For companies which as of 5 April 2009 or before notified a price of one or more medicinal products approved for marketing in ATC group A08

Decision on the future reimbursement status of medicinal products in ATC group A08 as a result of the reassessment process

3 July 2009

Case no.:
5315-16

This decision concludes the Danish Medicines Agency's reassessment of the reimbursement status of medicinal products in ATC group A08 (antiobesity preparations, excl. diet products).

The decision is an overall decision on the reimbursement status as of 13 July 2009 for all medicinal products of all strengths (unless otherwise stated) in ATC group A08, for which a price was notified to the Danish Medicines Agency as of 5 April 2009 or before.

Presentation
On 14 April 2009, the Reimbursement Committee presented its recommendation on the medicinal products' future reimbursement status to the Danish Medicines Agency. We refer to the information in the recommendation as regards the reassessment process. The Committee's recommendation is available at www.dkma.dk > Companies > General reimbursement > Reassessment of reimbursement status for medicinal products, notification of 27 April 2009[1].

The Reimbursement Committee's recommendation has been submitted to the concerned companies and relevant scientific societies for consultation. The consultation responses are available via the link above under the notification of 3 June 2009[2].

Below you may find the decision made, the grounds therefore, the regulatory framework and the complaint instructions.

Decision
All medicinal products in ATC group A08 (antiobesity preparations, excl. diet products) containing the individual substances:

- amfepramone
- sibutramine

[1] http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=14994
[2] http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=15130

- orlistat

maintain their current reimbursement status (no general reimbursement).

The Danish Medicines Agency finds that these medicinal products fall under the exception in section 1(3), item 5 of the executive order on reimbursement, as we assess that there is a risk that the medicinal products in question will be used as first-line treatment, regardless that the Danish Medicines Agency does not believe that this should be the case.

For medicinal products containing amfepramone, we also find that these medicinal products fall under the exception in section 1(3), item 7, as we assess that there is an imminent risk that the medicinal product will be abused.

We do not find that any exceptional circumstances apply which may give grounds for a different outcome.

With reference to section 1(4) of the executive order on reimbursement, it is, in our opinion, not possible to identify any parts of the indication ('certain diseases') for these medicinal products which independently meet the criteria set out in the executive order on reimbursement for being granted general reimbursement (general conditional reimbursement).

Grounds
The Danish Medicines Agency emphasises what the Reimbursement Committee wrote in its recommendation of 14 April 2009 about the fact that obesity is a chronic condition that requires long-term non-medical treatment, and that lifestyle changes is the first-line treatment of obesity. The Danish Medicines Agency concurs with the argument that medicinal products for obesity should only be used in special circumstances where the effect can be expected to go beyond the actual weight loss and lead to, e.g., improved diabetes control. In relation to amfepramone, we also emphasise the abuse potential of the medicinal product.

Like the Committee, the Danish Medicines Agency finds that general reimbursement for medicinal products containing these active substances entails a risk that the products are used as first line agents in the treatment of obesity.

Based on the same grounds, it is, in our opinion, not possible to identify parts of the indication ('certain diseases') for this medicinal product which independently meet the criteria set out in the executive order on reimbursement for being granted general reimbursement (general conditional reimbursement).

Legal framework

The legal basis for reassessment of reimbursement status is section 3 of Danish executive order no. 180 of 17 March 2005 on reimbursement and in accordance with the principles laid down in the Danish Medicines Agency's guidelines of 8 June 2005 on the procedure for reassessment of the reimbursement status of medicinal products as well as the Danish Medicines Agency's guidelines of 4 July 2006 for evaluation and comparison of medicinal products in reassessments of reimbursement status. A link to these documents can be found at www.dkma.dk > Companies > General reimbursement > Reassessment of reimbursement status for medicinal products (the factbox).

Reassessment
In connection with the introduction of the reassessment of the reimbursement status of medicinal products in 2005, it was decided that the reimbursement status of all medicinal products should be reassessed regularly. Therefore, the medicinal products' reimbursement status will be assessed again as part of this regular reassessment procedure.

In addition, the Danish Medicines Agency can initiate ad hoc reassessments, e.g. when we receive new information about inappropriate consumption, new treatment recommendations, changes in price etc. The Danish Medicines Agency monitors the development in consumption and prices comprised by this decision.

Complaints
This decision may be appealed to the Danish Ministry of Health and Prevention, Slotsholmsgade 10-12, 1216 Copenhagen K, Denmark. However, the Ministry cannot reassess the Danish Medicines Agency's scientific evaluation.

Best regards,

Elisabeth Thomsen