

Merck Sharp & Dohme B.V.

**Consultation with stakeholders – Reassessment of reimbursement status of combination products in ATC groups C02, C03, C07, C08 and C09 - Synerpril**

The Danish Medicines Agency is currently reassessing the reimbursement status of medicinal products for cardiovascular diseases in ATC groups C02, C03, C07, C08 and C09.

The Reimbursement Committee submitted its first recommendation on 29 January 2008 and an additional recommendation on 2 September 2008.

In its additional recommendation of 2 September 2008, the Reimbursement Committee states that the Committee presupposes that the Danish Medicines Agency in its decision will assess any changes in price and consumption and their influence on the Danish Medicines Agency's decision.

The Danish Medicines Agency has completed its assessment of the matter of future reimbursement status of all combination products in ATC groups C02, C03, C07, C08 and C09 with consideration of updated price and consumption information.

Based on the actual strengths and pharmaceutical forms marketed of the combination products in question, we have calculated the average lowest unit price in the period 25 August 2008 to 16 November 2008 for, respectively, combination products and individual substances of corresponding strengths and relevant comparable pharmaceutical forms. We have used this average lowest unit price as the basis for our evaluation. This price information can be found in **Appendix I**.

It appears from the updated price information that the average lowest unit price of the combination product Synerpril, tablets containing 20 mg of enalapril and 6 mg of hydrochlorothiazide, is DKK 5.93.

Against this it may be pointed out that the average lowest unit price of combination products containing 20 mg of enalapril and 12.5 mg of

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hydrochlorothiazide is DKK 0.34. The average lowest unit price of the individual substance enalapril, 20 mg tablets, is DKK 0.39. Hydrochlorothiazide is not marketed as an individual substance.

The Danish Medicines Agency agrees with the Reimbursement Committee that combination products may support good compliance in the use of medicinal products, The Danish Medicines Agency does not, however, find that the high price of the combination of enalapril 20 mg and hydrochlorothiazide 6 mg can be justified. With reference to the price of the combination of enalapril 20 mg and hydrochlorothiazide 12.5 mg, the Danish Medicines Agency thus does not find that the therapeutic value of Synerpril is reasonable relative to its price. The Danish Medicines Agency does not find that there are any other special circumstances related to Synerpril that can justify the price difference.

On this basis, the Danish Medicines Agency considers changing the reimbursement status of Synerpril, entailing that the medicinal product would no longer be eligible for general reimbursement.

We kindly request you to submit any remarks you may have to the above no later than **Thursday 11 December 2008**.

When the consultation period has expired, we will include your consultation response in our basis for decision on the medicinal products' future reimbursement status in Denmark. Please note that any consultation responses that we receive will be posted on our website.

This stakeholder consultation letter will be published on the Danish Medicines Agency's website. In parallel with this stakeholder consultation of your company, we have on this date initiated stakeholder consultations of companies holding marketing authorisations for combination products containing the individual substances verapamil and trandolapril, captopril and hydrochlorothiazide as well as metoprolol and felodipine. We will also publish our consultation letter in relation to the combination of perindopril and amlodipine. A copy of our stakeholder consultation letters are available at [www.dkma.dk](http://www.dkma.dk) > Companies > General reimbursement > Reassessment of reimbursement status for medicinal products.

A notification about this consultation will also be sent to the Danish Society of Cardiology, Danish Endocrine Society, Danish Hypertension Society, Danish Society for Vascular Surgery, Danish Surgical Society, Danish Medical Society, Danish Society of Nephrology, Danish Paediatric Society, Danish College of General Practitioners, Danish Stroke Society, Danish Society of Geriatrics, Danish Society of Internal Medicine, Danish Society of Clinical Pharmacology, Danish Patients and Disabled Peoples Organisations Denmark. In addition, the Danish National Board of Health,

the Institute for Rational Pharmacotherapy and the Reimbursement Committee have been notified.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Elisabeth Thomsen', with a long horizontal flourish extending to the right.

Elisabeth Thomsen