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2 July 2013

PBS Post-Market
Department of Health and Ageing
MDP 900
GPO Box 9848
CANBERRA ACT 2601

Dear PBS Post-Market Review members,

**Re: Stage 3 of the Post-Market Review of Products Used in the Management
Diabetes**

Janssen-Cilag Pty Ltd (herein referred to as Janssen) welcomes the opportunity to comment on Stage 3 of the Review for Medicines Used in the Treatment of Type 2 Diabetes. Janssen supports appropriate medication and treatment management consistent with the National Medicines Policy.

As the sponsor of a novel oral medicine for type 2 diabetes mellitus, INVOKANA[®] (canagliflozin), Janssen is a key stakeholder in supporting and delivering the appropriate use of these medicines. Janssen fully supports the Quality Use of Medicines (QUM) deemed cost-effective when assessed under rigorous Health Technology Assessment (HTA) pathways.

We note that the terms of reference relate to currently listed Pharmaceutical Benefits Scheme (PBS) medicines. Whilst Janssen does not supply a currently listed medicine, we are awaiting consideration by the Pharmaceutical Benefits Advisory Committee of a submission for the listing of INVOKANA[®] on the PBS. INVOKANA[®] is an orally active reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2), a novel class of medicines for use in the treatment of type 2 diabetes. Our submission addresses a number of elements relating to utilisation and cost-effectiveness regarding launch of a new product for type 2 diabetes mellitus.

Janssen looks forward to contributing further to the Post-Market Review as appropriate following the PBAC consideration of INVOKANA[®].

Sincerely,

Duncan O'Brien
Head, Health Economics and Pricing, Corporate and Government Affairs and Regulatory
Affairs