



Extract from the report to the
Public Accounts Committee on
the second-opinion programme

December
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1. Introduction and conclusion

1.1. Purpose and conclusion

1. This report concerns the Ministry of Health and Prevention's (Ministry of Health) programme for counselling on experimental treatment. On the website of the Danish Health and Medicines Authority, in annual reports and information booklets, the programme is also referred to as the *second-opinion programme*, which is the term that will be used in this report.

The second-opinion programme is directed at patients who have a life-threatening disease for which there are no well-documented treatment options.

The programme is administered by the Health and Medicines Authority, which has set up a panel of experts. Patients are referred to the panel by their treating doctor for an assessment of whether further treatment options, including experimental treatment, are available in Denmark or abroad that might benefit the patient.

The scope of this examination is more limited than the scope of Rigsrevisionen's usual reports and is therefore referred to as a narrow report.

The purpose of the examination is to assess whether the Ministry of Health has ensured that the second-opinion programme meets its objective of securing all patients with a life-threatening disease access to a final assessment of possible further treatment options.

In 2013, the **Danish Health and Medicines Authority's expert panel for experimental treatment** was composed of two specialists in medical oncology and one specialist in surgical oncology. The Health and Medicines Authority is required to establish an ad hoc panel of experts when approached by patients with other life-threatening diseases than cancer.

CONCLUSION

Since the second-opinion programme was launched on 1 January 2003, more than 7,000 cancer patients have consulted the expert panel of the Health and Medicines Authority on the options for further treatment, including experimental treatment. The programme is directed at all patients who have a life-threatening disease, but only 12 patients with life-threatening diseases other than cancer have consulted the panel.

The audit approach and quality requirements to **narrow reports** are identical with those applying to Rigsrevisionen's other reports, but the scope of narrow reports is more limited.

Rigsrevisionen finds it unsatisfactory that the Ministry of Health has not to the necessary extent ensured that the second-opinion programme achieves its objective of securing that all patients with a life-threatening disease are offered access to a final assessment of possible further treatment options.

In connection with the evaluation of the second-opinion programme in 2003 and 2005, respectively, the Ministry of Health became aware that the knowledge of the programme was limited. Yet, the ministry did not follow up whether the Health and Medicines Authority took steps to increase the knowledge of the programme. Not until 2013, did the authority issue a booklet that informed about the programme.

The two evaluations and regular annual reports on the second-opinion programme have only referred to cancer patients and it has thus not been clear whether also patients with other life-threatening diseases than cancer have received counselling by the panel. To this should be added that a questionnaire survey conducted by Rigsrevisionen shows that almost one third of the responding patient associations did not know of the programme and a few of them indicated that the programme could be relevant for their members.

The Health and Medicines Authority has focused on cancer patients and has not provided sufficiently clear information about the second-opinion programme.

In the opinion of Rigsrevisionen, the second-opinion programme has in practice developed from being a programme offering counselling to patients on possible experimental treatment options to a doctor-to-doctor programme offering advice on further treatment options in general, including experimental treatment.

The second-opinion panel has considered the cases of 12 patients with a life-threatening disease other than cancer. Five of these were referred to further treatment and thus derived benefit from having their case considered by the expert panel.

Rigsrevisionen finds that the Health and Medicines Authority's administration of the programme has had the consequence that patients with life-threatening disease other than cancer have not had easy and equal access to information on the second-opinion programme.