

Reassessment of reimbursement status for certain groups of medicinal products.

Future information about reassessments.

Reassessment of certain ATC subgroups

In a letter of 13 June 2005, the Danish Medicines Agency wrote to all companies holding a marketing authorisation for human medicinal products¹ that we would start looking at medicinal products in ATC subgroups A, C and J in the course of 2005. The letter also gave a brief description of the basis for reassessing reimbursement status and the expected procedure.

Afterwards, some companies asked for more precise indications of time for reassessment of medicinal products in each of the ATC subgroups A, C and J, which we promised in a letter of 31 August 2005 to The Danish Association of the Pharmaceutical Industry (Lif), The Danish Industry Association for Generic Medicines (IGL) and The Danish Association of Parallel Importers.

Both letters are available at the Danish Medicines Agency's website.

The Reimbursement Committee has recommended that the reassessments begin with groups A, C and J and that these groups are completed within a year. In this connection, it is important to emphasise that it concerns the preparatory review, which may constitute the basis for the Reimbursement Committee's recommendation for whether to initiate a case about a possible change of reimbursement status, cf. the guidelines².

During the first three months of 2006, we intend to work with the six following subgroups:

- C03 (diuretics)
- C04 (peripheral vasodilators)

¹ With the exception of companies holding marketing authorisations for medicinal products with limited dispensing, herbal medicinal products, potent vitamin and mineral preparations and radiopharmaceuticals are excepted, however.

² Guidelines of 8 June 2005 on the procedure for reassessment of the reimbursement status of medicinal products, appendix 2, please see the Danish Medicines Agency's website.

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- C05 (vasoprotectives)
- C08 (calcium channel blockers)
- C09 (agents acting on the renin-angiotensin system)
- C10 (serum lipid reducing agents)

We will announce it if any changes occur in relation to this.

The scientific societies and patient associations, which were also informed about the reassessment of medicinal products in ATC groups A, C and J in June 2005, will be notified in a similar letter.

In future, we intend to inform about indications of time for reimbursement reassessments as precisely and quickly as possible of the other subgroups within the ATC groups A, C and J, as well as subgroups within other ATC groups.

Future orientation via the Danish Medicines Agency's website

From the beginning of the reassessment project, we emphasised informing openly and as early as possible about procedures, guidelines, time frames, decisions and the basis for the project.

To ensure fast and exact information for interested parties, future messages of reassessment of reimbursement status for medicinal products will, as a general rule, only be posted on our website www.dkma.dk under the target group entrance for *Companies > General Reimbursement > Reassessment of reimbursement status*.

If you subscribe to our newsletter **NetNews** and choose news about **“Prices and Reimbursement”**, you will be informed directly about new notifications on prices and reimbursement.

Yours sincerely



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