For companies which as of 1 December 2008 or before notified a price of one or more medicinal products approved for marketing in ATC group C02

**Decision on future reimbursement status for medicinal products in ATC group C02 as a result of the reassessment process**

16 January 2009

Case no.:
5315-9

With this decision, the Danish Medicines Agency concludes the reassessment of the reimbursement status for medicinal products in ATC group C02 (antihypertensives).

The decision is an overall decision on the reimbursement status **as of 13 July 2009** for all medicinal products of all strengths containing the individual substances methyldopa (C02AB01) and moxonidine (C02AC05) in ATC group C02, for which a price is or has been notified to the Danish Medicines Agency as of 1 December 2008 or before.

The reassessment of medicinal products in ATC group C02 does not comprise medicinal products containing doxazosin (C02CA04). On the recommendation of the Reimbursement Committee, these medicinal products are reassessed together with medicinal products used for the treatment of prostatic hyperplasia. Nor does the reassessment comprise medicinal products in ATC group C02 containing the individual substances bosentan (C02KX01) and sitaxentan (C02KX03) as these are for hospital use only.

**Presentation**
The Reimbursement Committee has submitted two recommendations containing the Committee's recommendations for the future reimbursement status for medicinal products in ATC groups C02 (antihypertensives), C03 (diuretics), C07 (beta blocking agents), C08 (calcium channel blockers) and C09 (ACE inhibitors, angiotensin II antagonists and renin inhibitors). The first recommendation is dated 29 January 2008. The additional recommendation is dated 2 September 2008. The Committee's recommendations are available at www.dkma.dk > Companies > General reimbursement > Reassessment of reimbursement status for medicinal products, notifications of 14 February and 9 September 2008.

The recommendations of the Reimbursement Committee have been submitted to the affected companies, scientific societies, patient organisations etc. for consultation.

Please see the consultation memorandum enclosed as **Appendix 1** for the most important viewpoints stated in the consultation responses and the Danish Medicines Agency's comments thereon.

The decision made, the grounds therefore and the regulatory framework are stated below.

**Decision**

**1.** Oral medicinal products in ATC group C02 containing the individual substances
- methyldopa
- moxonidine

maintain their current reimbursement status (general reimbursement) as of 13 July 2009.

The Danish Medicines Agency finds that these medicinal products still *meet* the criteria for being granted general reimbursement, cf. section 1(2) of Danish executive order no. 180 of 17 March 2005 on reimbursement.

**Grounds**
In its recommendation of 29 January 2008, the Reimbursement Committee stated that, in the opinion of the Committee, the medicinal products individually have a well-defined place in the therapy in combination with other antihypertensives and are used in a rational manner.

The Reimbursement Committee's additional recommendation of 2 September 2008 was based on the assumption that the Danish Medicines Agency will include any changes in price and consumption occurring after the Committee submitted its first recommendation on 29 January 2008 in its assessment basis.

At the time of the Reimbursement Committee's first recommendation, consumption data for 2006 showed that approx. 1,000 persons received treatment with methyldopa, the median age was 35 years and 87 per cent of the users were women. Approx. 7,000 persons received treatment with moxonidine. The trend for 2007 for both medicinal products showed a small increase. The price of treatment per day calculated in reimbursement prices was DKK 3.76 for methyldopa and DKK 2.48 for moxonidine.

**Appendix II/C02** contains an updated price and consumption list for individual substances in ATC group C02 specifying the average lowest prices of treatment per day for the indication of hypertension, the consumption at active substance level as well as the names and pharmaceutical forms of all medicinal products comprised by this decision. The prices of treatment per day are calculated over six price periods for the period 22 September 2008 to 14 December 2008.

The prices on which the decision is based are calculated in accordance with the Danish Medicines Agency's guidelines of 4 July 2006 for evaluation and comparison of medicinal products in reassessments of reimbursement status, cf. below under Regulatory framework.

Changes in price and consumption which have occurred after 1 December 2008 do not give rise to a changed assessment, cf. below.

The figures for 2007 show that 1,208 persons received treatment with methyldopa, the median age was 36 years and 87 per cent of those treated were women. 7,286 persons were being treated with moxonidine. The trend for 2008 shows a small increase. The price of treatment per day stated at reimbursement prices is now DKK 3.68 for methyldopa and DKK 1.20 to DKK 1.88 for moxonidine.

The Danish Medicines Agency emphasises the Reimbursement Committee's recommendations of 29 January 2008 and 2 September 2008 and shares the Reimbursement Committee's opinion that these medicinal products individually have a well-defined place in the therapy in combination with other antihypertensives and hardly as first-line treatment and that the consumption is deemed to be rational. For methyldopa, it is emphasised that consumption data show that 87 per cent of the users are women and the median age is 36 years, which supports the recommendation that methyldopa be used for the treatment of pregnant women.

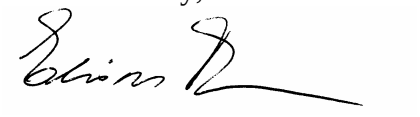
**Regulatory framework**
The legal basis for reassessment is section 3 of Danish executive order no. 180 of 17 March 2005 on reimbursement and in accordance with the principles laid down in the Danish Medicines Agency's guidelines of 8 June 2005 on the procedure for reassessment of the reimbursement status of medicinal products as well as the Danish Medicines Agency's guidelines of 4 July 2006 for evaluation and comparison of medicinal products in reassessments of reimbursement status. A link to these documents can be found at www.dkma.dk > Companies > General reimbursement > Reassessment of reimbursement status for medicinal products (the fact box).

**Reassessment**
In connection with the introduction of the reassessment of the reimbursement status of medicinal products in 2005, it was decided that the reimbursement status of all medicinal products should be reassessed regularly. The reimbursement status granted to the medicinal products following this decision will thus be reassessed in connection with this regular reassessment procedure.

In addition, the Danish Medicines Agency can initiate ad hoc reassessments, e.g. when receiving new information about inappropriate consumption, new treatment recommendations, changes in price etc. The Danish Medicines Agency monitors the development in consumption and prices comprised by this decision.

**Information**
Doctors and pharmacies will be informed of the content of this decision via articles in professional journals etc. Other stakeholders will receive a notification referring to the Danish Medicines Agency's website. All decisions with appendices for medicinal products in ATC groups C02, C03, C07, C08 and C09 as well as an overview of the current and future reimbursement status for all medicinal products comprised by these decisions will be available at the website.

Yours sincerely,



Elisabeth Thomsen

# Appendix II/C02: Price and consumption list of antihypertensives, individual substances

**Average lowest price of treatment per day calculated over six price periods (for the period 22 September 2008 to 14 December 2008)**

| 1. ATC | 2. Active substance/group | 3. Number of persons treated 2006 | 2007 | 4. Dose used (mg) | 5. Pharmaceutic. form | 6.Strength(s) (mg) | 7. Avg. lowest unit price(s) (DKK) | 8. Price per day (DKK) |
|---|---|---|---|---|---|---|---|---|
| **C02AB** | **Methyldopa** | 1,058 | 1,208 | | | | | |
| C02AB01 | Methyldopa (levorotatory) | 1,058 | 1,208 | 1000 [1 2] | Film-coated tablets | 250 | 0.92 | 3.68 |
| | | | | | | | | |
| **C02AC** | **Imidazoline receptor agonists** | 6,942 | 7,286 | | | | | |
| C02AC05 | Moxonidine | 6,942 | 7,286 | 0.3 [1 3] | Film-coated tablets | 0.2 / 0.4 | 1.25 / 1.60 | 1.20 - 1.88 [4] |
| | | | | | | | | |

**Notes/explanations:**

| | |
|---|---|
| 1 | DDD value (WHO) |
| 2 | Divided into 2-4 daily doses |
| 3 | Optionally divided into 2 daily doses |
| 4 | The medicinal product is not available in a strength that corresponds to the equieffective dose/the proposed dose |

**Name and form of medicinal product**

| ATC | Name | Form |
|---|---|---|
| C02AB01 | Aldomet | film-coated tablets |
| C02AC05 | Moxonat | film-coated tablets |
| | Moxonidine ‘Actavis’ | film-coated tablets |
| | Moxonidine ‘ratiopharm’ | film-coated tablets |
| | Physiotens | film-coated tablets |