Orifarm A/S
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Consultation with stakeholders – Reassessment of reimbursement status of combination products in ATC groups C02, C03, C07, C08 and C09 - Capozid/Capozide

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Case no.:
5315-9
Our ref.: Elisabeth Thomsen

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 Capozid/Capozide, tablets containing 50 mg of captopril and 25 mg of hydrochlorothiazide, is DKK 5.76.

The average lowest unit price of the individual substance captopril, 50 mg tablets, is DKK 0.51. Hydrochlorothiazide is not marketed as an individual substance.

This information shows that the price of the combination product Capozid/Capozide is significantly higher than the price of captopril alone.

The Danish Medicines Agency agrees with the Reimbursement Committee that combination products may support good compliance in the use of medicinal products, but the Danish Medicines Agency does not, however, find that this can justify a price that is so much higher for a combination of captopril and hydrochlorothiazide. At the same time, it should be taken into consideration that captopril, unlike other ACE inhibitors, must be taken twice daily and is thus assessed to be less appropriate and generally cannot be recommended. The Danish Medicines Agency does not find that there are any other special circumstances related to Capozid/Capozide that can justify the price difference.

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

The Danish Medicines Agency emphasises the Reimbursement Committee's viewpoints concerning the class effect within the group of ACE inhibitors, which is expressed in the Committee's recommendations of 29 January 2008 and 2 September 2008. In the light of this, the Agency also finds it significant that the average lowest unit price of combination products containing hydrochlorothiazide and equieffective doses of the ACE inhibitors enalapril, lisinopril and ramipril in the period 25 August 2008 to 16 November 2008 was between DKK 0.34 and DKK 0.92, cf. Appendix I.

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

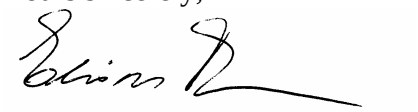
When the consultation period has expired, we will include your consultation response in our basis for decision on the medicinal products' future reimbursement status in Denmark. Please note that any consultation responses that we receive will be posted on our website.

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, metoprolol and felodipine as well as 20 mg enalapril and 6 mg hydrochlorothiazide. 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 > Companies > General reimbursement > Reassessment of reimbursement status for medicinal products.

A notification about this consultation will also been 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,



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