol*, 2009; 161:987-1019.

<sup>7</sup> National Institute for health and Clinical Excellence. Psoriasis – The assessment and management of psoriasis. Issued October 2012. NICE clinical guideline 153. <http://guidance.nice.org.uk/CG153>.

**evidence considered by the PBAC. Compare the efficacy in practice among the listed bDMARDs in terms of time on treatment and discontinuations from treatment.**

DUSC has provided a comprehensive review of the utilisation of biologic agents in the treatment of psoriasis. Clarification of this ToR however, is required. A suggestion for rewording is provided:

*Review and compare the utilisation and effectiveness of PBS biologics for the treatment of chronic plaque psoriasis and compare the patient response in practice to those observed in the clinical trial evidence considered by the PBAC. ~~Compare the efficacy in practice among the listed bDMARDs in terms of time on treatment and discontinuations from treatment.~~*

**4. Subject to the findings from terms of reference 1, 2 and 3, review the cost effectiveness of bDMARDs for severe chronic plaque psoriasis.**

The ToR should outline what findings and decision criteria for ToR 1 to 3 would lead to a recommendation by the PBAC to perform a review of cost-effectiveness. If ToR 4 were to proceed, the Review Reference Group should contain at least one member with experience in the economic evaluation of biologics and/ or psoriasis. Additionally, as it is likely that Sponsors submissions will include additional clinical data and economic evaluation components; sufficient time for formal clinical and economic evaluations should be factored into the review process and communicated to Sponsors and stakeholders.