For companies marketing one or more medicinal products
licensed in ATC group A06 or A02AA04
on or before 5 April 2009

Decision on the future reimbursement status of medicinal products in ATC group A06 and A02AA04 resulting from the reassessment procedure

3 September 2009

File no.:
5315-6

With this decision, the Danish Medicines Agency concludes the reassessment of the reimbursement status for medicinal products in ATC groups A06 (laxatives) and A02AA04 (magnesium compounds).

The decision is an overall decision with effect for all medicinal products of all strengths in ATC groups A06 and A02AA04 marketed on or before 5 April 2009.

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 in Danish only at www.dkma.dk > Companies > General reimbursement > '*Reassessment of reimbursement status for medicinal products*, announcement dated 29 April 2009[1].

The recommendation of the Reimbursement Committee has been submitted to the affected companies, scientific societies, patient organisations etc. for consultation. The consultation responses are available (in Danish only) and can be accessed via the above link above under the announcement dated 3 June 2009[2].

Please find below the decision and the grounds on which it was made, the regulatory framework and the complaint instructions.

[1] English translation uploaded to www.dkma.dk on 4 May 2009.
[2] English translation uploaded to www.dkma.dk on 4 June 2009

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Decision

1.
Oral and rectal medicinal products in ATC group A06 (laxatives) and A02AA04 (magnesium compounds) containing

the individual substances:

- bisacodyl (A06AB02)
- sodium picosulfate (A06AB08)
- ispaghula (A06AC01)
- magnesium oxide (A06AD02)
- lactulose (A06AD11)
- lactitol (A06AD12)
- sodium phosphate (A06AG01)
- bisacodyl (A06AG02)
- glycerol (A06AX01)
- magnesium hydroxide (A02AA04)

the combinations:

- macrogol 3350, sodium hydrogen carbonate, sodium chloride and potassium chloride (A06AD65)
- ascorbic acid, sodium ascorbate, macrogol 3350, sodium sulphate, sodium chloride and potassium chloride (A06AD)
- disodium phosphate dodecahydrate and sodium dihydrogen phosphate dehydrate (A06AD)
- docusate sodium in combination with glycerol or sorbitol (A06AG10)
- lauryl sulphate and sodium citrate (A06AG11)

maintain their current reimbursement status (no general reimbursement).

In the opinion of the Danish Medicines Agency, these medicinal products *do not meet* the criteria for being granted general reimbursement, cf. section 1(3)(iii) and (v) of the executive order on reimbursement[3].

With reference to section 1(4) of the executive order on reimbursement, we assess that it is 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).

2.
Medicinal products for injection in ATC group C06 (laxatives) containing

[3] Executive order no. 180 of 17 March 2005 on reimbursement. Danish title: Bekendtgørelse nr. 180 af den 17. marts 2005 om medicintilskud.

the individual substance:

- methylnaltrexone (A06AH01)

maintain their current reimbursement status (no general reimbursement).

In the opinion of the Danish Medicines Agency, these medicinal products *do not meet* the criteria for being granted general reimbursement, cf. section 1(3)(ii) of the executive order on reimbursement.

With reference to section 1(4) of the executive order on reimbursement, we assess that it is not possible to identify any 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).

Re item 1 - Grounds

We assess that these medicinal products are predominantly used for purposes for which it is unreasonable that the Regional Council should grant reimbursement. We also believe that there is a risk that the products are used as first-line treatment regardless of the Danish Medicines Agency's assessment that this should not be the case.

We have found no other exceptional circumstances which would justify a different decision.

The Danish Medicines Agency takes account of the Reimbursement Committee's recommendation of 14 April 2009 in which it states that first-line treatment of constipation is a nutrition programme (fiber-rich food, increased fluid intake), exercise and proper defecation habits.

The Danish Medicines Agency also takes account of the Reimbursement Committee's assessment that general reimbursement for laxatives or general conditional reimbursement for the cases laid down in the guiding criteria for single reimbursement would increase the risk that laxatives are inappropriately used as first-line treatment. The Reimbursement Committee bases its assessment on its clinical experience as well as the above-mentioned figures from the Register of Medicinal Product Statistics of the Danish Medicines Agency, which point to a significant sale without prescription.

We agree with the Reimbursement Committee that the use of laxatives may be appropriate for the treatment of acute or transient bowel obstruction, yet that it is a purpose for which it is unreasonable that the Regional Council should grant reimbursement. The vast majority of cases for which the Regional Council is expected to grant reimbursement are covered by the Danish Medicines Agency's criteria for single reimbursement.

Based on the same grounds, we do not find that it is possible to identify 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).

Re item 2 - Grounds
Methylnaltrexone for injection has a particular status in that it is licensed for the treatment of opioid-induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient.

The Danish Medicines Agency takes account of the Reimbursement Committee's recommendation of 14 April 2009 in which it states that there is a risk that the product is used outside of its licensed indication to treat opioid-induced constipation in non-advanced illness patients and/or patients who are not receiving palliative care. For these patients the Reimbursement Committee did not find the price of the medicinal product to be proportionate to its therapeutic value. There have been no changes to the price of the medicinal product that would justify changing this assessment.

We have found no other exceptional circumstances which would justify a different decision.

Based on the same grounds, we do not find it 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 reassessment of reimbursement status takes place in compliance with section 3 of executive order no. 180 of 17 March 2005 on reimbursement[4] and the principles laid down in the Danish Medicines Agency's 'Guidelines on procedure for reassessment of reimbursement status' of 8 June 2005 as well as the Danish Medicines Agency's 'Guidelines for evaluation and comparison of medicinal products in reassessments of reimbursement status' of 4 July 2006. 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

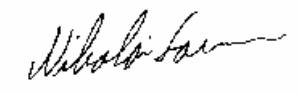
[4] Danish title: Bekendtgørelse nr. 180 af den 17. marts 2005 om medicintilskud

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 receiving 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.

Yours faithfully,



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