21st February 2013

[redacted]

Novo Nordisk would like to thank you for the opportunity to review and comment on the appraisal consultation document for dapagliflozin in combination therapy for treating type 2 diabetes. Our comments relate to the network meta-analysis evidence presented in the submission and its use for cost effectiveness modeling. These have been included under the relevant headings.

Has all of the relevant evidence been taken into account?

Novo Nordisk note from the evidence presented for triple therapy that the manufacturer has relied on an existing network meta-analysis that was conducted by the Canadian Agency for drugs and technologies in health (CADTH). It should be noted that this review excluded some studies that may have been relevant to the decision problem outlined by NICE. We are aware of one such study from the liraglutide clinical development programme that could have contributed further evidence to the GLP1 group.[1] This has not been considered in the current analysis.

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

Based on our review of the network meta-analysis and the use of these results in the cost effectiveness model, it is difficult for Novo Nordisk to comment whether these are reasonable interpretations of the evidence due to the way the information has been presented by the manufacturer. Much of the analysis is presented as confidential and it is not always possible to cross check which figures were being used for which analysis.

Novo Nordisk would however like to comment on the approach taken to the analysis of dapagliflozin as triple therapy. In this analysis post-hoc evidence for dapagliflozin was compared with an existing published network meta-analysis that did not include dapagliflozin. The manufacturer has used this data in an economic model to show that dapagliflozin dominates all of the possible comparators, GLP-1, DPP-4 and glitazone. We would like to point out that this analysis is based on an unadjusted comparison between dapagliflozin and the relevant comparators, that does not preserve randomisation and therefore this cannot be considered a robust basis on which to make a recommendation on the use of dapagliflozin in triple therapy.

We trust that this information is helpful. If you require any further information please do not hesitate to contact me.

Yours sincerely

[redacted]

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Calls may be monitored for training purposes

[1] Zinman B, Gerich J, Buse JB, Lewin A, Schwartz S, Raskin P, et al. Efficacy and safety of the human glucagon-like peptide-1 analog liraglutide in combination with metformin and thiazolidinedione in patients with type 2 diabetes (LEAD-4 Met+TZD).[Erratum appears in Diabetes Care. 2010 Mar;33(3):692]. *Diabetes Care* 2009;32(7):1224-30.