29 September 2006

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UK.b.290906

Consultation on the Reimbursement Committee's recommendation regarding the reimbursement status of lipid-lowering medicines

The Danish Parliament has decided that the reimbursement status of all medicinal products should be reassessed over a period of five years.

The Reimbursement Committee has held several meetings to discuss the reimbursement status of lipid-lowering medicines (ATC Group C10). The Committee has now recommended to the Danish Medicines Agency that a number of changes be made in the reimbursement status of these medicinal products, cf. the Reimbursement Committee's letter of 7 September 2006 to the Danish Medicines Agency ("the Recommendation", Appendix 1).

Based on the Committee's recommendation, the Danish Medicines Agency has decided to initiate the procedure for a potential change of the reimbursement status of these medicinal products and will thus carry out a consultation among relevant stakeholders on the Committee's recommendation, cf. the guidelines on the reassessment procedure[1].

Therefore, we kindly ask you to submit your comments, if any, to the Reimbursement Committee's proposed changes to the reimbursement status of lipid-lowering medicines, cf. Appendix 1,

by or before 20 December 2006.

The Danish Medicines Agency reassesses the reimbursement status of the medicinal products in pursuance of the Executive Order on Reimbursement[2], cf. Section 3.

[1] The Danish Medicines Agency's guidelines of 8 June 2005 on the procedure for reassessments of reimbursement status.
[2] Executive Order no. 180 of 17 March 2005 by The Danish Ministry of the Interior and Health on Reimbursement for Medicinal Products.

Consultation parties and other stakeholders

According to the above-mentioned guidelines, all companies whose products are affected by a proposed change of reimbursement status and all relevant scientific societies within the therapeutic area in question will be consulted. The Danish National Board of Health will also be heard.

We enclose a list of your products that were approved as at 7 August 2006 and which are comprised by the consultation procedure (Appendix 2).

The scientific societies consulted about the recommendation are:

- Danish Medical Society
- Danish Society of Cardiology
- Danish College of General Practitioners
- Danish Society of Internal Medicine
- Danish Society for Clinical Pharmacology

"Patientforum" will, as a central forum for patient interests, receive a copy of this letter for information.

In addition, this letter will be published at the website of the Danish Medicines Agency.

Information about the reassessment process so far

The guidelines on the procedure for reassessment of reimbursement status and the guidelines for evaluation and comparison of medicinal products[3] are available at the website of the Danish Medicines Agency:

> www.dkma.dk cf. *Companies > General reimbursement > Reassessment of reimbursement status for medicinal products*

The website also contains a memorandum on the background for the reassessment and the initial discussions as well as previous letters to companies, scientific societies and patient associations. Furthermore, a status report for the reassessment process is available at the site, including the status of the other medicinal products in ATC Group C.

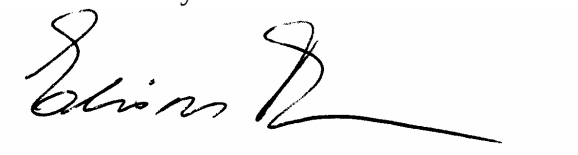
[3] The Danish Medicines Agency's guidelines of 4 July 2006 for evaluation and comparison of medicinal products in reassessments of reimbursement status *(will be available in English within a couple of weeks).*

Decision on reimbursement status

When the consultation phase has been finalised, the Danish Medicines Agency will make its decision, based on the recommendation by the Reimbursement Committee and the consultation responses received, regarding the reimbursement status of the individual medicinal products in the group of lipid-lowering medicinal products.

You will be notified of the Danish Medicines Agency's decision, which will also be published at our website, cf. above.

Yours sincerely



Elisabeth Thomsen

Appendices:

1. Letter from the Reimbursement Committee of 7 September 2006 to the Danish Medicines Agency with the recommendation for the reimbursement status for lipid-lowering medicines, ATC Group C10.
2. List of your products which were approved as at 7 August and which are comprised by the consultation.

THE REIMBURSEMENT COMMITTEE
THE SECRETARIAT
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The Danish Medicines Agency
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7 September 2006

Recommendation for the reimbursement status of lipid-lowering medicines, ATC Group C10

According to the decision of the Danish Parliament and as set out in Section 3 of the Executive Order on Reimbursement[1], the reimbursement status of the entire range of medicinal products is to be methodically reassessed. In connection with the reassessment of the reimbursement status of each medicinal product, the Danish Medicines Agency has asked the Reimbursement Committee to reassess the reimbursement status for lipid-lowering medicines, ATC Group C10. At its meetings held 22 March, 25 April, 13 June and 22 August 2006, the Reimbursement Committee discussed the reimbursement status of lipid-lowering medicines.

The Reimbursement Committee based its discussions on the guidelines for the procedure for reassessing the reimbursement status[2] and the guidelines for evaluation and comparison of medicinal products for reassessing the reimbursement status[3]. Appendix A presents a graphical overview of ATC Group C10.

Based on this, the Reimbursement Committee hereby issues the following:

Recommendation

General reimbursement
Medicinal products containing one of the following statins (C10AA) is recommended for general reimbursement without restrictions:

- C10AA01: Simvastatin
- C10AA02: Lovastatin
- C10AA03: Pravastatin

Restricted general reimbursement
Medicinal products containing certain statins (C10AA), bile acid sequestrants (C10AC), nicotinic acid derivatives (C10AD), ezetimibe (C10AX09) and the combination of simvastatin and ezetimibe (C10BA02) are recommended for restricted general reimbursement. This concerns products containing the following substances:

[1] Executive Order no. 180 of 17 March 2005 by The Danish Ministry of the Interior and Health on Reimbursement for Medicinal Products.
[2] The Danish Medicines Agency's guidelines of 8 June 2005 on the procedure for reassessments of reimbursement status.
[3] The Danish Medicines Agency's guidelines of 4 July 2006 for evaluation and comparison of medicinal products in reassessments of reimbursement status.

- C10AA04: Fluvastatin
- C10AA05: Atorvastatin
- C10AA07: Rosuvastatin
- C10AC01: Cholestyramine
- C10AC02: Colestipol
- C10AD06: Acipimox
- C10AX09: Ezetimibe
- C10BA02: Combination of simvastatin and ezetimibe

Restricted reimbursement for these medicinal products is recommended for

> "Patients with hyperlipidemia necessitating treatment for whom therapy with statins eligible for general reimbursement without restriction has proved insufficient or who do not tolerate these medicines. In case of primary prophylactic treatment, the indication must be justified by concurrent presence of risk factors for developing ischaemic heart disease."

Medicinal products containing fibrate

- C10AB04: Gemfibrozil

are recommended for restricted general reimbursement for

> "Patients with isolated, severely elevated triglycerides or patients with combined hyperlipidemia, possibly combined with statin."

The recommendation and the associated justifications by the Reimbursement Committee are largely based on substance types because of the class effects involved, but it should be emphasised that the Committee's evaluation comprises the individual medicinal products. The recommendation thus covers the medicinal products containing the substances mentioned that were approved on 7 August 2006.

Justification

It is the opinion of the Reimbursement Committee that the suggested changes to the reimbursement status will contribute to a more rational use of the various lipid-lowering medicines and that the criteria for granting general reimbursement, including restricted general reimbursement, have been met for the different types of lipid-lowering medicines as well as for the individual medicinal products, cf. Section 1 of the Executive Order on Reimbursement.

The Committee is of the opinion that also the more recent lipid-lowering medicines have substantially found their place in the therapy and that the risk of them being used as the first choice where this should not have been the case has been reduced. Over time, scientific studies have resulted in a change of the target lipid values that are pursued as therapeutic objectives. In addition, the Heart Protection Study from 2002 showed that the values indicating treatment were significantly lower than the values previously applied. The potential patient population eligible for treatment is consequently also increasing.

It should be emphasised that the Reimbursement Committee has not changed its perception of which patients should be treated with lipid-lowering medicines. It remains the opinion of the Committee that the existing reimbursement restriction and the recommended single reimbursement criteria together

cover the patients who should be treated, cf. the enclosed overview of the current and suggested reimbursement status for the individual groups of medicinal products (Appendix B).

General reimbursement
The medicinal products containing the statins *simvastatin, lovastatin and pravastatin,* which are recommended for general reimbursement without restriction, are all fully valid first choices in the treatment of most cases of hypercholesterolemia, and the reimbursement prices of the medicinal products correspond with their therapeutic value (Section 1(2), ii, of the Executive Order on Reimbursement).

By granting a general reimbursement for these medicinal products, it cannot be ruled out that some individuals will receive primary prophylactic treatment without meeting the currently applicable recommended criteria for single reimbursement, but the Committee assesses that the risk is not sufficiently substantial as to preclude general reimbursement without restriction. In this connection, it should also be mentioned that simvastatin 10 mg is now approved for over-the-counter sale in the UK.

Restricted general reimbursement
The effect of statins is extensively a class effect. The recommendation for restricted general reimbursement for medicinal products containing the other statins – *atorvastatin, fluvastatin and rosuvastatin* – is therefore justified by the reimbursement prices of the medicinal products which are not reasonable in relation to the therapeutic value when compared to the reimbursement prices for medicinal products containing simvastatin, lovastatin and pravastatin, cf. Section 1 of the Executive Order on Reimbursement.

Medicinal products containing the bile acid sequestrants *colestipol and cholestyramine* and the nicotinic acid derivative *acipimox* each have their place in the therapy, almost exclusively as a supplement to statins.

As concerns the more recent *ezetimibe*, the Reimbursement Committee is of the opinion that it has now also found its place in the therapy and that the risk of it being used as the first choice at the expense of statin is minimal by now.

Common to all these medicinal products is that the Reimbursement Committee does not believe that the price corresponds with their therapeutic value for the large number of patients who are treatable – solely or as a basis – with one of the more inexpensive statins recommended for general reimbursement without restrictions. For the significantly smaller number of patients who cannot be treated sufficiently with these statins or who do not tolerate them and thus need a nicotinic acid derivative, a bile acid sequestrant, a fibrate, ezetimibe or one of the other statins as a supplement or substitution, the price is more reasonable compared to the therapeutic value. These medicinal products are consequently recommended for general reimbursement restricted to the above-mentioned patients.

The combination of simvastatin and ezetimibe has not been marketed. The two products are recommended individually for general reimbursement and restricted general reimbursement, respectively, with the mentioned justifications. The Reimbursement Committee has elected to also recommend the combination product for restricted general reimbursement, as the combination is likely to enhance compliance. However, the Committee also believes that the medicinal product's place in the therapy – in accordance with the restriction – should be monitored closely.

The price of treatment (the reimbursement price) per day for each individual product appears from Appendix C, which is a price survey of lipid-lowering medicines. The Committee's considerations concerning the price aspect are elaborated in more detail below.

The fibrate *gemfibrozil* is used as the first choice for isolated, severely elevated triglycerides and for combined hyperlipidemia and is therefore recommended for restricted general reimbursement for these conditions in particular.

By making this division, the Reimbursement Committee wishes to support rational pharmacotherapy and encourage the use of the less expensive statins that are eligible for general reimbursement as the therapeutic starting point.

Since the mid-'90s, a long series of published studies have investigated the medical treatment of hyperlipidemia in patients suffering from ischaemic heart disease, apoplexy and diabetes, etc., and for primary prophylactic treatment. A number of clinical guidelines, reference programmes, etc., based on these studies have subsequently been prepared by scientific societies and others. The Reimbursement Committee bases its scientific evaluation on the Danish Society of Cardiology's clinical guidelines for the prevention of cardiovascular diseases (1), the recommendations and background notes on lipid-lowering medicines by the Institute for Rational Pharmacotherapy (2) and NICE's technological evaluation of statins (3) supplemented by subsequent studies (4).

In addition to clinically technical issues and prices, the recommendation by the Reimbursement Committee is also based on consumption data from the Register of Medicinal Product Statistics at the Danish Medicines Agency, cf. below.

Elaboration of the justification

The suggested reimbursement status in relation to the current reimbursement status
The recommendation entails not only an overall relaxation of the reimbursement conditions for all lipid-lowering medicines, as they are all proposed covered by the provisions for general reimbursement, restricted or non-restricted, but also a different distinction between the products, cf. Appendix B.

Furthermore, the Committee recommends that the reimbursement restriction be modified. The current restriction and the currently applicable recommended criteria for single reimbursement emphasises diagnoses, lipid values and – for primary prophylactic therapy – risk factors for developing ischaemic heart disease. This is a natural consequence of developments in the area and the publication of a number of studies following the 4S study in 1994, and, with the proposed restriction, the Committee proposes a partial continuation of these clarifications.

Patients suffering from ischaemic heart disease, TCI/ischaemic cerebral insult, peripheral arterial insufficiency and diabetes must in actual practice always receive lipid-lowering treatment, and the Reimbursement Committee does not find it necessary to give a more detailed clarification. The Committee is, however, of the opinion that, with regard to primary prophylactic treatment, it must be clarified that the indication for granting restricted general reimbursement, in addition to elevated lipid values following a lifestyle change, must be the presence of risk factors for developing ischaemic heart disease.

The overall purpose of the changed reimbursement restriction is to define the condition of a patient suffering from hyperlipidemia necessitating treatment and to encourage the use of the less expensive

statins eligible for general reimbursement where possible, in isolation or combined with one of the other lipid-lowering substances. Furthermore, it is emphasised that reimbursement for primary prophylactic treatment should be contingent on the presence of risk factors for developing ischaemic heart disease.

Prices and equiefficient doses
The Committee's evaluation of the price of treatment per day for the individual active substances has been carried out in accordance with the provisions set out in the guidelines for evaluation and comparison of medicinal products in reassessments of reimbursement status. The calculations are based on the equiefficient doses recommended by the Institute for Rational Pharmacotherapy in the national recommendation list as at 18 November 2005[4] (or possibly DDD values) and the reimbursement prices of the individual substances.

A price survey of the entire range of lipid-lowering medicines based on prices in 6 price periods (period start from 22 May to 31 July 2006) stating the applied equiefficient doses (or possibly DDD values) and relevant strengths is enclosed as Appendix C.

The survey indicates an overall spread in the price of treatment per day from DKK 0.91 to 24.32 based on reimbursement prices. The price structure in the medicinal products area, with free pricing and possible price adjustments every two weeks, necessitates a certain price spread. Consequently, the Committee recommends general reimbursement without restrictions for medicinal products containing one of three active substances, even though the reimbursement price for the most expensive of the three substances is more than three times higher than the reimbursement price of the least expensive substance.

A general reimbursement for three active substances helps ensure a reasonable product range for doctors based on class effect and – compared to all other lipid-lowering medicinal products – prices that are relatively close.

Consumption data for lipid-lowering medicines
The discussions and recommendation of the Reimbursement Committee also included data on consumption and developments in consumption of the individual substances. Appendix D is a survey of the consumption and sale of lipid-lowering medicines and the number of individuals treated with these medicinal products in the period 2001-2005.

Currently 307,000 individuals are being treated with medicinal products from ATC group C10 – of which 303,400, corresponding to 99 percent, receive statin treatment. A little less than 15 percent of statin-treated patients receive the more expensive statins (atorvastatin, rosuvastatin and fluvastatin). The expenses for these three medicinal products account for 65 percent of the total expenses for statins.

For some patients the use of expensive statins is rational. This applies, for instance, to patients whose cholesterol levels could not be reduced by the use of, e.g., simvastatin, pravastatin or lovastatin.

Some of the consumption of the more expensive statins appears not to be rational, however. Partly because 41 percent of the consumption of atorvastatin is at the strength 10 mg, and it must be assumed that a substantial number of patients could achieve the same lipid reduction by using simvastatin 40 mg, and partly because 31 percent of the new atorvastatin users in 2005 (1,779 of 5,725) did not receive simvastatin treatment immediately before. On the other hand, developments in recent years would appear to indicate a reduction in the consumption of atorvastatin.

[4] Institute for Rational Pharmacotherapy, cf. www.irf.dk.

The total consumption over the last five years of the four types of lipid-lowering medicines – statins, fibrates, bile acid sequestrants and nicotinic acid derivatives – shows that the increase is solely attributable to statins, which is a rational development.

As concerns ezetimibe, extracts from the Register of Medicinal Product Statistics at the Danish Medicines Agency show that some 900 individuals bought ezetimibe at least once in 2005. Of these, 80 percent bought a statin product at least once in the same period, while 20 percent did not buy a statin product in this period.

It is the overall evaluation of the Reimbursement Committee that there can presumably be a basis for converting part of the consumption to the more inexpensive statins that are eligible for general reimbursement and continue encouraging treatment with those statins first.

With this recommendation, the doctors will, in principle, no longer have to apply for single reimbursement for the currently marketed lipid-lowering medicines.

The Reimbursement Committee suggests at the same time that the consumption of lipid-lowering medicines, including the distribution between the medicinal products eligible for general reimbursement without restrictions and the medicinal products subject to restricted general reimbursement, be closely monitored.

On behalf of the Committee

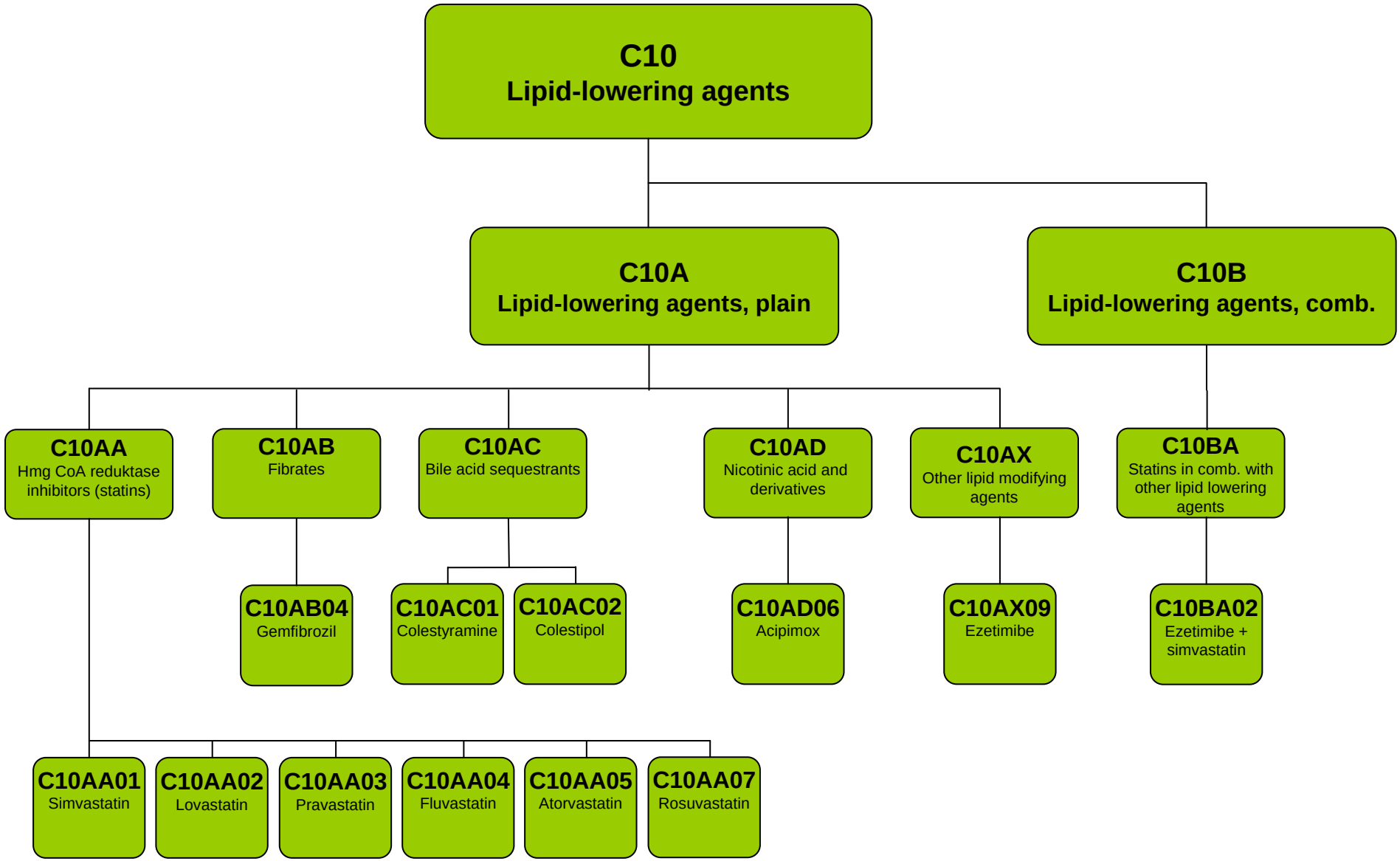
Mogens Laue Friis
Chairman

Literature:

1. The interdisciplinary task group for prevention of cardiovascular disease in Denmark established by the Danish Society of Cardiology. “Kliniske retningslinier for forebyggelse af kardiovaskulær sygdom i Danmark” (Clinical guidelines on the prevention of cardiovascular disease in Denmark – in Danish only). Danish Society of Cardiology, 2004 (www.cardio.dk).
2. Institute for Rational Pharmacotherapy. “Lipidsænkende lægemidler - Rekommandationer og baggrundsnotater”. (Lipid-lowering medicinal products – Recommendations and background notes – in Danish only). Institute for Rational Pharmacotherapy, 2005 (www.irf.dk).
3. National Institute for Health and Clinical Excellence (NICE). Statins for the prevention of cardiovascular events. Technology Appraisal 94. NICE, 2006 (www.nice.org).
4. SPARCL investigators. High-dose atorvastatin after stroke or transient ischemic attack. N Engl J Med 2006; 355: 549-59.

Appendices:

A. Graphical overview of ATC Group C10, lipid-lowering medicinal products.
B. Overview of the current and suggested reimbursement status for lipid-lowering medicinal products.
C. Price survey of lipid-lowering medicinal products for 6 price periods (period start from 22 May to 31 July 2006).
D. Survey of the consumption and sale of lipid-lowering medicines and the number of individuals treated with these medicinal products in the period 2001-2005.



Appendix A
24 August 2006

Appendix B. Overview of the current and suggested reimbursement status for lipid-lowering medicinal products

<table>
<tr><th>Substance</th><th>Reimbursement status August 2006</th><th>Reimbursement status suggested by The Reimbursement Committee</th></tr>
<tr><td>Simvastatin
Lovastatin
Pravastatin
(C10AA)</td><td rowspan="4">Restricted general reimbursement.
Restriction:

”Secondary prevention of ischaemic heart disease, TIA/ischaemic stroke, periphery artery insufficiency and patients with diabetes (all patient categories with a total cholesterol level above 3.5 mmol/L after lifestyle changes).”

Guiding criteria for single reimbursement for primary prevention, cf. below.</td><td rowspan="2">A. Restricted general reimbursement.
Restriction:

“Patients with hyperlipidemia necessitating treatment for whom therapy with statins eligible for general reimbursement without restriction has proved insufficient or who do not tolerate these medicines. In case of primary prophylactic treatment, the indication must be justified by concurrent presence of risk factors for developing ischaemic heart disease.”</td></tr>
<tr><td>Fluvastatin
Atorvastatin
Rosuvastatin
(C10AA)</td></tr>
<tr><td>Colestyramin
Colestipol
(C10AC)</td><td rowspan="2">B. Restricted general reimbursement.
Restriction:

“Patients with isolated, severely elevated triglycerides or patients with combined hyperlipidemia, possibly in combination with statin.”</td></tr>
<tr><td>Acipimox
(C10AD)</td></tr>
<tr><td>Gemfibrozil
(C10AB)</td><td></td></tr>
<tr><td>Ezetimibe
(C10AX)</td><td>Not eligible for general reimbursement:
Guiding criteria for single reimbursement for primary prevention, cf. below.</td><td>Restricted general reimbursement.
Restriction:
Cf. A.</td></tr>
<tr><td>Simvastatin + ezetimibe
(C10BA02)</td><td>Not eligible for general reimbursement:
(not marketed)</td><td>Restricted general reimbursement.
Restriction:
Cf. A.</td></tr>
</table>

Guiding criteria for single reimbursement for lipid-lowering medicines (with the exception of ezetimibe) in primary prevention:

1. Patients with familial hypercholesterolaemia (the patient has a persistent level of total cholesterol above 8 mmol/L and LDL cholesterol above 6 mmol/L in combination with known premature ischemic heart disease among first degree relatives and/or tendon xanthoma).
2. People with at least one risk factor and HDL cholesterol level below 1 mmol/L and triglyceride above 2 mmol/L.
3. People with a ten year risk of death by cardiovascular disease of 5% or above after 3 months of lifestyle changes and a total cholesterol above 5 or LDL cholesterol below 3 mmol/L.

Risk factors: Male sex, familial disposition for ischaemic heart disease, hypertension, obesity (BMI above 25) and smoking.

Guiding criteria for single reimbursement for ezetimibe:

Patients with one of 4 diagnoses below for whom therapy with statins has proved insufficient or who do not tolerate statins:

- Verified ischaemic heart disease
- TIA or ischaemic stroke
- Periphery artery insufficiency
- Diabetes mellitus

24 August 2006

Appendix C. Price survey of C10 - Lipid-lowering medicinal products

Average lowest unit price of lipid-lowering medicinal products for 6 price periods (period start from 22 May to 31 July 2006)

1. ATC	2. Medicinal product	3. Reimbursement status/dispensing terms		4. DDD (mg)	5. Daily Dose (mg)#		6. Pharmaceutical form	7. Strength (mg)	8. Average lowest unit price (DKK)	9. Price per day (DKK)
C10AA	**Statins**									
C10AA01	Simvastatin		B	15	40	~ r	Film-coated tablet	40	0.91	0.91
C10AA02	Lovastatin	⊗	B	30	40	~ r	tablet	40	3.26	3.26
C10AA03	Pravastatin	⊗	B	20	40	~ r	tablet	40	1.45	1.45
C10AA04	Fluvastatin	⊗	B	40	80	~ r	Capsule, hard	40	6.32	12.64
		⊗	B	40	80	~ r	Prolonged-release tab.	80	10.05	10.05
C10AA05	Atorvastatin	⊗	B	10	10	~ r	Film-coated tablet	10	11.31	11.31
C10AA07	Rosuvastatin	⊗	B	10	5	~ r	Film-coated tablet	5	9.38	9.38
C10AB	**Fibrates**									
C10AB04	Gemfibrozil	⊗	B	1200	900	~ rs	Capsule/tablet	300 600	3.96 / 5.26	11.88 / 7.89 £
C10AC	**Bile acid sequestrants**									
C10AC01	Colestyramine	⊗	B	14000	14000	^ § ir	Oral powder	4000	5.21	18.24 £
C10AC02	Colestipol	⊗	B	20000	20000	^ ir	Powder for oral susp.	5000	6.08	24.32
C10AD	**Nicotinic acid and derivatives**									
C10AD06	Acipimox	⊗	B	500	500	^ ¤ ir	Capsule, hard	250	4.25	8.50
C10AX	**Other lipid modifying agents**									
C10AX09	Ezetimibe	-	B	10	10	~ rs	Tablet	10	15.62	15.62
C10BA	**Statins in comb. with other lipid lowering agents**									
C10BA02	Ezetimibe+simvastatin	-	B			~ rs	Tablet	10+40	19.91&	19.91

Notes and explanations:

#	Can be given once a day unless otherwise noted
¤	Divided into 2 daily doses
§	Divided into 2-3 daily doses
~	Equieffective dose by the Institute for Rational Pharmacotherapy
^	DDD (Defined Daily Dose) by the WHO
£	The drug is not marketed in a strength equivalent to the daily dose
r	Recommended by the Institute for Rational Pharmacotherapy
rs	Recommended with certain restrictions or in special cases by the Institute for Rational Pharmacotherapy
ir	Not recommended by the Institute for Rational Pharmacotherapy
&	Not yet marketed. The listed price is the price stated by the company when applying for general reimbursement

24082006

Symbols and abbreviations

Reimbursement status	
-	Not eligible for general reimbursement
●	General reimbursement for prescription-only medicinal products
■	Restricted general reimbursement for over-the-counter medicinal products.
◪	Restricted general reimbursement for prescription-only medicinal products

Dispensing terms	
A	Only to be dispensed once on the same prescription, unless dispensed in smaller doses at a time.
AP4	Subject to the provisions of section 4 of the Executive Order on prescriptions.
AP4BG	Only to be dispensed to hospitals. Subject to the provisions of section 4 of the Executive Order on prescriptions.
AP4NB	Only to be dispensed to hospitals or following prescription by specific medical specialists. Subject to the provisions of section 4 of the Executive Order on prescriptions.
B	Only to be dispensed once on the same prescription, unless stated otherwise.
BEGR	Only to be dispensed to hospitals. Same terms apply as for dispensing group A.
HA	Over-the-counter drugs. Pharmacy-restricted medicinal product.
HF	Over-the-counter drugs. Non-pharmacy-restricted human medicinal product.
HX	Over-the-counter drugs. Non-pharmacy-restricted human medicinal product. Maximum 1 package/customer/day.
NBS	Only to be dispensed to hospitals or following prescription by specific medical specialists. Same terms apply as for dispensing group A.

Appendix D
Sale of lipid-lowering agents (C10), 2001-2005

Sale of lipid-lowering agents (C10), 2001-2005, calculated in terms of pharmacy retail price, inclusive of prescription charge (DKK millions) and volume (DDD per 1000 inhabitants per day)

		2001	2002	2003	2004	2005	2001	2002	2003	2004	2005
		---------- DKK millions ----------					------- DDD per 1000 inhab. per day ------				
C10	**Lipid-lowering agents**	**364.0**	**486.8**	**455.8**	**333.4**	**279.6**	**20.8**	**29.0**	**44.8**	**66.3**	**89.3**
C10A	***Lipid-lowering agents, plain***	**364.0**	**486.8**	**455.8**	**333.4**	**279.6**	**20.8**	**29.0**	**44.8**	**66.3**	**89.3**
C10AA	**Hmg CoA reduktase inhibitors (statins)**	**352.8**	**474.7**	**443.4**	**320.1**	**263.2**	**20.3**	**28.5**	**44.3**	**65.8**	**88.7**
C10AA01	Simvastatin	177.2	230.7	137.7	108.7	78.6	9.7	13.5	24.2	49.7	71.6
C10AA02	Lovastatin	14.3	14.0	12.3	4.9	2.4	0.7	0.7	0.6	0.4	0.4
C10AA03	Pravastatin	46.7	73.0	88.9	46.6	10.3	2.5	3.7	4.7	3.1	2.5
C10AA04	Fluvastatin	7.9	7.8	8.2	6.2	4.8	0.5	0.5	0.5	0.4	0.4
C10AA05	Atorvastatin	101.4	149.1	192.6	136.9	141.5	6.6	10.1	14.1	11.0	12.1
C10AA06	Cerivastatin	5.3	0.0	-	-	-	0.4	0.0	-	-	-
C10AA07	Rosuvastatin	-	-	3.8	16.8	25.6	-	-	0.3	1.2	1.8
C10AB	**Fibrates**	**6.1**	**6.7**	**6.9**	**7.3**	**7.9**	**0.4**	**0.3**	**0.3**	**0.3**	**0.3**
C10AB02	Bezafibrat	2.2	0.4	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0
C10AB04	Gemfibrozil	3.9	6.4	6.9	7.3	7.9	0.2	0.3	0.3	0.3	0.3
C10AC	**Bile acid sequestrants**	**4.1**	**4.2**	**4.2**	**4.1**	**4.2**	**0.1**	**0.1**	**0.1**	**0.1**	**0.1**
C10AC01	Colestyramine	3.4	3.5	3.5	3.4	3.6	0.1	0.1	0.1	0.1	0.1
C10AC02	Colestipol	0.7	0.7	0.7	0.6	0.6	0.0	0.0	0.0	0.0	0.0
C10AD	**Nicotinic acid and derivatives**	**1.0**	**1.2**	**1.3**	**1.3**	**1.2**	**0.1**	**0.1**	**0.1**	**0.1**	**0.1**
C10AD06	Acipimox	1.0	1.2	1.3	1.3	1.2	0.1	0.1	0.1	0.1	0.1
C10AX	**Other lipid modifying agents**	**-**	**-**	**-**	**0.7**	**3.3**	**.**	**.**	**.**	**0.0**	**0.1**
C10AX09	Ezetimibe	-	-	-	0.7	3.3	.	.	.	0.0	0.1

Appendix D
Number of persons in treatment with lipid-lowering agents (C10)

Number of persons in treatment with prescribed lipid-lowering agents (C10), 2001-2005. Share of women and median age (lower and upper quartile), 2005

		2001	2002	2003	2004	2005	2005 Share of Women	2005 Median age (lower-upper quartile)
C10	**Lipid-lowering agents .....**	**105,368**	**138,469**	**189,806**	**250,091**	**307,061**	**0.46**	**64 (57-72)**
C10A	***Lipid-lowering agents, plain .....***	**105,368**	**138,469**	**189,806**	**250,091**	**307,061**	**0.46**	**64 (57-72)**
C10AA	**Hmg CoA reduktase inhibitors (statins)**	**101,616**	**135,161**	**186,489**	**246,726**	**303,354**	**0.46**	**64 (57-72)**
C10AA01	Simvastatin	52,770	70,671	120,162	202,356	258,641	0.46	64 (57-72)
C10AA02	Lovastatin	4,425	4,159	3,810	2,874	2,338	0.52	67 (60-74)
C10AA03	Pravastatin	13,781	18,941	21,265	14,476	10,875	0.42	66 (59-74)
C10AA04	Fluvastatin	4,243	4,033	4,459	3,195	2,358	0.48	67 (59-73)
C10AA05	Atorvastatin	29,821	42,778	51,539	37,476	32,819	0.47	64 (57-71)
C10AA06	Cerivastatin	3,520	0	0	0	0	.	.
C10AA07	Rosuvastatin	0	0	3,261	6,417	8,691	0.50	62 (55-69)
C10AB	**Fibrates .....**	**3,533**	**3,210**	**2,891**	**3,044**	**3,245**	**0.38**	**59 (51-66)**
C10AB02	Bezafibrat	1,763	961	1	2	2	1.00	57 (55-59)
C10AB04	Gemfibrozil	1,850	2,732	2,890	3,042	3,243	0.38	59 (51-66)
C10AC	**Bile acid sequestrants .....**	**2,212**	**2,321**	**2,339**	**2,416**	**2,527**	**0.59**	**58 (45-69)**
C10AC01	Colestyramine	1,915	2,049	2,080	2,188	2,323	0.60	58 (44-69)
C10AC02	Colestipol	299	276	261	229	208	0.47	63 (58-71)
C10AD	**Nicotinic acid and derivatives ...**	**397**	**444**	**479**	**471**	**488**	**0.42**	**59 (52-66)**
C10AD06	Acipimox	397	444	479	471	488	0.42	59 (52-66)
C10AX	**Other lipid modifying agents .....**	**0**	**0**	**0**	**357**	**900**	**0.48**	**60 (52-66)**
C10AX09	Ezetimibe	0	0	0	357	900	0.48	60 (52-66)