Pharmacotherapeutic re-assessment report on atomoxetine (Strattera®) for the treatment of 'Attention Deficit Hyperactivity Disorder (ADHD)

The Medicinal Products Reimbursement Committee (CFH) has carried out a re-assessment of the medicine atomoxetine (Strattera®). Atomoxetine is intended, as part of a broad treatment programme, for the attention deficit hyperactivity disorder (ADHD) in children aged 6 years and older and adolescents.

The conclusion of earlier assessments was that evidence of clinically relevant differences in properties between atomoxetine and methylphenidate was lacking or insufficient. This is one of the criteria that led to atomoxetine being clustered with methylphenidate on List 1A.

The new data relevant to this re-assessment relate in particular to the direct comparative study of Wang (2007) and the meta-analyses and guideline of the NICE (2009),
This assessment is limited to the question of whether the new data provide sufficient substantiation for dissolving the cluster.
Due to the fact that during the first re-assessment there were indications of a possibly greater effect of methylphenidate in comparison with atomoxetine, and because the CBO 2005 guideline also expressed a preference for methylphenidate (as did the CFH in the '*Farmacotherapeutisch Kompas'*, this assessment focuses on examining the certainty of the claimed clinically relevant differences in properties. In order to warrant dissolution of the cluster, the differences in clinical properties must be established with sufficient certainty and may not be based mainly on expert opinions or a difference in experience or costs.
The addition of the Wang study means there are now 3 studies that directly compare atomoxetine and methylphenidate; all 3 studies have their shortcomings. One of the problems with the Wang study is not knowing whether the outcomes of this Asian study can be extrapolated to the Caucasian population with respect to side effects. These 3 direct comparative studies do not reveal consistent outcomes for efficacy and side effects.
The NICE concluded that atomoxetine is less effective than methylphenidate, but in the meta-analyses of the NICE, an indirect comparison of the placebo-controlled studies involving children with ADHD and a mixed comorbidity reveal that the difference between atomoxetine and methylphenidate on 3 out of 4 outcome parameters is not statistically significant. The NICE guideline confirms, furthermore, that only short-

term outcomes are known for atomoxetine and methylphenidate. There is a lack of sufficient data and there is still uncertainty about the advantages and disadvantages in the long term and of long-term treatment.

The conclusion is that the new findings do not form a reason to alter the previous conclusion drawn by the CFH. Atomoxetine and methylphenidate can remain in the same cluster on List 1A.