Medtronic

Innspill til prosess for medisinsk utstyr i Nye metoder

Thank you for sharing the ongoing work to optimize the Medtech process of Nye Metoder and allowing input. In this document Medtronic has summarized our feedback and identified questions that we believe will be important to consider to ensure that the new process will function as intended and support the continued optimization of the healthcare sector as well as patient access to safe and effective treatment options.

General comments

- Reading the document "Inspillsnotat" there seems to be a high focus on the scanning and selection of methods, whereas limited attention is given to the implementation phase. On the topic of implementation, the main conclusion seems to be that there is a need to establish guidelines. The discrepancy may be planned and expected to shift as the work on the revised Nye Metoder progresses. However, it's important that the whole process is optimized in its totality, rather than optimizing each step of the HTA system separately. This is to ensure a balance between input efforts and the end result, not only for actors such as medtech companies but also for health care professionals and regional and national agencies.

  In section 5.1 in "Innspillsnotat", it is mentioned that the change in the process is similar to that introduced for pharmaceuticals in may 2023. It is important to stress the importance of the clear differences in the market condition and impact on the healthcare system between medical device technologies and pharmaceuticals. Key distinctions include regulatory pathways and demands, weaker patent protection, competition and price pressure from market introduction, downstream value, learning curve and operator dependence, shorter life cycles and rapid rate of innovation and market introduction. Given these differences it is problematic to reform the product identification phase of Nye Metoder for Medtech using changes in the process for identifying new pharmaceuticals as the template, as described in the inpillsnotat: "For å sikre en mer formålstjenlig innmeldingsfunksjon foreslås det å legge om fra metodevarsling til anmodning om vurdering på linje med endringen som ble gjort for legemidler i mai 2023". Some of the problems that arise due to this will be covered later in this document.

  Recommendation: Develop a novel identification process that is tailored for the medtech market conditions rather than starting from a pharmaceutical process.

- It has previously been said that products undergoing assessment by Nye Metoder should not be used or procured while evaluated. Will this also be the case for when submitting for "anmodninger"? If so, what timelines do you expect from submission of "anmodning" to decision if it will be evaluated in the HTA system or not?

  It is important to have concrete timelines from submission to the decision. This will support the planning of introducing new medtech devices and ensure patients and healthcare providers are getting access to new technologies within a reasonable timeframe. Indeed, one of the issues identified in the Proba report was unclear timelines and long processes with limited accountability that delayed market access of new and effective technologies.

  Recommendation: Do not restrict use and procurement while an "anmodning" is under consideration. Do define clear timelines from submission of "anmodning" to decision if the technology will be selected for HTA, as well as clear timelines throughout the HTA process up until final decision and implementation.

- Reading the criterions strictly, we believe that most of our technologies could become categorized as a product where we must submit for "anmodning om vurdering av medisinsk utstyr". From the smallest screw in a spinal fusion system, to our largest multi-dimensional surgical imaging platform. Given that it's stated that there is a target of 5 – 10 performed HTAs per year, how many "anmodninger" are you expecting to have with these criteria? Maybe even more important to consider might be how many would be too many?

  If applying the current criterions strictly it's not out of the realm of possibility that the annual number of "anmodninger" would be counted by the thousands. At least, the way we interpret them currently. In the pharmaceutical industry, large companies may introduce 1 – 5 new molecules each year. In the medical technology industry multinational companies may introduce hundreds of products each year. Most with a limited incremental cost impact to the healthcare sector.

  For example, let's say that Medtronic is introducing an updated model of a stapling device, often used in bariatric surgery. This will be CE-marked, it will replace a product currently in use and the patient population will be more than 2 000 individuals. Therefore, it falls under the obligation of submitting an "anmodning". This device will then take the form of two different products depending on if the surgeon is left-handed or right-handed. Then there will be an option to have the stapling button at the back of the handle or the side of the handle, in order to serve surgeon preferences. So, four products. But then there will be five different lengths of

metal adapters. There will also be several options on how many degrees the hook can bend and there will be different sizes of hooks and sets of clip size magazines.

All in all, one product line update may require up to a hundred submissions for “anmodning” if proposed criterions are to be strictly interpreted.

Recommendation: Consider stricter criteria for when to submit for “anmodning”, built on the specificities of the medtech market.

- It seems unclear if companies are supposed to submit an “anmodning” before CE-mark, at CE-mark or post CE-mark?

  If submission is to be done before CE-mark, product pipelines and evidence generation plans are often confidential. How can that be handled by the proposed processes?

  If submission is to be done at CE-mark comparative evidence is often limited according to the MDR regulation, different to the regulatory requirements for pharma. How will this be taken into account during a potential HTA process?

  If submission is to be after CE-mark, how do companies know when will be the right time to submit an “anmodning”? If the companies are expected to make a submission for all products currently in the market, it would mean a heavy administration burden to the companies as well for Nye Metoder.

Comments on section 1b

The heading of this section says ”Opplysninger om det medisinske utstyret (metoden)”. Does this mean that a medical device, i.e. a product, is the same as a method in this process and in the “anmodningsskjema”? Is, as in the example given under general comments, a screw in a spinal fusion system a method? If not, what is the definition of a method as compared to a product or a medical device?

Recommendation: Clearly define what constitutes a “medisinskt utstyr” and what constitutes a technology. This will support understanding of the intent and purpose in the latter paragraphs.

Comments on section C

The question in this section does seem to fit most products, if read strictly. Especially if going with the terminology of method and a product being the same thing. Is there ever a method/product that neither replaces another method/product nor adds benefit or covers an unmet need? Even basic me-too products would at the very least aim to replace a product on the market. If continuing with the example of a screw in a spinal fusion system, a new version of the screw will likely replace the use of the old version of the screw. Thus, warranting a check in the yes-box in section C.

Recommendation: Consider what type of products you would not want to have submitted and ensure the wording in section C clearly excludes these.

Comments on section D.1

What is the relevant way to define the patient population in this section? For example, if Medtronic is launching a new advanced diabetes pump system that is CE-marked for type 1 diabetes, is the population in this question Norwegian patients with type 1 diabetes? Or is it Norwegian patients with type 1 diabetes and currently using pump systems? Or is it even the Medtronic market share of diabetes pump systems related to Norwegian patients with type 1 diabetes? Depending on how broadly speaking we should look at patient population, the end result will differ significantly.

Another question on the patient population is if it should be defined by the product CE-mark or, for example, Norwegian clinical guidelines?

Is the 2000 patient cut-off point also relevant for capital equipment? If so, should that be calculated over the expected capital life length? For example, scoliosis patients in need of surgery may not be over 2000 in any given year, but over 5 – 6 years the total number of patients having surgery with the capital equipment in the OR room may exceed 2000. Should that scenario warrant a yes or no in the check-box?

Recommendation: Given the difficulties in clearly defining the patient population, consider if this really is a critical criterion given what will anyway be captured in the other questions in section D. If a product does not have a significant impact on budget, costs, organization, healthcare staff or have a high-risk class, is it then important if the potential patient population is more or less than 2000?

This question becomes important as the patient population criteria will likely be the critical one for capturing trivial products such as spine screws, stapling magazines etc. unless section C gets revised. It additionally introduces the complexities of estimating patient population for capital equipment.

Comments on section D.2

Is the 50mkr cut-off point meant as total costs or total added costs over the current alternative? If it's the former, lots of products that will have minimal economic impact will still need to be submitted. If it's the latter, sufficient cost modelling might be difficult to achieve for many products as it would require cost modelling both new and current patient pathways as well as defining what parts intersect with the spesialisthelsetjenest. It might be tall order for many products that will not have a significant impact on the Norwegian healthcare system.

Recommendation: Consider, in dialogue with medtech device companies, if budget consequences could be replaced by expected sales under confidentiality clauses. This may be easier to estimate for companies and easier to monitor by Nye Metoder. The potential downside is that it may not capture non-device related cost increases but those will likely be captured anyway by question D.3 (organizational aspects) and D.4 (healthcare staff resource aspects).

Comment on specific questions:

Det bes om innspill på:

- Hvilken prosess bør følges for metoder hvor det ikke blir gitt oppdrag om nasjonal metodevurdering av Bestillerforum?

The HTA process is designed to pick up and focus on technologies that have comparatively larger impact on patient outcomes and/or healthcare budgets. Technologies that do not fall under this definition should follow the current standard process involving procurement and tendering. Additional focus on product value and quality should be included in the tender criteria when possible.

We hope these comments are helpful for your continued process. Please feel free to reach out to us in case of any questions or concerns.

With kind regards,

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