LÆGEMIDDEL STYRELSEN

DANISH MEDICINES AGENCY

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Systematic, periodic re-assessment of the reimbursement status of medicinal products

The Danish Parliament has decided that the reimbursement status of medicinal products should be re-assessed on a continuing basis. This means that all medicinal products must undergo an assessment of whether their reimbursement status continues to meet the criteria for general reimbursement.

The criteria which a medicinal product must meet in order to be granted general reimbursement were introduced when the Danish Health Security Act was amended in 2000, and are set out in Executive Order no. 180 of 17 March 2005 on Reimbursement of Medicinal Products.

The re-assessment includes an assessment of whether the medicinal products that currently qualify for general reimbursement continue to meet these criteria and whether medicinal products not subject to general reimbursement continue not to meet these criteria.

In 2005, the Danish Medicines Agency will initiate a review of all ATC groups

- A (alimentary tract and metabolism)
- C (cardiovascular system) and
- J (anti-infectives for systemic use)

The review will be carried out simultaneously in the three groups.

The Danish Medicines Agency has established a procedure for regular re-assessment of the reimbursement status of medicinal products following discussions with the Reimbursement Committee and a number of stakeholders in the area. The procedure, including the criteria for general reimbursement and a flow-chart of the practical implementation of the procedure appears in *Guidelines of 8 June 2005 on procedure for re-assessment of the reimbursement status of medicinal products, (www.dkma.dk under "Companies").* This site also contains mention of the preceding discussions with the stakeholders and the background for the parliamentary decision on re-assessments (memorandum of 8 June 2005).

When deciding on the order in which to review the ATC groups, emphasis is primarily on the relevance to the primary sector, particularly the general practitioners. In addition, factors such as turnover in terms of price and/or quantity, any health-related implications, new evidence-based therapeutic guidelines etc. are also considered.

Our preliminary estimate is that approximately 3 main ATC groups can be assessed each year.

Also in the future, the Danish Medicines Agency will send a joint letter to inform all companies that hold a marketing authorisation for human medicines[1] about the next ATC groups that will be reviewed. At the same time, relevant scientific societies and patient associations will be informed.

You are generally not required to take any action at the time being. If the Danish Medicines Agency decides to initiate a procedure regarding a change of reimbursement status, your company and relevant scientific societies will be consulted, and you will have a deadline of three months for submitting any comments.

The actual procedure in the form of the Danish Medicines Agency's review of relevant conditions affecting the reimbursement assessment (see the section on the basis for the re-assessments in the guidelines) of the medicinal products in question, presentation to the Reimbursement Committee, a possible consultation on the Committee's recommendation regarding the reimbursement status, and the Danish Medicines Agency's decision are described in more detail in the guidelines and the accompanying flowchart of the management of the re-assessment procedure.

During the initial stages, there has been much focus on openness in the process and the procedure, the decisions made, and the basis for such decisions. This openness is described in the guidelines and encompasses not only the affected companies and the relevant scientific societies and patient associations, but also other stakeholders, such as doctors, patients, and the general public.

Yours sincerely

Elisabeth Thomsen

[1] Companies holding marketing authorisations for medicinal products with limited prescription, herbal medicinal products, potent vitamin and mineral products and radioactive medicinal products are excepted, however.