Evaluation of the Danish Medicines Council: Fulfills its purpose, but room for improvement

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Two years after its establishment, the Danish Medicines Council has been evaluated. The evaluation, published on 16 May 2019, concludes that the Danish Medicines Council fulfills its purpose and is in line with the principles provided by the Danish Regions and the Danish Parliament, including the arm's length principle. However, there is room for improvement e.g. regarding the shortening of the processing time of the assessment of new medicines. Similarly, it is recommended that the Danish Medicines Council is provided with more resources to prepare more therapeutic instructions.

Background

The Danish Medicines Council was established in January 2017 following a decision by the Danish Regions. The Danish Medicines Council replaced two former councils: The Danish Council for the Use of Expensive Hospital Medicines (RADS) and Coordination Council for the use of Hospital Medicines (KRIS).

The Danish Medicines Council assesses new hospital medicines / new indications and publishes therapeutic instructions. The Danish Medicines Council is to:

- Ensure fast and homogeneous use of new and existing medicines across hospitals and regions

- Impose stricter requirements for documentation to support that patients will benefit from new and existing medicines
- Enhance the basis for Amgros' price negotiations and calls for tenders.

The evaluation was carried out by an external consultant, Oxford Research, in the period January-March 2019 on behalf of the Danish Regions.

Main conclusions

The evaluation arrived at the following four conclusions:

1. The Danish Medicines Council fulfills its purpose and is in line with the principles provided by the Danish Regions and the Danish Parliament. The Danish Medicines Council makes independent decisions with an arm's length to the political system, i.e. the regions do not directly or indirectly influence the decisions of the Danish Medicines Council.

2. The Danish Medicines Council has increased its demands for documentation that new and existing medicine is beneficial for the patients. In addition, the Danish Medicines Council handles the documentation more systematically and uniformly than before.

3. The Danish Medicines Council has helped to ensure that Amgros (the Danish Regions' wholesale purchaser of hospital medicine) has a stronger basis for negotiation with the pharmaceutical companies.

4. There is a high degree of transparency in the work of the Danish Medicines Council, except for the last council meeting where the final decision on a recommendation is made.

Recommendations

The evaluation presents the following recommendations for the future work of the Danish Medicines Council:

1. Increased focus on shortening the processing time for assessment of new medicines. In the past two years, the Danish Medicines Council has recommended 46 new medicines or new indications of which only about one quarter remain below the fixed processing time of 12 weeks. One important factor that affects the processing time is disagreement between the specialist committees and the council regarding "added value". This results in the case being sent back to the specialist committee for further deliberation. It is therefore recommended that the Danish Medicines Council focus on strengthening the dialogue between the council and the specialist committees.

2. More resources for preparation of therapeutic instructions. Due to lack of time, the Danish Medicines Council had only prepared five therapeutic instructions by January 2019. The arguments for increasing the number of therapeutic instructions are the following: 1) it would lead to increased competition among the medicines and thus better prices, 2) the therapeutic instructions are needed in the everyday work of the hospital's and, 3) the medicines are in fact not "on the market" before the medicine appears in a therapeutic instruction.

3. Involvement of QALY in the Danish Medicines Council's assessment of whether there is a reasonable relationship between effect and cost of a new medicine. According to the informants who have participated in

the evaluation, this will provide a better and more consistent basis for assessing whether there is a reasonable relationship between effect and cost.

4. Focus on reducing the workload of the members of the Danish Medicines Council, for instance by making the preparatory work on which decisions are made simpler and clearer.

Next step

Following the evaluation, relevant stakeholders will be consulted. On this basis the Danish Regions will consider potential changes in the Danish Medicines Council.

The evaluation can be found here (in Danish).

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