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DANISH MEDICINES AGENCY

Consultation with stakeholders – Reassessment of reimbursement status for medicinal products for cardiovascular diseases in ATC groups C02, C03, C07, C08 and C09 – Additional recommendation from the Reimbursement Committee

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On the Danish Medicines Agency's request, the Reimbursement Committee has reassessed the reimbursement status for medicinal products authorised for marketing in Denmark in ATC groups C02, C03, C07, C08 and C09. Reassessment means an assessment of whether there is basis for opening a case as to whether the reimbursement status of a medicinal product should be changed.

The Reimbursement Committee submitted its first recommendation to the Danish Medicines Agency on 29 January 2008. The recommendation can be found at www.dkma.dk under *Companies > General reimbursement > Reassessment of reimbursement status for medicinal products* under "Information on reassessment of reimbursement status" (message of 14 February 2008), where you can also find links to the references on which the Reimbursement Committee based its recommendation.

The recommendation has been submitted for consultation with all companies that as of 13 January 2008 had submitted a price to the Danish Medicines Agency for one or more medicinal products authorised for marketing in one or more of the above mentioned ATC groups C02, C03, C07, C08 and C09. Moreover, the recommendation was submitted for consultation with a number of scientific societies and other stakeholders in the area. The consultation deadline was 5 May 2008, and the published consultation responses (in Danish only) can be found under the message of 7 July 2008.

The Reimbursement Committee has discussed the submitted consultation responses and on 2 September 2008 it provided an additional recommendation. This recommendation can be found at www.dkma.dk under *Companies > General reimbursement > Reassessment of reimbursement status for medicinal products* under "Information on reassessment of reimbursement status" (message of 9 September 2008).

As of 25 August 2008, your company has notified the Danish Medicines Agency of a price of one or more medicinal products authorised for marketing in Denmark in one or more of the above mentioned ATC groups C02, C03, C07, C08 and C09, and therefore your medicinal products are comprised by the Reimbursement Committee's recommendation of 29 January 2008 and the Reimbursement Committee's additional recommendation of 2 September 2008.

A list of all medicinal products marketed in the period 13 January 2008 to 25 August 2008 that are comprised by the Reimbursement Committee's recommendations can be found under the above mentioned message of 9 September 2008. The Committee's recommendation concerning these medicinal products is in accordance with the recommendation of 29 January 2008 for the active substances and pharmaceutical forms in question.

We would like to emphasise that both the recommendation of 29 January 2008 and the additional recommendation of 2 September 2008 are based on the price and consumption figures available at the time of the recommendation of 29 January 2008. The prices at which your medicinal product(s) has/have been marketed after 13 January 2008 have not been considered by the Reimbursement Committee.

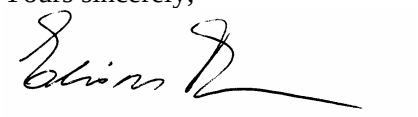
In connection with its decision on the future reimbursement status of the medicinal products concerned, the Danish Medicines Agency will include updated price and consumption data for all medicinal products comprised, cf. the information in appendices B1-B5 and C1-C5 to the recommendation of 29 January 2008, including for example the observed decrease in prices of medicinal products containing trandolapril.

We would like to encourage you to carefully read the Reimbursement Committee's additional recommendation of 2 September 2008, and if you have any comments to the material, please submit them no later than **Friday 19 September 2008**.

We would also like to direct your attention to the fact that all consultation responses will be published on our website in compliance with the "Guidelines on procedure for reassessment of reimbursement status for medicinal products" of 8 June 2005.

If you would like us to send you a printed version of the material, please call us on tel.: +45 44 88 93 11.

Yours sincerely,



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