Expert peer review on application for inclusion of additional classes of oral hypoglycaemics (alpha-glucosidase inhibitors, dipeptidylpeptidase-4 inhibitors, meglitinides, thiazolidinediones)

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes ✓  No (if no, please provide reference and information)

   Although based primarily on the most recently published systematic reviews and not on a comprehensive review of the primary literature (apart from the Cochrane Central Register for Controlled Trials), this proposal has competently summarised the current state of knowledge regarding these newer classes of oral hypoglycaemics.

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      There is insufficient evidence to show that any of the newer classes of oral hypoglycaemics (alpha-glucosidase inhibitors, dipeptidylpeptidase-4 inhibitors, meglitinides, or thiazolidinediones) offer any efficacy advantages over the existing agents included in the WHO Model EML (biguanides and sulphonylureas). In particular, evidence of improved hard clinical outcomes is lacking.

   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes ✓  No (if no, please provide reference and information)

   As above.

   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      Particular safety concerns have been expressed in relation to the thiazolidinediones, which have resulted in regulatory action by stringent authorities. None of the newer classes of oral hypoglycaemics (alpha-glucosidase inhibitors, dipeptidylpeptidase-4 inhibitors, meglitinides, or thiazolidinediones) offer any safety advantages that would justify their inclusion in the WHO Model EML or the replacement of the current classes.

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
a. Have all relevant data on cost and availability provided  
   Yes ✓  No  (if no, please provide reference and information)

b. Summarize the data on cost and cost effectiveness, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   There are limited data on the costs of the newer agents in resource-constrained settings. In developed settings, these agents are more expensive than those already included in the WHO Model EML (biguanides and sulphonylureas).

c. Please provide any additional relevant information with reference

d. Is the product available in several low and middle income countries?

4. Assessment of public health need
   a. Please provide the public health need for this product (1-2 sentences)

   The need for an effective, safe and affordable oral hypoglycaemic agent is clearly demonstrated. Diabetes mellitus is common in all countries and is particularly prevalent in the elderly.

   b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable


5. Are there special requirements for use or training needed for safe/effective use?
   If yes, please provide details in 1-2 sentences

   No.

6. Is the proposed product registered by a stringent regulatory authority?
   Yes ✓  No

7. Any other comments

8. What is your recommendation to the committee (please provide the rationale)

   The proposed course of action – "Evidence on efficacy, safety, cost and availability on selected NEMIs does not support the addition of any agent from the four classes of oral hypoglycemics reviewed – glitazones, DPP-4 inhibitors, alpha-glucosidase inhibitors and meglitinides – to the EML at this time" – is supported.