



Transition to New HTA Process in Denmark

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Introduction / Objectives

The Danish Medicines Council (DMC) was founded in January 2017 to assess medicines for inclusion in the publicly funded inpatient medicines list. The DMC is composed of three units: the Secretariat, consisting of methodological experts; Subject Committees, consisting of clinical experts; and the Council, which makes final decisions.

In 2017, the original DMC HTA process required manufacturers to submit both an overview of clinical outcomes and a limited economic evaluation comparing the technology to standard of care over lifetime horizon, without consideration of quality-of-life outcomes. Beginning January 2021, a new HTA process was introduced which required detailed health economic evaluations within submissions to the DMC, incorporating quality-adjusted life-years (QALYs) as a measure of treatment efficacy. HTA processes initiated prior to January 2021 continued to be evaluated under the old process.

Manufacturers initiate a DMC HTA process by submitting a "Request for Assessment" and may request a meeting with members of a relevant clinical expert Subject Committee to minimise uncertainties over key issues relevant for preparing their submissions. Once a submission package is accepted as complete by the DMC Secretariat, "Day 0" is declared, and a 16-week (112 days) period to arrive at a reimbursement decision is targeted.

The Secretariat, in consultation with the relevant Subject Committee, prepares an Assessment Report. The Assessment Report is sent to AMGROS, an organisation which facilitates purchasing of medicines in Denmark and negotiates confidential discounts with manufacturers. Confidential discounts are then considered in conjunction with the Assessment Report by the DMC Council to make a reimbursement decision.

In some cases, where DMC has a pre-existing treatment guideline in a disease area with many similar medications, manufacturers can alternatively apply to have their medicine assessed as clinically equivalent to an already recommended treatment and considered for direct inclusion into a treatment guideline. This does not require a full economic evaluation, but the recommendation will then be the lowest cost option. The DMC also has the remit to initiate their own HTA processes for medicines of interest, and this includes the possibility of continuing HTA processes which manufacturers have initiated but withdrawn from.

The transition to the new DMC HTA process was investigated.

Methods

DMC website was examined, and records of HTA submissions and decisions made were extracted (22nd of September 2022). The status of all HTA processes initiated since 2017 were examined, with a focus on the new-process DMC submissions. Amongst the new process submissions, submission type was assessed, and time durations between distinct milestones along the new HTA pathway were assessed. Monthly rates of DMC reimbursement decisions were reviewed to estimate when the transition to the new HTA process would complete.

Results

On August 31, 2022, the 70th meeting of the DMC Council was held, marking the 21st meeting since the implementation of the new HTA process in January 2021.

As of 22nd September 2022, there have been 86 "full" submissions (i.e., including cost-minimisation or cost-effectiveness analyses) initiated under the new process, 3 of which were withdrawn by the manufacturer. Time between submitted request for assessment and initial delivery of a full submission package is not reported. Of the 86, the DMC has accepted 37 completed submission packages, averaging 277 days post initiation to be considered complete. Of the 37, the DMC has completed Assessment Reports of 26, averaging 98 days. Of the 11 full submission packages without completed Assessment Reports, the average time since "Day 0" has been 136 days. Only 16 reimbursement decisions have been made based on these submissions, taking an average 68 days following the DMC's completed review (including confidential price negotiations). There have been "Clock-Stops" applied in 7 of the new processes.

Of the 16 completed processes, the average time from "Day 0" of an application to the Council's final reimbursement decision has been 173 days (158 days adjusting for Clock-Stops) in the new process, compared to the official 112 days target according to the DMC process guidelines. Since the first new process decision in September 2021, an average rate of 1.7 new process decisions per month has been met.

Of 6 cost-minimisation-based applications, 3 decisions were positive. Of 10 cost-effectiveness-based applications, 5 decisions were positive and 2 were partially positive. In one case under the new process, it was determined that it was outside of the Council's competence to evaluate and decided to "Archive" the process without making a final decision.

A spike in the number of Requests for Assessments submitted to the DMC in December 2020, immediately prior to the change in the HTA process implemented from January 2021 was observed. There were 59 old processes initiated when the transition to the new process took place, of which the monthly clearance rate of reimbursement decisions has been 3.4. As of September 22, 2022, only 5 old-process HTA submissions remain under consideration at the DMC.

Conclusion

The transition to the new DMC HTA process is likely to be complete in Q4 2022. However, given the rate of completion of reviews of manufacturers' submissions and the rate of DMC Council decisions, it is likely to take some time before the rate of reimbursement decisions under the new HTA process is equal to that of decisions made under the old process.

More transparency is desired to improve understanding of the timelines in the earlier phases of the process, particularly between the initial submission date and the technical validation of the submission documents by the DMC Secretariat.

References

www.medicinraadet.dk

New DMC HTA Process: Times Between Process Milestones (86 Full Submissions, as of 22 nd September 2022)						
	Request for Assessment to "Day 0"	"Day 0" to Completion of Assessment Report	Completion of Assessment Report to Completion of Negotiation with AMGROS	Completion of AMGROS Negotiation to DMC Council Decision	Completion of Assessment Report to DMC Council Decision	"Day 0" to DMC Council Decision (Adjusted for Clock-Stops)
Submissions Reaching Process Milestone	37	26	18	16	16	16
Average Days	278	98	30	36	68	173 (158)
Minimum Days	78	23	9	19	30	65
Maximum Days	467	183	243	98	266	449 (365)

