

Annual report of the Reimbursement Committee 2010

The Reimbursement Committee advises the Danish Medicines Agency on applications regarding reimbursement for medicines. This goes for both general reimbursement (applied for by pharmaceutical companies) and reimbursement for individual patients (applied for by a physician). Furthermore, the Committee advises the Danish Medicines Agency when the Agency reviews the reimbursement status of medicines. The Reimbursement Department of the Danish Medicines Agency acts as Secretariat to the Committee.

Members appointed by the Danish Minister for the Interior and Health

The Committee has up to seven members of which two must be general practitioners. The members are appointed by the Danish Minister for the Interior and Health upon nomination by the Danish Medicines Agency. One member is appointed by the Regions' Board for Wages and Tariffs. The Committee members are appointed for four years, and together they have a wide-ranging expertise. The Committee members' declaration of interest forms can be seen at www.dkma.dk in Danish.

In 2010, the members of the Reimbursement Committee were:

MD Mogens Laue Friis (Chairman),

MD Karine Bech,

MD Gorm Jensen,

GP Ellen-Christine Beiter,

GP John Larsen,

GP Palle Mark Christensen,

Head of Development, Peder Ørnsholt Ring (Danish Regions).

16 meetings in 2010

In 2010, the Reimbursement Committee held 16 meetings, of which six addressed the review of the reimbursement status of medicines. The minutes are available at www.dkma.dk.

20 applications for general reimbursement

The Reimbursement Committee gives advice to the Danish Medicines Agency on general reimbursement applications pursuant to the criteria laid down in Danish executive order no. 180 of 17 March 2005 on reimbursement (Danish title: bekendtgørelse nr. 180 af 17. marts 2005 om medicintilskud).

In 2010, the Reimbursement Committee reviewed 20 general reimbursement applications, many of which were transacted at more than one meeting. Five medicines were recommended for general unconditional reimbursement, 15 medicines were recommended for refusal, and three of them all were reapplications.

The number of applications for general reimbursement reviewed by the Committee is shown in figure 1.

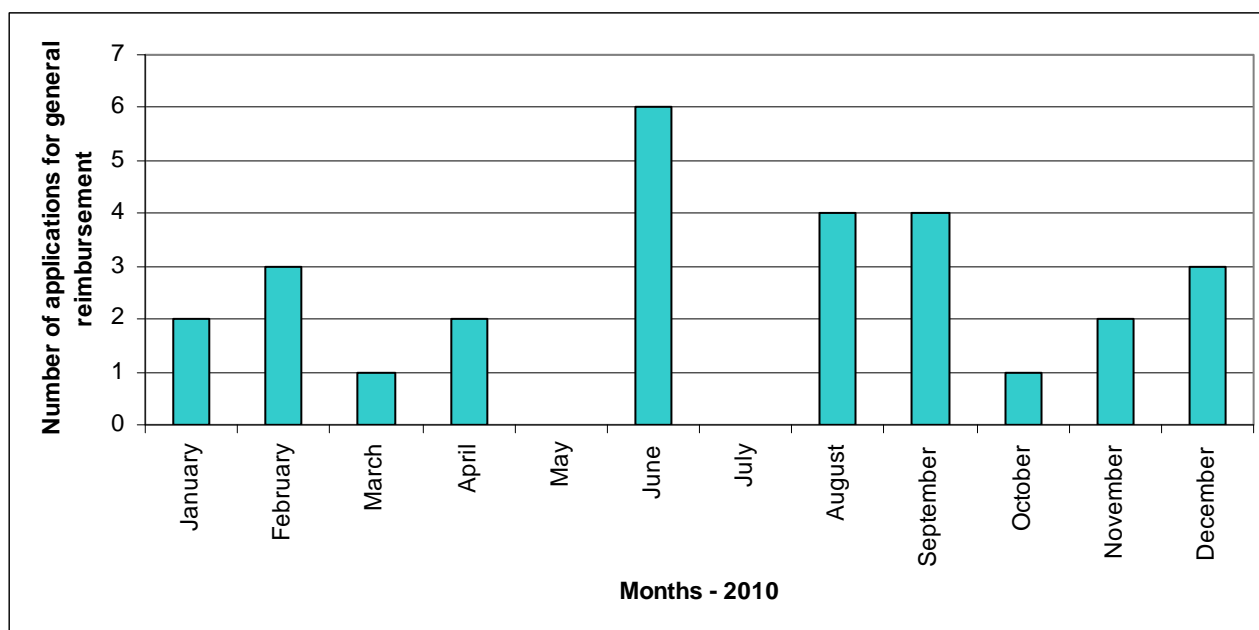


Figure 1. Number of applications for general reimbursement reviewed by the Committee per monthly meeting held in 2010.

Grounds

The Committee's recommendations regarding general reimbursement applications are published on the Danish Medicines Agency's website. The recommended refusals in 2010 were justified in e.g. the high price of the concerned medicine compared to other comparable products and the risk that the concerned medicine would be used as first-line treatment even though it would be inappropriate.

Most often, the grounds for recommending general reimbursement were that the therapeutic value was found to be commensurate with the price of other comparable medicines.

1719 applications for individual reimbursement

In 2010, the Danish Medicines Agency reached decisions in a total of 144,326 individual reimbursement applications. 1719 of these applications were presented to the Reimbursement Committee because the Secretariat found that individual reimbursement could not be granted offhand. In 30 % of these applications, the Committee recommended that individual reimbursement should be granted. The number of applications for individual reimbursement reviewed by the Committee is shown in figure 2.

When the Reimbursement Committee reviews single reimbursement applications, it regularly discusses if the guiding criteria for single reimbursement of the many medicines still comply with the most recent knowledge within the disease area concerned. During the course of 2010, the Committee discussed the guiding criteria for single reimbursement of medicines for dyssomnia, severe chronic refractory hand eczema, osteoporosis, dementia, antithrombosis, atrial fibrillation, hypertension, gastric ulcers, chronic obstructive pulmonary disease and angina pectoris. The guiding criteria for the medicines generating the most applications are available at the Danish Medicines Agency's website.

Annual review of the number of applications for single reimbursement

Every year, the Danish Medicines Agency makes a report on the number of single reimbursement applications submitted over the year. Based on this report, the Committee discusses whether the distribution of granted and refused applications for the respective medicines/medicine groups, and the volume of applications give reasons to consider changing the reimbursement status of the medicines. In

2010, no medicines/medicine groups were recommended for general or general conditional reimbursement as a result of these discussions.

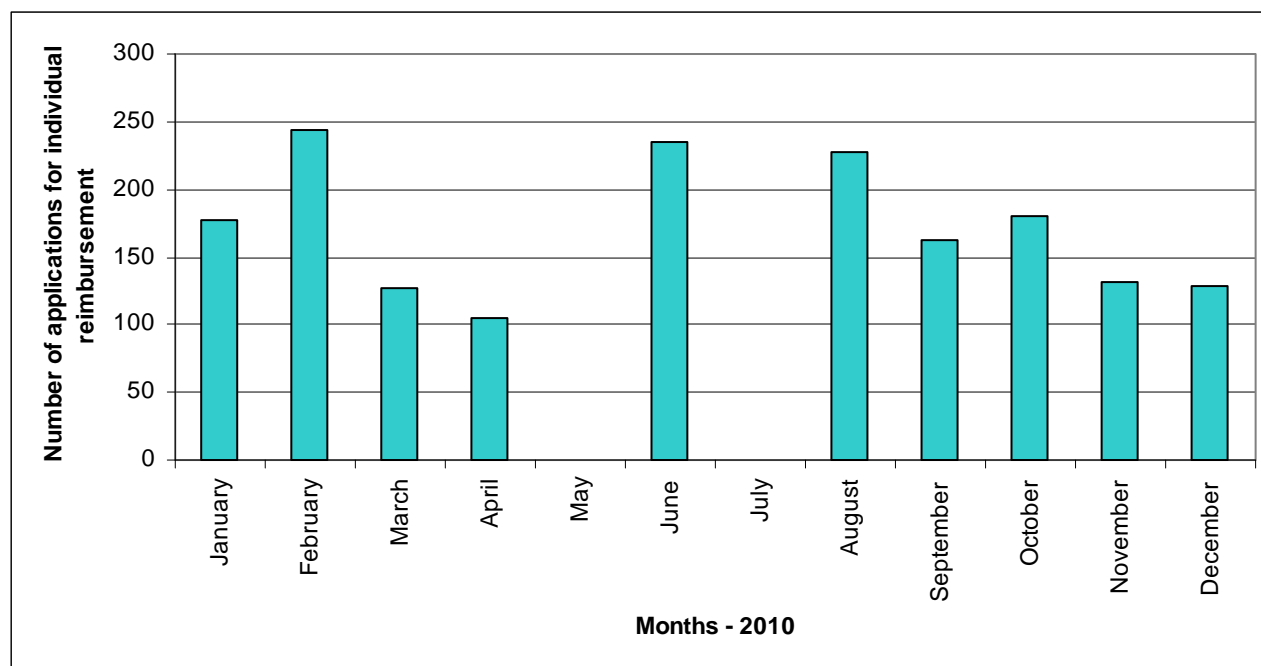


Figure 2. Number of applications for individual reimbursement reviewed by the Committee per monthly meeting held in 2010.

Price drop after patent expiry

During 2010, the Danish Medicines Agency and the Reimbursement Committee received a number of enquiries from doctors regarding clopidogrel, which – after the patent expiry of the original product and the marketing of generics – became significantly cheaper. The enquiries entailed that the reimbursement status for clopidogrel was discussed by the Committee, which recommended clopidogrel-containing medicines for general unconditional reimbursement. The reason for the recommendation was that the Committee found the price of clopidogrel to be commensurate with its therapeutic value when compared to treatment with acetylsalicylic acid (and possibly dipyridamole).

Advice from scientific societies

In its assessment of applications for general reimbursement and preparation of guiding criteria for single reimbursement, the Committee may need to obtain statements from external experts. Consequently, the Secretariat sends requests to the relevant scientific societies. In 2010, statements were gathered from the following societies: Danish Society for Allergology, Danish Society of Cardiology, Danish Society of Respiratory Medicine and Danish Society of Dermatology.

Digitisation of the Reimbursement Committee

At the end of 2010, all the Danish Medicines Agency's workflow processes were digitised, and as a corollary of this digitisation, the Committee's meeting material was also digitised. The Committee received its own digital forum.

Reassessment of the reimbursement status of medicines

Pursuant to the Danish Health Act, the Danish Medicines Agency must regularly review the reimbursement status of all medicines. The Reimbursement Committee prepares recommendations for the future reimbursement status of medicines for the Danish Medicines Agency. The key criteria for determining the priority in which the individual medicine groups should be reassessed are: the significance of the medicines to the primary sector and especially general practice, public health aspects, new evidence-based recommendations, high costs for patients and regions as well as a high consumption. Based on these criteria, the Reimbursement Committee discussed in 2010 the reimbursement status of the following groups of medicines:

- Antihypertensives (angiotensin II antagonists and renin inhibitors)
- Drugs for acid-related disorders
- Glucosamine
- Antibacterials for systemic use
- Antidepressants and medicines indicated to treat anxiety disorders

On 8 March 2010, a number of generic products containing losartan or a combination of losartan and hydrochlorothiazide were marketed. As a result of the marketing of generics, the expense of treatment with these medicines was reduced significantly compared with the expense before the patent expiry of the original medicine. The Danish Medicines Agency therefore decided to initiate ad hoc reassessment of the groups of angiotensin II antagonists and renin inhibitors. The Committee's recommendations for angiotensin II antagonists and renin inhibitors were submitted for consultation to the affected companies, relevant organisations and relevant scientific societies. The consultation responses were discussed by the Committee.

In December 2009, the Committee's recommendation for drugs for acid-related disorders was submitted for consultation. The consultation responses for these medicines were received at the beginning of 2010 and discussed by the Committee.

The Danish Medicines Agency followed the Committee's recommendations and reached a decision on 11 June 2010. The change in reimbursement status for drugs for acid-related disorders and antihypertensives (angiotensin II antagonists and renin inhibitors) entered into force on 15 November 2010.

The Committee has advised the Danish Medicines Agency to reassess the reimbursement status for glucosamine as soon as possible, because a Norwegian study published in the British Medical Journal showed that the effect of glucosamine on arthritic pain is at placebo level.

The Committee has completed its discussions of the reimbursement status of antibacterials for systemic use and will in 2011 make a recommendation to the Danish Medicines Agency.

The Committee has had the initial discussions of the reimbursement status of antidepressants and medicines indicated to treat anxiety disorders. The affected companies, relevant patient organisations and relevant scientific societies have been informed, and an announcement has been posted on the Danish Medicines Agency's website.

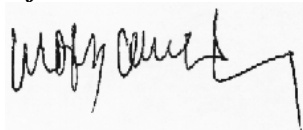
Read the Committee's recommendations, consultation responses received from stakeholders and the Danish Medicines Agency's decisions at www.laegemiddelstyrelsen.dk (in Danish only).

Information about the work of the Reimbursement Committee

Mogens Laue Friis gave a presentation on 22 September at the Danish Association of the Pharmaceutical Industry's course in *Medical Market Access III – Kvalitet og patientens perspektiv* (*Quality and the patient's perspective*). In his presentation he explained the Reimbursement Committee's work and workflows.

On 2 December, Mogens Laue Friis gave a presentation in *the Patient-Physician Forum*, which is a forum where the Danish Medical Association and several of the largest patient associations meet to exchange opinions and mutual information. Mogens Laue Friis' presentation was about the work of the Reimbursement Committee, and focused on the procedure for the reassessment of the reimbursement status of medicines.

On behalf of the Reimbursement Committee

A handwritten signature in black ink, appearing to read 'Mogens Laue Friis', is written over a light gray rectangular background.

***Mogens Laue Friis
Chairman***