

-----Oprindelig meddelelse-----

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Cc: JYTTE LYNGVIG - 9555; DORTHE POULSEN - 9308; METTE AABOE HANSEN - 9317; ELISABETH THOMSEN - 9306

Emne: Comments of DKMA on the Preliminary Report on Pharmaceutical Sector Inquiry

Dear Benjamin,

We appreciate the extended deadline for commenting on the preliminary report, in particular Chapter 2.5 and Chapter D.

The Danish Medicines Agency has no comments on Chapter 2.5 and Chapter D but as the national competent authority for reimbursement decisions we have a few comments in this regard.

In paragraph 292 the originator companies reported that in France, Italy, the Netherlands and Sweden, they may submit a pricing and reimbursement dossier before the marketing authorisation is officially granted. In Denmark, it is also possible to submit an application for reimbursement before the granting of the marketing authorisation. The timing of the application for reimbursement depends on the procedure for authorisation of the medicinal product:

- For medicinal products being authorised under the centralised procedure in the EU, an application for general reimbursement can be submitted once the CHMP (the Committee for Medicinal Products for Human Use) has issued a positive opinion.
- For medicinal products being authorised under the decentralised procedure, an application for general reimbursement can be submitted once the participating Member States have issued a positive opinion.
- For medicinal products being authorised under the mutual recognition procedure, an application for general reimbursement can be submitted after day 90.
- For medicinal products being authorised under the national authorisation procedure, an application for general reimbursement can be submitted after day 210.
- For medicinal products in a new pharmaceutical form with the same active substance and same route of administration as a medicinal product already eligible for reimbursement, an application for general reimbursement can be submitted at the time when the marketing authorisation application for the product is filed.

In table 13 at page 120 Denmark is ticked off only in the column "Free pricing". The tick in that column is correct, but with regard to the reimbursement decision, which we understand is a supply-side practice, we do take into consideration clinical performance of the medicinal product in question and its price (set by the company) compared to the clinical performance and price(s) of current treatment(s) for the same disease as well as other relevant aspects. The company applying for reimbursement of its medicinal product may submit with the application a health economic analysis to substantiate that the price is reasonable for the therapeutic value.

We have had checked the report from the Andalusian School of Public Health but have not been able to determine if Denmark should be ticked off in more columns as there were no clear definitions for the other columns.

Kind regards,
Tina

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