Proposal for assessment of new health technologies

Important information – read this first!

- Submitted proposals for national health technologies (HTAs) will be published in full. If the proposer thinks there is information necessary for filling out the form, that should not be made public, please contact the secretariat (Nye Metoder) before submission.

  The proposer is aware that the form will be published in its entirety (tick): ☒

- Proposer has filled out point 19 below «Interests and, if any, conflicts of interest» (tick): ☒
- This form serves the purpose to submit proposals for health technology assessment (HTA) at the national level in Nye Metoder - the national system for managed introduction of new health technologies within the specialist health service in Norway. The form does not apply to proposals for research projects. A health technology assessment is a type of evidence review, and for this to be possible, documentation is required, e.g. from completed clinical trials. Lack of documentation may be one of the reasons why the Commissioning Forum (Bestillerforum RHF) does not assign a health technology assessment.
- If the proposal concerns a medical device, the proposer is familiar with the document «Guidance criteria for management of medical devices in the National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway» (link) (tick): ☐

Contact information:

Name of the proposer (organization / institution / company / manufacturer)**:**

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Date and locality:

3. March 2023 – Birkerød Denmark.

1. Proposer's title on the proposal: *
   *This may be changed during the course of the process"

Methoxyflurane (Penthrox®) for acute pain relief of moderate to severe pain following trauma in conscious adult patients. [1]

2. Brief description of the health technology proposed to be considered:

Penthrox® is a fast onset, non-invasive and non-opioid, inhaled analgesic indicated for the emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain in the emergency department and prehospital sector. Penthrox® is self-administered under the supervision of a *physician, nurse, emergency- or health care personnel* at 3mL. The maximum dose cannot exceed 15 ml per week. Penthrox® takes less than one minute to administer, its onset of action is rapid – within 6-10 inhalations the effect starts, and it provides pain relief for up to 25-30 minutes. Patients can assess their own pain level and titrate the amount of inhaled Penthrox® for adequate pain control.[1] In addition, Penthrox® has a well-established safety profile with no reported respiratory depression nor clinically significant effects on vital signs, and adverse events are usually mild and transient.[2]

3. Brief description of current standard of care (SOC) (Which health technology (ies) are currently used. What is the status of the technology (ies)? Whether it provides curative treatment, life extension, etc.)
   Will the proposed technology replace or be a supplement to today's SOC?

The Norwegian Association for Physicians (Norsk Legeforening) issued treatment guidelines for pain in 2009.[8] Normally, acute pain is treated with analgesics, and the choice of analgesics is based on the World Health Organization's (WHO) pain ladder. The following treatments are given, as based on the WHO ladder: 1. **Non-opioids** (e.g., paracetamol and/or possibly NSAIDs) ± adjuvant. [8] 2. **Weaker opioids** (codeine or tramadol) for mild to moderate pain (*if the pain is persisting or increasing*) ± non-opioid and adjuvant. [8] ○ *If needed, this step can be skipped, with direct transition to treatments in step 3.* 3. **Stronger opioids** (e.g., morphine [8], fentanyl [IV/intranasal], esketamine [sometimes + benzodiazepine] [10]) for moderate to severe pain (*if the pain is persisting or increasing*) ± non-opioid and adjuvant, can be given until the patient has achieved good pain relief. [8] According to health care professionals in Norway, Penthrox® is already in use in the prehospital sector in the ambulance service. POA Pharma Scandinavia AB applies for evaluation of the use of Penthrox® for conscious adult patients with trauma and associated pain in the hospital/ED and prehospital sector either as a sole agent replacing the use of, or as a bridging agent to, current standard anagelsic agents in Norway, e.g., morphine and fentanyl.

4. This proposal concerns:

	Yes	No
A brand new and innovative health technology	☒	☐
A new application, or a new indication for an established method	☐	☒

A comparison between several methods	☐	☒
A technology that is already in use	☒	☐
If yes – technology used in clinical practice	☒	☐
If yes – technology used in research/clinical trials	☐	☒
A re-evaluation of technology used in clinical practice	☒	☐
The technology is relevant for disinvestment	☐	☒

Despite the decision from the decision forum not to implement Penthrox® for use in the specialist health services, Penthrox® is currently used in Norwegian clinical practice, highlighting the demand for a new fast and effective treatment for trauma and associated pain.

Penthrox® has been used in 2022 across the following regions in Norway: **Rogaland/Nordland/Oslo/Viken/Innlandet/Vestfold&Telemark/Agder/**

Vestland/Trøndelag/Troms & Finnmark

5. This health technology involves (Multiple ticks are possible)

Pharmaceutical	☒
Medical device/IVD medical device that is CE-marked*	☐

N/A

Medical device/IVD medical device that is not CE-marked	☐
Procedure	☐
Screening	☐
Highly specialized services / national offers	☐
Organization of the health services	☐
Other (describe)	☐

N/A

6. Application of the technology:

Prevention	☐
Assessment and diagnostics	☐
Treatment	☒
Rehabilitation	☐
Specialist health care	☒
Primary health care	☐

Penthrox® is a fast onset, non-invasive and non-opioid, inhaled analgesic indicated for acute pain relief of moderate to severe pain following trauma in conscious adult patients. [1] Hence, Penthrox® will be used in the emergency department and prehospital sector.

7. Responsibility for funding

	Yes	No
Is the specialized health service responsible for financing the technology today?	☒	☐
May the specialized health service become responsible for funding the health technology?	☒	☐

It is assumed that it is the specialist health services that currently have and will have the financing responsibility for Penthrox®, even though it has not been recommended for implementation by Nye Metoder.

8. Is the technology mentioned in the national guidelines or action programs prepared by the Norwegian Directorate of Health?

Yes	No
☐	☒

N/A

9. Does the technology involve the use of radiation (ionizing/ non- ionizing)?

Yes	No
☐	☒

N/A

10. Which discipline(s) does the health technology apply to, and which patients are affected? (Could the health technology also affect other groups (e.g. health personnel or relatives)?)

As previously mentioned, Penthrox® is indicated for acute pain relief of moderate to severe pain following trauma in conscious adult patients.[1] Hence, Penthrox® will be used in both the prehospital (e.g., ambulance service) and the hospital (e.g., emergency department) setting.

The patient population of interest include adult conscious patients with moderate to severe pain [1], and Penthrox® is expected to be given either as a sole agent replacing the use of, or as a bridging agent to, current standard anagelsic agents in Norway (e.g., morphine and fentanyl).

Including Penthrox® in Norwegian clinical practice will lead to an increase in efficiency and safety of pain management in patients with trauma and associated pain in the prehospital and hospital/ED setting. In addition, Penthrox® will not lead to any negative consequences for other parties.

11. Which aspects are relevant to the assessment? (Multiple ticks are possible)

Clinical efficacy	☒
Safety/adverse effects	☒
Costs/resource use	☒
Cost-effectiveness	☐
Organizational consequences	☐
Ethical	☐
Legal	☐

12. Please suggest the main scope/objective for the health technology assessment, as well as secondary scopes/objectives (in compliance with question 10). For those familiar with "PICO" (Patient, Intervention, Comparator, Outcome) – please include tentative suggestions for PICO.

The following PICO is relevant for this assessment:

- **Patient**: conscious adult patients with trauma and associated pain in the hospital/ED and pre-hospital sector
- **Intervention**: Methoxyflurane (Penthrox®)
- **Comparator**: Standard Analgesic Agents (SAT), e.g., morphine and fentanyl
- **Outcome**: Moderate to severe acute pain relief (measured with the Numeric Rating Scale [NRS] and/or Visual Analogue Scale [VAS]).

13. Please give a brief explanation of why it is important that the health technology assessment proposed should be conducted.

Penthrox® was assessed by NoMA in 2018 (ID2017_074), following a request for a budget impact analysis from the ordering forum. Following the assessment, the decision forum decided to not implement Penthrox® for use in the specialist health services.

The first submitted proposal for evaluation of Penthrox® included information for the STOP! trial only. This new proposal for evaluation is submitted since **two additional clinical trials have been undertaken and published** and a third **investigator initiated Norwegian study (PreMeFen)** is ongoing *(please see section 14 on clinical efficacy for more information)*. In addition, **Penthrox® has been taken into clinical practice in Norway, which highlights the demand for a new fast and effective treatment for trauma related pain replacing the use of, or as a bridging agent to, current standard anagelsic agents.**

The most common complaint of acute trauma patients attending the emergency department (ED) is pain, with a prevalence of 70% in the prehospital setting and 91% in the hospital/EDs. Despite this, undertreatment of pain is a widespread problem in the emergency setting. [2, 3] Effective pain management improves both patient comfort and satisfaction, but also aids mobilization and subsequent treatment of the patient, which leads to shorter hospital stays. [3]

There are several reasons for suboptimal pain management in the emergency setting (both prehospital and hospital setting), including underassessment of pain, time or resource constraints, lack of training, aversion to opioid analgesia and patient reluctance.[3] In addition, there are also limitations of currently available treatments/limited pain relief toolbox (especially in the prehopsital setting), such as requirement for intravenous (IV) line placement and limited efficacy of weak analgesics.[3]

The first attempt of inserting peripheral intravenous catheterization fails in 12-26 % in adults and in 24-54% in children in acute care setting [4]. (Penthrox is indicated for adult conscious patients). Patients are at risk of inadequate analgesia due to challenges in achieving an intravenous access when the patients are distressed, uncooperative [5] or are in a hostile environment [6]. Despite increased awareness of pain management, any delay in obtaining an access route, encounter delay in administration of pain treatment [7].

Current treatment options include paracetamol, non-steroidal anti inflammatory drugs (NSAIDs) and weak and strong opioids. NSAID and paracetamol have a risk of overdose if the patient has previously self-medicated, NSAIDs is associated with several adverse events, opioids require patient monitoring for side effects, and IV analgesia requires additional healthcare resources and may fail or lead to inadequate pain analgesia.[2,8]

In Central Norway, following “Fellesfunksjonen Ambulansetjenesten i Midt-Norge (2021)”, the treatment strategy for pain relief for immediate use in the prehospital/ambulance setting was previously morphine, but the recommendation was changed in early 2022 to Fentanyl (both intranasal and IV) due to its more rapid and short-term effect.[9]

In the ED, negative patient outcomes and longer ED stays are often caused by slow onset of pain relief and delays in analgesia administration. Therefore, there is a high unmet medical need for a rapid-acting, safe, effective, and easy-to-use treatment for trauma and associated pain in the emergency setting.

The simple and fast administration of Penthrox® in combination with its rapid pain relief as a fast-acting analgesia along with its established safety profile and proven clinical efficacy, fullfills the unmet medical need for the group of conscious adult patients with trauma and associated pain (moderate to severe acute pain) in the hospital and pre-hospital setting. In addition, Penthrox® is established use in several areas of Norway, which indicates a demand. Therefore, it is of high importance that the assessment of Penthrox® is undertaken. Penthrox has been in use during 2022 in the following regions:

Rogaland/Nordland/Oslo/Viken/Innlandet/Vestfold&Telemark/Agder/

Vestland/Trøndelag/Troms & Finnmark

14. Please comment on the technology that is proposed to be assessed with regard to the following points:

    The severity of the disease/condition the health technology targets

Moderate-to-severe acute trauma and associated pain.

Expected effect

As mentioned in section 3, currently, three clinical trials have assessed the clinical efficacy and safety of methoxyflurane (Penthrox®) for the treatment of acute pain. **Two of these trials were undertaken and published after the previous submission to Nye Metoder – InMEDIATE and MEDITA**. These two additional clinical trials were conducted as active-controlled trials, with standard analgesic treatment (SAT) as comparator. In addition, a Norweigan investigator-initiated multicenter, randomized controlled, open-label trial has been initiated, to assess the effectiveness and safety of Penthrox®, intranasal fentanyl and intravenous morphine for the treatment of acute pain (PreMeFen; NCT05137184) [10]. Study background and results for the first three clinical trials (STOP!, InMEDIATE and MEDITA) are presented in this section.

The first clinical trial, STOP! [NCT01420159, MEOF-00, phase III, Penthrox vs placebo] [11], were described in the previous assessment of Penthrox, and will therefore not be presented in detail in this proposal for assessment. A short summary of the clinical efficacy is provided below. For patients in the methoxyflurane vs placebo groups, respectively:

- mean change in VAS pain score:
  - from baseline to 5 minutes, -23.1 vs -11.3 mm;
  - from baseline to 10 minutes, -28.9 vs -14.8 mm;
  - from baseline to 15 minutes, -34.0 vs -15.5 mm;
  - from baseline to 20 minutes, -35.0 vs -19.0 mm;
- median time to first pain relief, 4 vs 10 minutes;
- use of rescue medication, 2 vs 25 patients

The second clinical trial, InMEDIATE [NCT03256903] [3]. Phase 3b randomized, controlled study with the objective to evaluate the change in intensity of traumatic pain over the first 20 minutes in adult patients treated with methoxyflurane (Penthrox) vs. SAT (NSAIDs for moderate pain and IV locally approved opioid and non-opioid analgesics for severe pain) in Spain. The first randomized, active-controlled, multicenter trial of Penthrox in the emergency setting in Europe (N=305, 1:1 randomization). The primary objective was the change in pain intensity measured with the Numeric Rating Scale (NRS) from baseline to 5, 10, 15 and 20 minutes.

Results InMEDIATE [3]

- The overall **reduction in pain intensity was greater** in the **Penthrox group** compared to SAT up to **20 minutes**, post analgesia administration, regardless of class of SAT administered.
  - The estimated overall treatment effect for Penthrox vs SAT expressed as adjusted reduction in NRS from baseline (during 20 minutes after treatment start) was 1.00 (2.47 vs 1.39), where the greatest treatment effect occured at 15 minutes with 1.44 (2.89 vs 1.45).
  - All time-to-event endpoints were significantly shorter (i.e., more favorable) for Penthrox compated with SAT, including median time to first pain relief: 3.17 vs 10.0 minutes, time to first meningful pain relief: 10.00 vs 20.00 minutes.
  - The proportion of pain responders (patients with ≥30% improvement from baseline in NRS pain intensity score) was significantly higher in the Penthrox group vs the SAT group (87.9% vs 57.7%).
  - The use of rescue medication (as requested by the patient) until discharge was low in both treatment group (13 patients [8.5%] in the Penthrox group and 18 patients [12.1%] in the SAT group).
  - Penthrox exceeded patients' expectations in 77% of cases compared with 38% with SAT (clinicians: 72% vs 19%).

The third clinical trial, MEDITA [NCT03585374] [2]. Phase 3b randomized, active-controlled, parallel-group, open-label trial, with the objective to investigate the analgesic efficacy, practicality and safety of inhaled methoxyflurane (Penthrox) vs SAT (morphine for severe pain and paracetamol or IV ketoprofen for moderate pain) in Italy, for acute trauma pain in the emergency setting (N=270, 1:1 randomization). The primary objective was the overall change in VAS pain intensity from baseline to 3, 5 and 10 minutes.

Results MEDITA [2]

- This study showed that overall, **Penthrox provided greater pain relief** vs SAT over the first **25 minutes**, in patients with IV access already established.
- The authors concluded that **Penthrox provided superior pain relief** compared to SAT in patients with moderate-to-severe trauma pain and may offer a **simple**, **fast**, **effective**, **non-opioid** treatment option.
    - The overall change in VAS pain intensity in the first 10 min was significantly greater in the Penthrox group compared with the SAT group (adjusted mean treatment difference -5.94 mm; 95% CI -8.83, -3.06; p>0.001).
    - Analysis of changes in VAS pain intensity from baseline to 15, 20, 25 and 30 min showed a significant treatment difference in favour of Penthrox, with the greatest treatment effect at 20 minutes (-5.89; 95% CI -10.60, -1.17 mm).
    - Median time to onset of pain relief was shorter for the Penthrox group compared with the SAT group (9 min; 95% CI 7.72, 10.28 min vs 15 min; 95% CI 14.17, 15.83 min).
    - The use of rescue medication was low in both treatment groups (3 patients [2.2%] in the Penthrox group and 5 patients [3.7%] in the SAT group).
    - Significantly more patients rated the overall efficacy of Penthrox as **excellent**, **very good** or **good** compared to SAT.
        - Methoxyflurane exceeded patients' expectations in 72.7% of cases compared with 60.9% with SAT (p=0.001).
    - Significantly more clinicians rated the practicality of Penthrox as **excellent**, **very good** or **good** compared to SAT.
        - Health-care professionals rated the practicality of using study treatment as «excellent», «very good», or «good» for methoxyflurane than SAT (90.3% vs 64.4%; p<0.001).

In summary, all three studies showed that Penthrox® provide superior pain relief to placebo and SAT in patients with acute trauma and associated pain (both moderate and severe). Therefore, Penthrox® may offer a non-opioid, easy-to-administer, rapid-acting, alternative to currently available analgesic treatments for trauma and associatedpain. Norwegian clinicians already use Penthrox® in clinical practice, which further stresses the unmet need for Penthrox® in Norway (see reference to these regions in section 13 of this form)

Safety

Penthrox® is well tolerated, with most adverse events being mild and transient. This section provide an overview of the safety results from the three clinical trials STOP!, InMEDIATE and MEDITA.

STOP! [11]

- The proportion of patients experiencing treatment emergent adverse events (TEAE) was higher in the Penthrox group (59.1%) than in the placebo group (40.9%).
- The proportion of patients experiencing drug related TEAEs higher in the Penthrox group (36.2%) than in the placebo group (13.4%).

InMEDIATE [3]

- No safety concerns regarding emergency use of Penthrox were raised in the study (consistent with the STOP! Trial).
- More adverse events reported for patients in the Penthrox group (24.4%) compared with the SAT group (5.4%).
- The most frequently occurring adverse event in the Penthrox group was dizziness, reported for 14.1% of patients. The incidence of dizziness was notably lower than in the STOP! Trial (36.3%).
- Biochemical and hematologic analysis and vital signs showed no clinically notable changes or differences between the treatment groups.

MEDITA [2]

- More adverse events reported for patients in the Penthrox group (17%) compared with the SAT group (3%), but most were minor and transient, and only 5.9% discontinues treatment because of adverse events.
- No clinically notable changes from baseline in mean vital sign parameters.

In summary, all three studies showed more AEs with Penthrox®, however patient-reported outcomes in these studies indicated high patient acceptance of treatment. Indeed, 78% and 72.7% of patients in STOP! and MEDITA trials, respectively, rated Penthrox as `excellent´, `very good´ and `good´, and patients in InMEDIATE rated it a median of 9 out of 10 for pain control, comfort of treatment and safety (AEs).

Total number of patients in Norway the health technology is applicable to

Up to 40.000 patients per year after full implementation across ED and Ambulance services are estimated to use Penthrox® in Norway, either as a sole agent or/and as a bridging agent to standard analgesic agents. The number of patients is estimated on basis of the yearly units of Penthrox® sold in another European Country of similar size as Norway across the ED & ambulance services.

However, not all of these 40,000 patients will have a budget impact on the Norwegian specialized health services, since many of the patients using Penthrox® are likely imported cases, i.e., stemming from the considerable level of tourism (primarily Ski Tourism), where the economic burden instead fall on their respective countries. Penthrox® has been tested and proved safe and effective during alpine rescue operations. [12]

Consequences for resource use in the public health service

Penthrox® is associated with potential savings in regards to healthcare resource use. For example, a Brittish evaluation of Penthrox® found that the mean overall time spent in the ED for patients with injuries was reduced by 71 minutes for patients administered with Penthrox® vs standard analgesic agents.[13] In addition, another study found that patients who were administered pain relief within 90 minutes after arrival to the ED were discharged 2,3 hours earlier in comparison to patients who received pain relief after 90 minutes.[14] Hence, the use of Penthrox® is expected to have a positive impact on healthcare resource use for patients with moderate-to-severe acute trauma and associated pain, through its reduced need of surveillance/healthcare resources vs standard analgesic agents.

Need for revision of existing national guidelines or preparation of new guidelines

Penthrox® has established use in several areas of Norway (**Rogaland/Nordland/Oslo/Viken/Innlandet/Vestfold&Telemark/Agder/Vestland/Trøndelag /Troms & Finnmark)**, which indicates a demand. Therefore, it is suggested that the national guidelines for moderate-to-severe acute trauma and associated pain will be revised to include Penthrox®.

15. Please provide references to documentation of the health technology's effect and safety (i.e. previous technology assessments). (Up to 10 key references can be provided, please do not send attachments in this step of the process):

[1] Legemiddelverket. SPC - Product Information Penthrox. Available from: https://www.legemiddelsok.no/_layouts/15/Preparatomtaler/Spc/16-11456.pdf
[2] Mercadante S, Voza A, Serra S, et al. Analgesic Efficacy, Practicality and Safety of Inhaled Methoxyflurane Versus Standard Analgesic Treatment for Acute Trauma Pain in the Emergency Setting: A Randomised, Open-Label, Active-Controlled, Multicentre Trial in Italy (MEDITA). *Adv Ther*. 2019;36(11):3030-3046. doi:10.1007/s12325-019-01055-9
[3] Borobia AM, Collado SG, Cardona CC, et al. Inhaled Methoxyflurane Provides Greater Analgesia and Faster Onset of Action Versus Standard Analgesia in Patients With Trauma Pain: InMEDIATE: A Randomized Controlled Trial in Emergency Departments. *Ann Emerg Med*. 2020;75(3):315-328. doi:10.1016/j.annemergmed.2019.07.028
[4] Sabri A, Szalas J, Holmes KS, Labib L, Mussivand T. Failed attempts and improvement strategies in peripheral intravenous catheterization. Biomed Mater Eng. 2013;23(1-2):93-108.
[5] Lord B, Jennings PA, Smith K. Effects of the Introduction of Intranasal Fentanyl on Reduction of Pain Severity Score in Children: An Interrupted Time-Series Analysis. Pediatr Emerg Care. 2019;35(11):749-54.
[6] Wilkes M, Heath EC, Mason NP. Methoxyflurane for Procedural Analgesia at 4470 m Altitude. Wilderness Environ Med. 2018;29(3):388-91.
[7] Boccio E, Wie B, Pasternak S, Salvador-Kelly A, Ward MF, D'Amore J. The relationship between patient age and pain management of acute long-bone fracture in the ED. The American journal of emergency medicine. 2014;32(12):1516-9.
[8] Den norske legeforeningen. Retningslinjer for smertelindring. 2009. Available from: https://www.legeforeningen.no/contentassets/6d9a7062741b4ef397e6868a31b88dc0/smertelindringshefte-retningslinjer.pdf
[9] Helse-Midt. Årsrapport 2021 – Ambulansetjensten i Midt-Norge Fellesfunksjonen. Availabel from: https://helse-midt.no/PublishingImages/%C3%85rsrapport%20Fellesfunksjonen%20Ambulansetjenesten%20i%20Midt-Norge%202021.pdf
[10] ClinicalTrials.gov. A comparison of Three Regimens of Acute Pain Management: Methoxyflurane; Intranasal Fentanyl; Intravenous Morphine (PreMeFen) [NCT05137184]. Available from: https://clinicaltrials.gov/ct2/show/NCT05137184
[11] Coffey F, Wright J, Hartshorn S, et al. STOP!: a randomised, double-blind, placebo-controlled study of the efficacy and safety of methoxyflurane for the treatment of acute pain. *Emerg Med J*. 2014;31(8):613-618. doi:10.1136/emermed-2013-202909
[12] Egger A, Huber T, Heschl S, et al. Efficacy and Safety of Methoxyflurane for Treatment of Acute Traumatic Pain by EMTs during Alpine Rescue Operations: The "PainDrop" Trial [published online ahead of print, 2022 Aug 12]. *Prehosp Emerg Care*. 2022;1-6. doi:10.1080/10903127.2022.2107125
[13] Young L, Bailey GP, McKinlay JAC. Service Evaluation of Methoxyflurane Versus Standard Care for Overall Management of Patients with Pain Due to Injury. *Adv Ther*. 2020;37(5):2520-2527. doi:10.1007/s12325-020-01294-1
[14] Sokoloff C, Daoust R, Paquet J, Chauny JM. Is adequate pain relief and time to analgesia associated with emergency department length of stay? A retrospective study. *BMJ Open*. 2014;4(3):e004288. Published 2014 Mar 25. doi:10.1136/bmjopen-2013-004288

16. Please provide the name of the marketing authorization holder/manufacturer/supplier of the health technology (if applicable/available):

Medical Developments NED B.V. Strawinskylaan 411, WTC Tower A 1077 XX Amsterdam Nederland

17. Marketing Authorization Status (MA) or CE-marking: When is MA or CE- marking expected? If possible, provide the time of planned marketing:

16-11456

DATO FOR FØRSTE MARKEDSFØRINGSTILLATELSE/SISTE FORNYELSE

Dato for første markedsføringstillatelse: 22. mars 2018

Dato for siste fornyelse: 07. november 2022

18. Additional relevant information (up to 300 words.)

N/A

19. Interests and potential conflicts of interests

Please describe the proposer's relationships or activities that may affect, be influenced by, or be perceived by others to be important for further management of the health technology that is proposed assessed. (E.g. proposer has financial interests in the matter. Proposer has or has had assignments in connection with the technology or to other actors with interest in the technology)

N/A