



Australian Government

Department of Health and Ageing

Mr Hadar Barsheshet
ASTS Enterprises
11 Evans Streets
BURWOOD VICTORIA 3125

Dear Mr Barsheshet

Application to list the Injex Needle Free Insulin Delivery System on the National Diabetes Services Scheme

Thank you for your initial correspondence of 10 January 2012, regarding a request to consider listing of the Injex Needle Free Insulin Delivery System (Injex) under the National Diabetes Services Scheme (NDSS) Product Schedule.

As stated in the Department's previous correspondence, the Department sought advice from the Medical, Education and Scientific Advisory Council (MESAC), which exists under the NDSS, for evaluation of the Injex system. Advice from MESAC is that, based on the evidence provided, Injex is neither clinically superior nor inferior to injections by needle for the delivery of insulin and that its main benefit would appear to be in people with needle-phobia (estimated at 0.1-1%). In addition, the Injex submission provided to MESAC did not provide a health benefit rationale to support the additional costs of using Injex.

Following due consideration of your submission, MESAC's advice, and the overall cost of the product, the Department has decided not to recommend the listing of Injex on the NDSS Product Schedule at this time.

I note that you supplied further clinical documentation on 9 August 2012. However, this study did not involve a population diagnosed with diabetes and using multiple daily injections, and as it is of a small sample size (18 subjects), it is difficult to base decisions on listing under the NDSS on this evidence.

Further evidence of the clinical efficacy of Injex as compared to traditional needle and syringe therapy would be required to determine its superior clinical benefit for users and to support the significant cost of this technology.

If you would like to supply further clinical documentation, highlighting additional health benefits which may assist in the justification of the increased costs when compared to other methods of insulin delivery, Injex may be considered for listing on the NDSS in the future.

If you have any questions relating to any of the above, please place them in writing to ndss.products@health.gov.au

Yours sincerely

A handwritten signature in black ink, appearing to read 'Steve Dunlop', written over a circular stamp or mark.

Steve Dunlop
A/g Assistant Secretary
Pharmaceutical Products and Support Branch

29 August 2012